सत्यमेव जयते

REPORT

OF

The Committee on Drugs and Pharmaceutical Industry

(Hathi Committee Report)

1975

MINISTRY OF PETROLEUM & CHEMICALS
GOVT OF INDIA
April, 1975.

CONTENTS

CHAPTER I

INTRODUCTION

The functioning and growth of the Drugs and Pharmaceutical Industry in India over the past few years were engaging the attention of Government for quite sometime, particularly with a view to finding out ways and means to meet the growing requirements and broad social objectives before the country. Questions about the performance of the public sector units, multi-national firms' gaining stronghold in this field, prices of locally produced medicines, etc. were raised in the Parliament. Following a suggestion made in the Parliament, the Government of India in the Ministry of Petroleum and Chemicals, set up a Committee by a Resolution No. 3 (26)/73-Ch. III dated the 8th February, 1974, consisting of the following members :—

1. Shri Jaisukhlal Hathi	Chairman
2. Shri Yashpal Kapur, M.P.	Member
3. Shri Vasant Sathe, M.P.	,,
4. Dr. Ranen Sen, M.P.	,,
5. Shri K.S. Chavda, M.P.	,,
6. Shri C.M. Stephen, M.P.	,,
7. Dr. M.L. Dhar, Director, Central Drugs Research Institute, Lucknow.	,,
8. Dr. B.D. Tilak, Director, National Chemical Laboratory, Poona.	,,
9. Shri S.S. Marathe, Chairman, Bureau of Industrial Costs & Prices.	,,
10. Shri Vinod Kumar, Joint Secretary, Ministry of Petroleum & Chemicals.	,,
11. Shri P.S. Ramachandran, Drugs Controller, D.G.H.S.	,,
12. Dr. B. Shah, Dy. Director General, D.G.T.D.	,,
13. Dr. B.V. Ranga Rao, Centre for Studies in Science Policy, Jawaharlal Nehru University.	,,
14. Shri M.K. Rangnekar, Commissioner, Food and Drug Administration, Government of Maharashtra, Bombay.	,,
15. Dr. P.R. Gupta, Adviser (Drugs), Ministry of Petroleum & Chemicals.	Member-Secretary.

2. The Government of India appointed the above Committee to go into the various facets of the Drug Industry in India with a view to promoting growth of the Drug Industry particularly of the Indian and small scale sectors, improve technological development, take effective Quality Control measures on drugs, reduce the prices of medicines, as well as to rationalise the prices tructure, provide essential drugs throughout the country, and make available raw materials to the industry particularly to the small-scale sector, etc. Appointment of such a Committee was also felt necessary in the context of the large-scale expansion of the drug and pharmaceutical industry envisaged during the Fifth Five Year Plan period, with a view to ensuring the regulated and rapid growth of drug manufacture. The terms of reference were as under :—

(i) To enquire into the progress made by the industry and the status achieved by it.

(ii) To recommend measures necessary for ensuring that the public sector attains a leadership role in the manufacture of basic drugs and formulations, and in research and development.

(iii) To make recommendations for promoting the rapid growth of the drugs industry and, particularly, of the Indian and Small Scale Industries Sector. In making its recommendations the Committee will keep in view the need for a balanced regional dispersal of the industry.

(iv) To examine the present arrangements for the flow of new technology into the industry, and make recommendations therefor.

(v) To recommend measures for effective quality control of drugs, and for rendering assistance to small-scale units in this regard.

(vi) To examine the measures taken so far to reduce the prices of drugs for the consumer, and to recommend such further measures as may be necessary to rationalise the prices of basic drugs and formulations.

(vii) To recommend measures for providing essential drugs and common house-hold remedies to the general public, especially in the rural areas.

(viii) To recommend institutional and other arrangements to ensure equitable distribution of basic drugs and raw materials especially to the Small Scale Sector.

A copy of the Government Resolution setting up the Committee is at Annexure I.

3. At the meeting held on 21st March, 1974, the Committee coopted Dr. B.B. Gaitonde, Director, Haffkine Institute, Bombay. Shri P.S. Ramachandran, Drugs Controller (India) retired from Government service but continued as a Member of the Committee. On the advice of the Minister of Health and Family Planning Dr. S.S. Gothoskar, who succeeded as Drugs Controller (India) was coopted as a member in the meeting held on the 5th January, 1975.

4. The first meeting of the Committee was held on the 6th March, 1974 wherein during the course of discussion a Sub-Committee consisting of the following members, was set up to examine the question of issue of Permission/ No objection Letters and C.O.B Licences by Government :

1. Shri K.S. Chavda, M.P.
2. Dr. Ranen Sen, M.P.
3. Dr. B. V. Ranga Rao
4. Shri P. S. Ramachandran — Convenor

Shri Jaisukhlal Hathi as Chairman attended the meetings.

5. At the second meeting held on the 21st March, 1974 the Committee finalised the various questionnaires for issue to the various Organisations etc. A copy of each of the Questionnaires prepared and issed to the units in the Organized Sector, Associations representing the Drug Industry, Indian Medical Associations and other Specialists' Organisations in the medical field is at Annexures II—IV. Subsequently, another Questionnaire was also issued to the State Governments to elicit their views/suggestions (Annexure V).

6. While the work of the Committee was in progress an unfortunate and tragic incident took place in Kanpur following administration of a Transfusion solution to some patients in a Hospital resulting in the death of some persons. As the question of quality of the medicine used was involved in this incident, both the Government and the Committee felt that the question of quality control should be examined on a priority basis. Following the advice of the Ministers of Health & Family Planning and Petroleum & Chemicals, the Committee took up the term of reference, namely, "to recommend measures for effective quality control of drugs and rendering assistance to the small-scale units in this regard", for immediate examination and to report to Government. A Sub-Committee consisting of the following members was appointed on 2nd May 1974 to go into this question thoroughly and expeditiously :—

1. Dr. Ranen Sen
2. Dr. M. L. Dhar
3. Shri M. K. Rangnekar
4. Dr. B B. Gaitonde
5. Dr. B. V. Ranga Rao
6. Shri P S. Ramachandran — Convenor

The report of the Sub-Committee was considered by the Committee on Drugs and Pharmaceutical Industry on the 16th May, 1974 and the report was submitted to Government on 25th May, 1974. The report is incorporated as Chapter IX of this report.

7. With a view to obtaining first hand knowledge of the operations undertaken by the various sectors of the Drug Industry and particularly to assess the problems faced by the Indian sector in expanding their drugs manufacturing activity and also to obtain the views of the manufactururs and Associations/Organizations of drug manufacturing units, the Committee undertook a tour to Maharashtra & Gujarat in June-July, 1974 and visited some drugs and pharmaceutical manufacturing units both in the organised as well as the small-scale sector of the industry. The Committee also held discussions with the Local Associations/Organizations of the drugs manufacturers, to obtain their views on the various aspects involved and particularly as to how this industry could grow to meet the requirements of the country and also to assess the possibilities/potentiality of the Indian sector to develop at a faster pace.

8. The Committee made similar visits to Rishikesh in August, 1974, Hyderabad and Madras in September 1974, Calcutta in September, October 1974 and Durgapur in November 1974. In Pimpri, Rishikesh and Hyderabad, the Committee visited the public sectof units namely Hindustan Antibiotics Limited, Antibiotics Plants and Synthetic Drugs Plants of the Indian Drugs and Pharmaceuticals Limited.

9. Besides visiting the drug manufacturing, large and small scale units, situated at the various places, the Committee met the representatives of the Associations at Bombay, Baroda, Ahmedabad, Calcutta, Madras and Hyderabad. It also visited the Research centres of Ciba-Geigy, Sarabhais and Bengal Immunity separatetly. The Committee also met the representatives of Organisation of Pharmaceutical Producers of India, Development Council of Drugs and Pharmaceuticals, Indian Drugs and Pharmaceuticals Limited, State Trading Corporation, and the Indian Medical Association. The names of the manufacturing units visited by the Committee and those of the various Associations with whom discussions were held along with the dates, are shown in Annexure VI.

10. The Committee during the course of discussions, particularly on the question of making the esecntial medicines available in adequate quantities to the wider section of the people including those in the rural areas, felt that a list should first be drawn up to identify the essential medicines which are required to be produced in large quantities for mass consumption. It considered that although the question of substitution of brand names by generic names in respect of the medicines marketed by the Industry was not specifically mentioned in the terms of reference for this Committee, the subject followed clearly from the other terms of reference such as reduction/rationalisation of prices of formulations for the consumers, making essential drugs available in larger quantities to the general public etc. The Committee, therefore, appointed a panel consisting of some of the members of the Committee and Specialists in the medical field, from all over the country. The panel consisted of the following members :—

1. Dr. Ranen Sen, Member of Parliament.
2. Dr. A. B. Chowdhury, M.B., PH.D, F.A.M.S., F.N.A., Director, Calcutta School of Tropical Medicines, Chittranjan Avenue, Calcutta-12.
3. Dr. S. Padmavati, Director-Principal, Maulana Azad Medical College, New Delhi.
4. Dr. B. Ray Chaudhury, M.D. (Cal.) FRCP, Ph.D. (Edin), Associate Professor of Medicine, Institute of Post Graduate Medical Education and Research, 22-Lower Circular Road, Calcutta-17.
5. Dr. K.V. Thiruvengadam, B.Sc., M.D., FAMS, Professor of Medicine and Vice Principal, Stanley Medical College, Physician, Government Stanley Hospital, Madras.
6. Shri P.S. Ramachandran, Drugs Controller (India), D.G.H.S., New Delhi.
7. Dr. K.G. Nair, MD (Bombay) Ph.D. (Chicago) FACC (U.S.A.) FICA (U.S.A.). of Director-Professor of Medicine, Head Department of Cardiology and Radio-Isotope Unit, KEM Hospital and Seth G.S. Medical College, Bombay.
8. Dr. B.J. Vakil, Hony. Professor, Gastroenterology, Grant Medical College, Hospital, Bombay.
9. Dr. B.B. Gaitonde, M.D.M.Sc. (Med.), F.A.Sc. Director, Haffkine Institute, Bombay.....Convener

Dr. P.R. Gupta and Shri M.K. Rangnekar assisted the panel in its work.

11. The terms of refeence for this panel were as follows :—

(i) To recommend measures for providing essential drugs and common house-hold remedices to the general public especially in the rural areas, and

(ii) whether it would be in the national interest to substitute brand names by generic names and if so, the manner and extent to which it should be done.

The Panel submitted its report on the 29th June, 1974, which was considered by the Committee on 25th July, 1974 and 21st and 22nd January, 1975. The report as modified and adopted by the Committee was sent to Government on the 21st February, 1975. This constitutes Chapter X of the Report.

12. The schedule of the programme of the Committee including its sittings on the Sub-committees, meeting with the representatives of the Associations at Delhi are also shown in Annexure VI.

13. The time for submission of the report was extended up to 7th February, 1975 and later upto 7th April, 1975 by Government Resolutions No. 3(26)/73-Ch. III dated the 23rd August, 1974 and 5th February, 1975 respectively.

14. The Committee has tried to collect the data and statistics of production, capital invested, turnover, etc., from authentic sources and wherever possible, based on replies given in the Parliament. These may be taken as indicative and not exhaustive.

ANNEXURE I

(Chapter I-Para 2)

TO BE PUBLISHED IN PART II—SEC. 3—SUB-SEC. (ii) OF THE GAZETTE OF INDIA—EXTRAORDINARY

No. 3(26)/73-Ch. III

MINISTRY OF PETROLEUM & CHEMICALS

New Delhi, the 8th February, 1974

Resolution

Subjects—Constitution of Committee on the drugs and pharmaceuticals industry.

In the context of the large-scale expansion of the drugs and pharmaceuticals indutsry envisaged during the Fifth Five Year Plan, with a view to ensuring the regulated and rapid growth of drugs manufacture, and further with a view to ensuring that all essential durgs are made available to the consumers at reasonable prices, Government have decided to constitute a Committee with the following membership :—

1. Shri Jaisukhlal Hathi, M.P. . . . . Chairman
2. Shri Yashpal Kapur, M.P. . . . . Member
3. Shri Vasant Sathe, M.P. . . . . ,,
4. Dr. Ranen Sen, M.P. . . . . ,,
5. Shri K.S. Chavda, M.P. . . . . ,,
6. Shri C.M. Stephen, M.P. . . . . ,,
7. Dr. M.L. Dhar, Director, Central Drugs Research Institute, Lucknow. . . ,,
8. Dr. B.D. Tilak, Director, National Chemical Laboratory, Poona. . . . ,,
9. Shri S.S. Marathe, Chairman, Bureau of Industrial Costs & Prices. . . . ,,
10. Shri Vinod Kumar, Joint Secretary, Ministry of Petroleum & Chemicals. . . ,,
11. Shri P.S. Ramachandran, Drugs Controller, DGHS. . . . . ,,
12. Dr. B. Shah, Dy. Director General, D.G.T.D. . . . . ,,
13. Dr. B.V. Ranga Rao, Centre for Studies in Science Policy, Jawaharlal Nehru University . . . . . ,,
14. Shri M.K. Rangnekar, Commissioner, Food and Drug Administration, Government of Maharashtra, Bombay. . . . . ,,
15. Dr. P.R. Gupta, Adviser (Drugs), Ministry of Petroleum & Chemicals. . . Member-Secretary.

2. The Committee will examine and report upon the following matters :—

(i) To enquire into the progress made by the industry and the status achieved by it.

(ii) To recommend measures necessary for ensuring that the public sector attains a leadership role in t manufacture of basic drugs and formulations, and in research and development.

(iii) To make recommendations for promoting the rapid growth of the drugs industry and, particularly, of t Indian and small scale industries sector. In making its recommendations the Committee will keep in vi the need for a balanced regional dispersal of the industry.

(iv) To examine the present arrangements for the flow of new technology into the industry, and make re mmendation therefor.

(v) To recommend measures for effective quality control of drugs, and for rendering assistance to small sc units in this regard.

(vi) To examine the measures taken so far to reduce the prices of drugs for the consumer, and to recomm such further measures as may be necessary to rationalise the prices of basic drugs and formulatio

(vii) To recommend measures for providing essential drugs and common house-hold remedies to the gen public, specially in the rural areas.

(viii) To recommend institutional and other arrangements to ensure equitable distribution of basic drugs and raw materials especially to the Small Scale Sector.

3. The Committee will ascertain and take into consideration the views of the State Governments and other interests concerned, as may be found necessary.

4. The Committee's headquarters will be at New Delhi.

5. All Secretariat assistance required by the Committee will be provided by the Ministry of Petroleum and Chemicals.

6. The Committee will meet as often as may be considered necessary by the Chairman and shall submit its final report to Government within six months. The Committee may also, at its discretion, submit interim reports on specific matters from time to time.

Sd/-
(P.K. DAVE)
Secretary to the Govt. of India

ORDER

Ordered that this Resoultion be communicated to all the Ministries of Government of India, all State Governments, the Comptroller & Auditor General of India, Accountant General, Commerce, Works & Miscellaneous, and Accountant General, Central Revenues.

Ordered also that the Resolution be published in the Gazette of India for general information.

Sd/-
P.K. DEVE,
Secretary of Govt. of India.

ANNEXURE II

Questionnaire I

(Chapter I-Para 5)

1. Please give a complete list of drugs manufactured by you dividing them into (a) pharmacopoeial product (b) 'New drugs' (as defined in the Drugs and Cosmetics Rules) within the last five years and (c) other non-pharmacopoeial products and the value (cost to the wholesaler) of each of these drugs in (a) (b) and (c) produced by you during your last financial year.

2. Please list out separately the drugs which you manufactured in 1952 and those manufactured subsequently quoting the Government authority against which the expansion in manufacture has undertaken.

3. Have you any products licensed to be manufactured under the Industries (Development and Regulation) Act 1951 and whose manufacture has *not* been commenced by you ? If so, please list those products with capacities.

4. What is the range of products other than drugs which are manufactured by you ? Please specify such products and their turnover for your last financial year under the following heads :—

(a) Laboratory chemicals

(b) Cosmetics

(c) Insecticides and Pesticides

(d) Nutritional products

(e) Confectionary items

(f) Other items

5. What is the amount of money spent by you separately on the following during your last financial year?

(a) Office establishment (b) Finance and Accounts Department (c) Planning and Development (d) Sales-Promotion (excluding expenditure covered under 6 and 7 below) (e) Product development (f) Production of Drugs (g) Quality control (h) Research (i) other heads.

6. What is the strength of the field force of medical representatives employed by you on 1-1-74 and the annual expenditure thereon ?

7. What is the strength of the field force of sales promotion representatives employed by you on 1-1-74 for non-drug items and your annual expenditure thereon ?

8. Have you any research organisation ? If so, please give a brief resume of the nature of the research activities and the money spent on research during your last financial year. As a result of your research in this country, what basic drug/chemical is being manufactured by you in this country ?

9. Have you been assisting the medium and small-scale firms by getting intermediate raw-material pharmaceutical aids or pharmaceutical formulations manufactured by them ? If so, please supply details with the names and addresses of firms so assisted.

10. What is the value of your import licence under the ITC regulations for raw materials (1973-74) and what the value of your export earnings during the same period ? Also specify the quantities of items imported and the value of each under the ITC regulations.

11. What is the extent of foreign exchange remittances made by you during 1973-74 towards (a) profit for the foreign equity holders (b) patent royalties (c) know-how fee (d) scientific contribution and (e) other heads.

12. Please state whether you have opted for compliance with para 7 of the Drugs (Prices Control) Order 197 or para 14. In the latter case, what has been your progressive sales turnover during each of your last three compa years and the dividends declared by you for those years.

13. Have you any suggestions to offer to make the Patents Act more useful to the drug industry in this country

14. Are you satisfied with the quality control measures over drugs taken by the Central and State Drug Contr Administrations ? Have you any suggestions to make for improvement in this connection ? Is there adequa rapport between the Drug Control Administration and the Industry ?

15. In what way does the industry cooperate with the Drug Control Administration in tackling spurious drugs and in what manner can Government's efforts in this direction be tightened ?

16. Drugs marketed under brand names [illegible] expensive brand names influence the [illegible] practices of physicians and are a [illegible] to boost the sales of products. In the face of these facts [illegible] your views on the abolition of brand names of drugs ? If total abolition is not considered advisable, to [illegible] can the use of brand names be restricted ?

17. Sampling of drugs by manufacturers to the medical profession it is reported leads to malpractices [illegible] different types. What will be your reaction to stopping the distribution of such samples ?

18. What are your views on (a) the need to avoid multiplicity of drug formulations of the same composition (b) combinations of drugs and the need to prohibit irrational and ineffective combinations (c) the desirability of reducing the number of vitamin preparations to the absolute minimum and (d) prohibition of advertisement of drugs in the lay press, in the public and through other audio-visual media ?

19. What role do you expect the public sector concerns to play in the development of the drug industry over the next 10 years ?

20. Are you satisfied with the performances of the STC and IDPL as canalising agencies for distribution of raw-materials ? In what way can the working of these organisations be improved ?

21. Are the Government departments at the Centre, namely, the Ministry of Petroleum & Chemicals, the CTD and the Central Drug Control Organisation helpful and prompt in their dealing with the industry ?

22. Do you own any other company ? If so, give particulars of the names of such companies and the products manufactured by each of them.

23. Have you any associated companies ? If so, give particulars of the names of such companies and the products manufactured by each of them.

24. Do you think that in any particular case the country's resources are being wasted in obtaining technical know-how from abroad when it could have been developed indigenously with proper planning and guidance ?

25. The Drugs (Prices Control) Order 1970 has been welcomed by the general public. Without detracting from the essential features of this order, have you any suggestions to make for simplifying the implementation procedure under this Order ?

26. What measures do you suggest for providing essential durgs and common household remedies to the general public, especially in the rural areas and to the weaker sections of the community, at reasonably cheap prices ?

27. What measures do you suggest to increase the production of drugs and pharmaceutical products so as to meet the quantitative requirement of the country at the end of the Fifth Five Year Plan.

28. In case your company has more than 26% foreign equity, please furnish the information also for the questions covered by the enclosed statement separately.

Statement referred to in Question No. 28

1. Kindly supply photostat copies of :—

(a) Industrial Licences for drugs secured under the Industries (Development and Regulation) Act 1951.

(b) Permission/No objection letters granted by the concerned authorities.

(c) Applications for diversification and replies received from Government.

(d) Applications made for COB licences and the licences issued by Government.

2. Please supply information as to the dates on which manufacturing licences under the Drugs and Cosmetics Act were granted for the items covered by COB licences granted to you.

3. Please supply details about the foreign personnel employed by you during the last five years together with particulars of the salaries/honorarium and perquisites paid to them.

4. Please supply copies of your Balance Sheets for the last five years.

5. How many products are marketed by you under brand names ?

6. How many drug patents have been sealed/are under registration by your principals in this coutrywo and how many of these patens are being operated by you in this country ?

ANNEXURE III

QUESTIONNAIRE II

(Chapter I—Para 5)

1. What are your Association views on the role so far played by the medium and small-scale sectors of the industry in the country for its development ? What role do you envisage for these sectors in the future development of the industry ? There is a common impression that big firms, particularly the foreign ones, have so far made the major contribution to the development of the industry. Do you agree with this view ? Give reasons.

2. What are the handicaps that hamper the development of the medium and small-scale sectors especially in attaining the rated capacities of production ? Please specify in terms of :—

(a) Raw material supplies. (b) Packaging materials, (c) Import of Machinery, laboratory chemicals and equipment, (d) the Patents Act (e) New Drug clearance, (f) Manufacture of basic drugs. (g) Import substitution, (h) Export, (i) Financial resources, (j) ITC Regulations and procedures, and (k) any other aspects.

3. Do you suffer from the disability of obtaining sufficiently qualified technical personnel for manufacturing your products ?

4. Testing facilities, product development, sales promotion techniques, dissemination of technical information about drugs to doctors, professional management, planning for future development-these aspects, it is said are not given sufficient importance by the small and medium scale sectors of the industry. What are your views on these observations and your suggestions to improve the performance of your member firms in this regard ? In what way can Government assist the industry in these fields ?

5. In the context of the development profiles that have been prepared for the drug industry over the next 10 years, what contributions can the medium and small-scale sectors of the industry make ?

6. What measures to do you suggest to increase the production of drugs and pharmaceutical products so as to meet the quantitative requirements of the country at the end of the Fifth Five Year Plan ?

7. Big firms, as they expand production of bulk drugs, can encourage small and medium scale firms by assisting them with the know-how for development of intermediate raw materials, pharmaceutical aids, etc. Have you any views on this point, particularly as to how big firms can be persuaded to help the small-scale and medium-scale firms ?

8. The Price Control Order in respect of drugs has been welcomed by the general public. What is the impact of this Order on the medium and small-scale sectors of the industry ? Without detracting from the essential features of the Price Control Order, have you any suggestions to make for simplifying the implementation procedures under this order ?

9. It is said that the prices of drugs could be maintained and even lowered if drug firms can diversify into areas such as nutritional products, laboratory chemicals, cosmetics, veterinary preparations, insecticides, etc. Has your Association specific idea on these aspects particularly in regard to the potentiality of the firms in the small and medium-scale sectors ? Can the Government (Central & State) assist in any way ?

10. In what manner can the medium and small-scale firms promote drug research ? Do you think that the facilities for research and development in the fields of Fine Organic Chemicals and Microbiology are adequate for the requirements of the small and medium scale sector of the industry And what assistance do these firms expect from Government in this regard ? What are your view on having regional research laboratories with government subsidiary ?

11. Are you satisfied with the quality control measures over drugs taken by the Central and State Drug Control Administrations ? Have you any suggestions to make for improvement in this connection? Is there adequate rapport between the Drug Control Administration and the industry?

12. In what way does the industry cooperate with the Drug Control Administration in tackling spurious drugs and in what manner can Government's efforts in this direction be tightened?

13. The medical profession in India, it is generally reported is not favourably disposed towards drugs manufactured by the medium and small-scale sectors of the industry vis-a-vis those marketed by big companies and foreign companies. What steps do members of your Association propose to take to win the confidence of the medical profession and to convince them of the quality of drugs marketed by your member firms?

14. Drugs marketed under brand names are generally expensive. Brand names influence the prescribing practices of physicians and are used as a lever to boost the sales of their products by big firms, particularly the foreign ones. In the face of these facts, what are the views of your Association on the abolition of brand names of drugs? If not, if abolition is not considered advisable, to what extent can the use of brand names be restricted?

15. What are the views of your Association on (a) the need to avoid multiplicity of drug formulations of the same composition,

(b) Combinations of drugs and the need to prohibit irrational and ineffective combinations (c) the desirability of reducing the number of vitamin preparations to the absolute minimum and (d) prohibition of advertisement of drugs in the lay press, in the public and through other audio-visual media.

16. Distribution of samples of drugs by manufacturers to the medical profession it is reported, lead to malpractices of different types. What will be the reaction of your Association to stopping the distribution of such samples?

17. What role does your Association expect the public sector concerns to play ?

18. Are you satisfied with the performance of the STC and IDPL as canalising agencies for distribution of raw-materials ? Do you think that the system of allotment of canalised raw-materials and indigenously manufactured bulk drugs requires any modification to augment the supply of these items to the puerly Indian sector of the industry, particularly the small and medium sector ? In what way can the working of these organisations be improved ?

19. Are the Government departments at the Centre, namely, the Ministry of Petroleum and Chemicals, the DGTD and the Central Drug Control Organisation helpful and prompt in their dealing with the industry ?

20. What measures do you suggest for providing essential drugs and common household remedies to the general public, especially in the rural areas and to the weaker sections of the community, at reasonably cheap prices ?

ANNEXURE IV

QUESTIONNAIRE III

(Chapter I—Para 5)

1. What is your general impression about the drug industry in India and its performance ?

2. Has the industry satisfied your expectations in regard to the range of drugs offered by it ? In general, are the drugs marketed by the industry useful to the medical profession or of the type which could be considered as "money spinners" ?

3. Has your Association any observations to make on the quality control aspects of the drug industry in this country in general and with special reference to :—

(a) the multi-national firms operating in this country (such as CIBA-GEIGY, Glaxo, Boots, Sandoz, Cyanamid, Pfizer, etc.);

(b) the big firms of the Indian sector (such as Alembics, Bengal Immunity, Unichem, Sarabhai etc.); and

(c) the small-scale sector in the drug industry ?

4. In the opinion of your Association, are drug prices beyond the reach of the common man ? Does any sector of the drug industry or do any categories of drugs deserve special mention in this connection ?

5. Is the medical profession "baffled" by the multiplicity of the same type of preparations ? If so, can your Association suggest any solution for this problem ?

6. One way of minimising the multiplicity of drug formulations could be through wide-spread use by the medical profession of the National Formulary of India published by the Ministry of Health, in the Government of India, and with which representatives from various medical associations have been associated. Does your Association feel that the National Formulary of India has been put to proper use by the Medical profession ? One of the criticisms voiced is that this Formulary is biased towards use by doctors in Government hospitals and that the prescribing practices of the physicians outside hospitals have not been given adequate consideration. Has your Association any suggestions for the improvement of the National Formulary ?

7. What is your Association's view on combination of drugs ? Would you like any specific category of combinations to be prohibited ?

8. What is the view of your Association on the usefulness of the vitamin products marketed by drug manufacturers ? Is there any scope for restricting or regulating their number ?

9. Drugs marketed under brand names are generally expensive. Promotions of brand names, it is stated, interferes with the prescribing practices of physicians. Further, brand names are used as a lever to boost the sale of products. In the face of these arguments, what is your Association's views on abolition of brand names of drugs ? If total abolition is not considered advisable at this stage, what steps would you suggest for progressive abolition of such names ?

10. There is criticism about the drugs being advertised :—

(a) through the All India Radio.

(b) in the lay press, and

(c) in streets, cinema houses, etc.

should advertisement of drugs through these media be prohibited or regulated in any specific manner ?

11. Scripts relating to advertisement of drugs broadcast through the All India Radio are at present screened by a Committee which includes a representative of the Indian Medical Association. Has your Association any suggestions to make for more stringent screening of advertisement so as to prevent false, exaggerated or misleading claims being made ?

12. What is the Association's view on the usefulness of advertisements that are mailed by drug manufacturers to the medical profession ? Since manufacturers include package inserts about the drug is there any need for mailing of literature on drugs to doctors, especially as doctors are busy and seldom find time to go through them ?

13. Distribution of samples of drugs to the medical profession by drug manufacturers, it is reported, leads malpractices of different types. Would your Association support this practice being stopped ? If total stoppage is not considered advisable, please indicate the manner in which distribution of drugs samples could be regulated.

14. What are your Associations' views on the quality control measures over drugs taken by Government ? Is there any rapport between your Association and the Drug Control Organisation at the Centre and the States ? Has your Association any views on the improvement of quality control measures ? Would it *not* be useful if Medical Associations also arrange for study of drug manufacturing and convey their views to the Drug Control Organisations ?

15. In the opinion of your Association, what is the extent of prevalence of adulterated and counterfiet drugs in the country ? What remedial measures would you suggest for tackling the problem ?

16. It has been represented that the dispensaries run by medical practitioners are deficient in the adequacy of arrangements for dispensing operations, the qualifications and experience of the dispensing personnel at the conditions of storage of drugs. What are the views of your Association on the dispensaries of medical practitioners being licensed under the Drugs and Cosmetics Rules and subjected to the same regulatory measures as licensed drug establishments?

17. Does your Association have specific "Drug Panels" to study the problems relating to drugs and the drug industry? Does the journal of your Association devote itself, among other things, to subjects, such as the development of the drug industry; the profits made by drug firms, particularly, the foreign ones; the economics of prescribing drugs and the quality control measures observed by drug manufacturing firms?

18. There is an impression that the medical profession generally tilts towards the products of foreign firms and that this is partly due to the high pressure sales promotional methods employed by such firms and the massive scale of sampling of drugs resorted to by them. What is your Association's reaction to this?

19. What measures do you suggest for providing essential drugs and common household remedies to the general public, especially in the rural areas and to the weaker sections of the community, at reasonably cheap prices?

20. What measures do you suggest for increasing the production of drugs and pharmaceutical products so as to meet the quantitative requirements of the country at the end of the Fifth Five Year Plan?

21. Does your Association have any specific view on drug research in this country? Do you think the facilities for research and development in the fields of Fine Organic Chemicals and Microbiology adequate to meet the country's requirements? What are your views on having Regional Research Laboratories with Government subsidy?

22. Does your Association have any observations to make on "New Drugs", their screening and their clinical trials in this country?

ANNEXURE V

Questionnaire For The State Governments

(Chapter I—Para 5)

1. What are your views on the quality and availability of medicines produced by :

(a) Small-Scale units;

(b) Large wholly—owned Indian units;

(c) Large foreign coliaborating units; and

(d) Public-sector units *viz.* IDPL and HAL.

2. Please indicate in terms of value and quantity the purchases made for State Government hospitals/Dispensaries etc. from the above four categories of drugs manufacturers, during the last 3 years, separately.

3. What are your purchase policies?. Do you insist on procuring the medicines produced by the well-known foreign collaborating firms only? Or, have you been switching over from the well-established foreign collaborating firms to Indian firms' products, particularly those produced by the public sector units and small-scale firms? If not, indicate your reasons.

4. What are your views about the availability of medicines in general? What measures you would like to suggest to improve the supply/availability position of drugs and medicines particularly in the rural areas?

5. What measures do you consider necessary for improving the status of the public sector units, both in the manufacture of bulk drugs and formulations, and other areas like propaganda, distribution of medicines, research and development etc.?

6. What steps, in your opinion, should be taken, for the following :—

(a) to produce all the bulk drugs in the quantities as required in the country;

(b) to promote rapid growth of this industry, particularly the Indian and small-scale sectors, keeping in view the need for balanced regional dispersal of the indstury;

(c) to ensure the availability of essential drugs and common house-hold remedies to the general public, especially those in the rural areas;

(d) to ensure equitable distribution of basic drugs and raw materials, particularly for the small-scale sector units.

7. Do you think the present quality control on drugs is effective? If not, what measures would you suggest for effective quality control on drugs and for rendering assistance to the small-scale units, in particular, in this regard?

8. Whether any efforts have so far been made for setting up of any drug manufacturing unit under the State control? If so, the name of such unit along with their detailed activity and sales turnover may be indicated.

9. What measures would you recommend for adoption by the industry to reduce the price of medicines in the country to the minimum possible level, keeping in view the requirements of funds for its further growth, Research and Development etc.?

10. What are your views about the multi-drug formulations as are presently marketed by some of the manufacturers? Do you consider that the production of formultations should be limited to those only as given in the National Formulary of India?

11. What are your views on the use of Brand Names?

12. Any other point to suggest?

ANNEXURE VI

Details of sittings of the Committee on Drugs and Pharmaceutical Industry and its Sub-Committees; visits to various drug manufacturing units, etc., and discussions held with officials of Government and representatives of Associations Organisations.

(Chapter—I—Paras 9 & 12)

6th March, 1974 . .	*First meeting of Committee on Drugs and Pharmaceutical Industry.*
18th March, 1974 . .	Meeting of the Sub-Committee for drafting questionnaires.
21st March, 1974 . .	Second meeting of the Committee.
8th April, 1974 17th April, 1974 29th April, 1974 . .	Meeting of the Sub-Committee on Permission/No Objection Letters and C.O.B. Licences.
2nd May, 1974 . .	Third meeting of the Committee on Drugs and Pharmaceutical Industry.
14th May, 1974 15th May, 1974 . .	Meeting of the Sub-Committee on quality Cont rol of drugs and related matters.
16th May, 1974 . . .	Fourth meeting of the Committee on Drugs and Pharmaceutical Industry.
17th May, 1974 . . .	Meeting of the Sub-Committee on Permission Letters.
8th June, 1974 9th June, 1974	Meetings of the Medical Panel on essential drugs and abolition of brand names, (Bombay).
28th June, 1974 Bombay .	*Visits to :*
	M/s. Chemical, Industrial & Pharmaceutical Laboratories Limited, Bombay.
	M/s. Abbott Laboratories, Bombay.
	M/s. Hoechst Pharmaceuticals, Bombay.
	M/s. Unique Pharmaceutical Lab., Bombay.
	M/s. Nitson Laboratories, Bombay.
	M/s. Sandoz (India) Limited, Bombay. Ciba Research Centre, Bombay.
29th June, 1974 Bombay .	*Visits to :*
	M/s. Haffkine Institute, Parel, Bombay.
	M/s. Labs. Vifor, Bombay.
	M/s. Unichem Labs., Bombay.

	Meetings with : (i) All India Manufacturers Organisation, Bombay. (ii) Indian Drugs Manufacturers Assn., Bombay. (iii) Indian Pharmaceutical Assn., Bombay.
30th June, 1974 Bombay .	*Visit to :* M/s. Themis Chemicals, Vapi. M/s. Themis Orgasyn Chemicals, Vapi. M/s. MAC Labs., Vapi.
1st July, 1974 Pimpri .	*Visit to :* Hindustan Antibiotics Limited, Pimpri.
2nd July, 1974 Ahmedabad	*Visits to :* M/s. Cadila Laboratories, Ahmedabad. M/s. Gujarat Pharmaceutical and Chemical Works, Ahmedabad. *Meeting with :* Pharmaceutical Manufacturers Association, Ahmedabad.
3rd July, 1974 Baroda .	*Visits to :* M/s. Alembic Chemicals Works, Baroda. M/s. Vaccine Institute, Baroda. Drug Control Labs., Gujarat, Baroda.
4th July, 1974 Baroda .	*Visits to :* Operations Research Centre, Baroda. M/s. Sarabhai Chemicals, Baroda. Sarabhai Research Centre, Baroda.
25th July, 1974 . .	Fifth Meeting of the Committee on Drugs and Pharmaceutical Industry.
31st August, 1974 Rishikesh	*Visit to :* Antibiotics Plant, Rishikesh.
16th September, 1974 Madras.	Visits to . M/s. Orient Pharma Private Limited. M/s. Mount Mettur Pharmaceuticals Limited. M/s. Tamil Nadu Dadha Pharmaceuticals Ltd.
17th September, 1974 Madras.	*Visits to :* M/s. Medo Pharma. M/s. Citadel Fine Pharmaceuticals Limited. *Meetings with :* Pharmaceuticals Chemical & Allied Manufacturers Association of South India. Joint Council of Indian Pharmaceutical Trade.
18th September, 1974 Hyderabad.	*Visits to :* Synthetic Drugs Plant, Hyderabad. M/s. Bio-Chemical & Synthetic Products Limited. M/s. Warner Hindustan Limited. *Meetings with :* All India Manufacturers' Organisation A.P. State Board, Hyderabad, Andhra Pradesh. Pharmaceutical & Chemical Manufacturers' Associations.
19th September, 1974 Hyderabad	*Visits to :* M/s. Biological Evans Limited, Hyderabad. M/s. Uni Sankyo Limited, Hyderabad. *Discussions with :* Minister of Health—A.P. and other Officers.

30th September, 1974 Calcutta.	*Visits to :* M/s. Dolphin Laboratories, Calcutta. M/s. Organon Laboratories, Calcutta. M/s. Bengal Immunity Co., Calcutta. Bengal Immunity Research Institute, Calcutta. *Discussions with :*—Hon'ble Minister of Health & Family Planning, West Bengal. Courtesy call on Hon'ble Chief Minister, West Bengal. *Meeting with :* All India Manufacturers Organisation, (West Bengal State Board).
1st October, 1974 Calcutta	*Visits to :* M/s. Smith Stanistreet, Calcutta. M/s. Bengal Chemical & Pharmaceutical Works, Calcutta. Central Drugs Laboratory, Calcutta. M/s. Dey's Medical Stores, Calcutta. M/s. Dey-Se-Chem, Calcutta. M/s. Calcutta Chemicals Limited, Calcutta. *Meeting with :* Indian Drugs Manufacturers Association.
2nd October, 1974 Calcutta	*Discussions with :* (i) Director of Drugs Control, West Bengal. (ii) Specialists in the field of medical research.
3rd October, 1974 Calcutta	*Visits to :* M/s. Accto Chemicals, Calcutta. M/s. East India Pharmaceuticals Limited, Calcutta. M/s. Standard Pharmaceuticals Limited, Calcutta.
19th October, 1974 20th October, 1974 21st October, 1974	Sixth Meeting of the Committee on Drugs and Pharmaceutcial Industry.
16th November, 1974 Durgapur.	*Visits to :* M/s. Durgapur Projects Limited, Durgapur. M/s. Durgapur Chemicals Limited, Durgapur. Discussions with the Senior Officials of the Undertakings.
4th January, 1975 5th January, 1975	Seventh Meeting of the Committee on Drugs and Pharmaceutical Industry.
20th January, 1975 21st January, 1975	Eighth Meeting of the Committee on Drugs and Pharmaceutical Industry.
22nd January, 1975	Meeting of the Sub-Committee on Permission/No Objection Letters etc.
7th February, 1975	Meeting of the Sub-Committee on Permission Letter/No Objection Letter/COB Licences with the Secretaries of Ministry of I.D., DGTD and P & C.
8th February, 1975	Meeting of the Sub-Committee on Permission/No Objection Letters.
9th February, 1975 10th February, 1975 11th February 1975 12th February, 1975	Ninth Meeting of the Committee on Drugs and Pharmaceutical Industry.
25th February, 1975 26th February, 1975	Tenth Meeting of the Committee on Drugs and Pharmaceutical Industry.
4th March, 1975 5th March, 1975 6th March, 1975	Eleventh Meeting of the Committee on Drugs and Pharmaceutical Industry.
5th April, 1975	Twelfth Meeting of the Committee on Drugs and Pharmaceutical Industry.

CHAPTER II

PROGRESS MADE AND STATUS ACHIEVED

by

THE PHARMACEUTICAL INDUSTRY

The drugs and Pharmaceutical industry in India is well established today. It now produces a wide range of drugs including the sophisticated ones like antibiotics, hormones, vitamins in addition to a large number of other synthetic chemo-therapeuticals. This industry has an important role to play in maintaining the health of the nation and has the responsibility of meeting the expanding needs of the country. The task before this industry, therefore, is not only to produce more medicines and provide them in the required quantities but also to ensure that the medicines produced are of the right quality and would relieve the suffering patients of their illness at low cost.

2. The drug needs of the country are diverse and the industry has to meet all such demands. Because of the diverse nature of the requirements, the industry has to adopt widely different and varied techniques for the production of the medicaments. These cover fermentation technology, synthetic operations, extraction and purification of the active principles available in the plant and animal kingdom etc., besides converting these active ingredients into the finished formulated dosage form of the right type. Basically, this is a highly research-oriented chemical-based industry.

3. It would be worthwhile to trace the history of development of the drugs and pharmaceutical industry in India and the stages it has trekked in achieving the present status. It has a long way to go to achieve the objectiv placed before this industry, and indeed, it has to strive hard to make the country self-sufficient.

4. Modern system of medicine embraces a large variety of products ranging from phyto-chemicals t identifiable highly complex chemical substances like antibiotics, hormones etc. A beginning was made in the pro duction of medicines required under the modern system by starting cinchona plantation in the States of Bengal an Madras, presently known as West Bengal and Tamil Nadu respectively. Factories we set up in the vicinity of th plantation areas for the extraction and purification of quinine. Even a brief resume of this chemical-based industr would be incomplete if no reference is made to the pioneering work done by late Acharya P.C. Ray followed b similar efforts of late Messrs T.K. Gajjar, B.D. Amin and Koti-bhaskar. Their efforts resulted in the establishmen of units for local manufacture of galenicals and some other simple drugs. Cessation of imports during the first worl war years gave impetus to the industry to produce the medicines locally. A new compound, urea-Stibamine, wa developed through local R & D activity, which was found to be highly effective against Kala-azar, a scourge which w afflicting people much those days. The most remarkable success was achieved in the manufacture of Sera an Vaccines in the period that followed thereafter. Pioneering work in the field of phyto-chemicals was done by lat Col. R.N. Chopra. Manufacture of Caffeine from tea-waste, anaesthetics like other form alcohol and a few simp drugs based on coal-tar distillation products were also taken up in the country. In spite of such developments, t progress was far from being satisfactory. During the second world-war, the local industry made further progr by producing a number of other products indigenously out of the locally available raw materials. These were mai in the category of phyto-chemicals, although some progress was also made in the fields of synthetic drugs and bio gical products. The country, by then, produced substantial quantities of Sera and Vaccines. Some industrial un also took up the manufacture of synthetic anti-dysentery drugs, anti-leprosy drugs and arsenicals. Side by si formulating activities were also increasing considerably based on imported bulk drugs and several new formulatio were also developed locally. Here again, the bulk of the activity was confined only to the processing of impor bulk drugs except for a few items which were produced from late intermediates. The slow progress of the local chemi industry also affected the growth of the pharmaceutical industry. Besides, the appearance of number of synth drugs and antibiotics, which were developed abroad and imported into the country, also tended to change the pat of drug use in India. The medicines that were available out of indigenous production, failed to keep pace with competition offered by the products of imported origin.

5. In the year 1953, the Government of India set up the Pharmaceutical Enquiry Committee with the follo terms of reference :—

(i) To study the working of the existing pharmaceutical manufacturing concerns in India with particular reference to:—

(a) the demand for the drugs produced and their essentiality;

(b) the quality of the drugs;

(c) the cost of production;

(d) the efficiency of the process employed; and

(e) whether the product is made from imported intermediates and penultimate products, or from basic raw materials and chemicals.

(ii) To study the operations of foreign, and/or Indian concerns, who import drugs and pack them in the country. The extent and tie-up between the wholly or partly owned Indian concerns with foreign companies.

(iii) To recommend steps for encouraging the manufacture of important drugs, which are imported into the country.

(iv) To enquire into the scheme of distribution of pharmaceutical products, whether imported or manufactured or packed in the country, the profit margin to trade or industry and the part played in this by purely Indian as well as other concerns.

(v) All ancillary matters connected with the above.

6. The above Committee, after a detailed enquiry, made certain recommendations as to how the various aspect and problems concerning this industry should be examined and handled for its growth in the country. It also observed that the then existing pharmaceutical industry in India when compared with the industry in UK and USA could be considered to be almost non-existent. It also noted that even after the end of the hostilities, the world shortage of pharmaceuticals and drugs continued and the tempo of development of the pharmaceutical industry was maintained in the country, and export markets for glandular products, alkaloids etc. were also developed. But this happy position did not continue for long. Competition from the better established and well-known pharmaceutical producers, in other countries soon replaced the Indian products from the export markets. Even within the country, the Indian industry faced severe competition from foreign products/producers.

7. In spite of the gorwth and progress made so far, the Indian sector still faces competition from the foreign units and the reasons are not far to seek. It has been so because of the deeply entrenched impression created in the minds of the medical profession by the well-established multi-national manufacturing concerns of their products These multi-national units entered the Indian market with their vast resources with the result, that the Indian sector of the industry now finds it difficult to compete with the former.

8. The Pharmaceutical Enquiry Committee also suggested to make the production of the basic drugs economical, each manufacturer of pharmaceuticals should endeavour to produce as many of the basic drugs as practical from intermediates and basic raw materials in quantities sufficient not only to meet his own requirements, but also to dovetail the production programme with the requirements of others in the country. While some of the firms did tend to undertake the manufacture of bulk drugs, they came across several difficulties due to lack of technology, basic chemicals etc.

9. The drugs industry presently comprises of 116 units in the organised sector (units registered/licenced under the Industries (Development and Regulation) Act, 1951 and more than 2500 units in the small scale sector. The organised sector has 25 units with foreign equity exceeding 50% and 26 units with foreign equity of 50% or less. In the small scale sector, 9 units have foreign equity exceeding 50%, while 6 units have 50% or less of foreign equity.

10. According to the Industrial Policy Resolution of 1956, the pharmaceutical industry can be developed both in the public and private sectors. The Government of India set up in 1954 the Hindustan Antibiotics Limited, at Pimpri for the manufacture of antibiotics, and Indian Drugs and Pharmaceuticals Limited in 1961 with two drugs manufacturing units, one at Hyderabad for the production of synthetic drugs and the other at Rishikesh for the production of antibiotics, with the following objectives :—

(i) to make the country self-sufficient in drugs and pharmaceuticals;

(ii) to free the country from foreign exploitation; and

(iii) to provide cheaper medicines in adequate quantity to the people.

11. Out of 116 units borne on the books of the Directorate General of Technical Development (DGTD) 64 units produce bulk drugs and formulations. While 15 manufacturer bulk drugs only, 18 others manufacture only formulations and 5 have been recently issued industrial licences or have been registered for manufacture of bulk drugs and formulations. There are 14 units which are engaged in the production of gelatine capsules, plasma volumes expanders, sutures, etc., with or without other drug formulations.

12. The industry has been expanding its manufacturing activity, and the total turnover of this industry in respect of bulk drugs during the year 1973, has been estimated at about Rs. 75 crores, and that of formulations at Rs. 370 crores.

13. The statement (Annexure—1) shows the names of the various antibiotics and other major bulk drugs presently produced in the country. The statement also shows the production of individual units during the years 1970 1971, 1972 and 1973 along with their licensed capacities, as well as the further capacities which have been approved under the Letters of Intent issued. The targets for the years 1978-79 and 1983-84 estimated by the Task Force set up by the Planning Commission have also been shown in columns 4 and 5 of the statement. This statement, however, does not cover the data in respect of small-scale sector.

14. While the industrial units in the small-scale sector are mostly engaged in the production of formulations, some of the units are also producing bulk drugs, which are either formulated by themselves or offered for sale to other formulating units, both in the small-scale and organised sectors including the foreign units. The data furnished by the small-scale sector units, in response to a query made by the Ministry of Petroleum & Chemicals, has been compiled in *Annexure II*. It will be seen therefrom, that a number of bulk drugs like Nicotinic acid/amide, I.N.H. Paracetamol, Lignocaine, Phenyl butazone, Diazepam, Diphenhydramine, Diethyl Carbam cizine Citrate, Imipramine, Meprobamate, Tolbutamide etc. are produced by this sector. These drugs are also produced by the organised sector of the industry. According to the data available, it is noted that in a number of cases the starting materials utilised by the small-scale sector are the same as those used by the organised sector units while in some other cases, they differ. Examples of the first category i.e. where both the small-scale sector and the organised sector units utilise the same raw materials in the manufacture of the concerned drugs, are as under :

Paracetamol	Diazepam
Di-iodo-oxy-Quinoline	Thiacetazone
Methanamine mandalate	Imipramine hydrochloride
Nicotinic acid/amide	Chlorpromazine Hydrochloride
Isonicotinic acid Hydrazide	Meprobamate
Oxy-phenybutazone	

Names of the bulk drugs where the small-scale sector use later stage raw materials as compared with those used by the organised sector are :—

Diethyl Carbamazine Citrate	Sulphamethiazole
Sulphadiazine	Aspirin
Piperazine salts	Tolbutamide
Riboflavine 5-Phos. Sodium	Phenyl butazone
Phenacetin	

15. The quantum of production during 1973 of bulk drugs, which are produced both by the small-scale as well as the organised sector units has been shown separately in *Annexure III*. It will be seen that the production of such drugs which are already undertaken in the small-scale sector alongwith the capacities licensed or covered by letters of Intent issued in favour of the organised sector units if utilised fully would take care of the estimated requirements of such drugs for the 5th Plan period in many cases.

16. The quantities of synthetic drugs and antibiotics produced by the different sectors of the industry in 1973 are shown below :—

Item	Unit	Public Sector	Wholly Indian owned units and units with equity participation upto 50%	Units having foreign equity of more than 50%
1	2	3	4	5
I. Antibiotics				
Penicillin	MMU	136.88	110.64	..
Streptomycin	T	95.73	84.12	..
Tetracyclines	T	24.21	7.04	58.02
Chloramphenicol	T	..	15.82	31.37
Others	T	0.27	3.54	..
II. Synthetic Drugs				
Sulphas	T	670.13	453.81	136.75
Anti T.B.	T	144.61	315.64	159.64
Anti Dysentery	T	..	85.62	28.70
Anti-leprotic	T	..	1.07	7.09
Anti-diabetics-Insulin	MMU	..	..	898.03
Synthetics	T	..	58.02	9.08
Anti-malarials	T	29.02	6.01	20.21
Anti-filarials	T	..	1.04	6.61
Anaesthetics	T	..	417.98	..
Anti-pyretics				
Analgesics and Anti-gout	T	276.43	1487.79	0.87
Anthelmintics	T	66.53	..	..
Barbiturates	T	9.18	..	..
Corticosteroids, hormones	Kgs.	..	314.14	2262.65
Phyto-chemicals	T	5.95	42.15	0.13
Vitamin A	MMU	..	..	47.38
B 1	T	27.39	..	..
B 2	T	1.21	..	..
B 12	Kgs.	..	55.08	123.60
C	T	..	261.58	..
Folic Acid	T	2.12	..	..
Nicotinic acid/amide	T	14.92	86.18	..
Vitamin D2/D3	Kgs.	..	75.99	..
E	T	..	..	5.52
K	Kgs.	..	366.40	..
Pantnenol	T	..	..	0.60
Anti-histaminics	T	..	4.85	1.51
Diuretics	T	..	0.67	0.63
Vasodilators	T	..	..	4.47
Anti-depressants	T	..	6.85	4.78
Anti-hypertensive and CVS Drugs	T	..	1.00	..
Immunological agents	T	..	Produced by Govt and Indian units.	
Others	T	..	115.60	117.16

17. The production of various bulk drugs by the organised sector of the industry during the year 1952, 1957, 1960, 1965, 1970 and 1973 is indicated in Annexure IV. This shows the extent to which the industry has been able to take up the production of the bulk drugs and the growth attained by it during this period. Whatever laudable progress may have been achieved by this industry so far, it is still far from meeting the requirements of the country. The progress attained so far is not commensurate with the increasing needs of the country particularly in respect of the bulk drugs. Even for a number of items which are currently produced within the country substantial imports are being made. The quantum of imports during the last 3 years in respect of the bulk drugs produced indigenously, is shown in Annexure V. This would give an idea of the extent to which the industry would need to gear itself to meet the country's requirements. It would also be seen when compared with Annexure I, that in respect of a number of items, while capacities have been covered by industrial licences issued, there has been no production in 1973 in respect of certain items, while in respect of a number of other, the production achieved is much below the approved capacities. The reasons for such non-implementation or under-implementation of proposals/capacities are many, such as delay in the procurement of equipment/raw materials, poor technology, management problems, uneconomic production, etc.

18. It has been mentioned earlier that more than 2500 units are there in the small-scale sector. Although authentic data are not available, their production is estimated to be about 20% of the over-all turnover of the industry. Some of these small-scale units are run by technologists and they are playing an important role in the production of bulk drugs from basic, stages as well as intermediates and pharmaceutical chemicals required by this industry. Such units would be able to play a vital role in the future growth of this industry by taking up the manufacture of additional new bulk drugs as well as in expanding the production of the existing items to help meet the future requirements of the country. The pharmaceutical industry provides a wide opportunity to this class of entrepreneurs, particularly in respect of items which involve relatively less capital investment and where techology would pose no serious problem for their manufacture. The small-scale sector could then be expected to make a major break-through and contribute substantially to the nation's efforts towards self-reliance. Annexure II shows the quantum of bulk drugs and pharmaceutical chemicals presently produced in this sector. The Committee during its visits to the various parts of the country, noted with satisfaction that a number of small-scale units are confining their manufacturing activities only to the manufacture of bulk drugs, without the support of formulations It is necessary to provide adequate incentives and assistance to this sector for its growth, particularly in the field of basic manufacture.

19. In spite of the considerable growth attained so far by this industry, a large number of bulk drugs still require to be imported to meet the present demands. Annexure VI shows the names of the bulk drugs imported into the country during the year 1973-74. The items have been identified in the statements (a) those whose individual imports were more than Rs. 10 lakhs each and (b) those whose imports were valued between Rs. 5 lakhs and Rs 10 lakhs. It will be seen therefrom that the following 6 antibiotics alone accounted for a total import of about Rs. 5 crores.

	(Rs. in lakhs)
1. Ampicillin	160.69
2. Erythromycin	66.39
3. Gentamycin	42.23
4. Streptomycin	63.14
5. Tetracycline	73.59
6. Chloramphenicol	86.54
Total	492.58

20. The number of items whose individual imports were valued at more than Rs. 10 lakhs, is 38, while 26 items were imported whose individual values ranged between Rs. 5 and Rs. 10 lakhs. To summarise, the following number of bulk drugs were imported during 1973-74, having individual value range as indicated against each :—

	(Rs. in Lak
Above Rs. 50 lakhs	9
Between Rs. 25 lakhs and Rs. 50 lakhs each	10
Between Rs. 10 lakhs and Rs. 25 lakhs each	19
Between Rs. 5 lakhs and Rs. 10 lakhs each	26

In respect of a number of items where the imports during 1973-74 were more than Rs. 10 lakhs each, expansion in their local production has been taken on hand and the imports during the next year are expected to come down substantially with increased local output. The items covered under this category would be Analgin, Tetracycline, Streptomycin, Chloramphenicol, Chloroquin, Sulpha-guanidine, Sulphamethoxypridazine, Vitamin C, and Ampicillin. In respect of number of other products, additional capacities have been approved for their manufacture and with the increased production their imports would also come down in course of time. Examples under this group are, Procaine, Dilaxonide, Panthenol, Vitamin E, Vitamin P, Metronidazole, Diazepam and Frusemide. In the case of the following bulk drugs, the projected requirements for the Fifth Plan period have been covered by industrial licences and Letters of Intent issued.

Kanamycin	Chloroquin/salts	Vitamin B-1
Sulphaguanidine	Analgin	B-2
Sulphadimidine	Indomethacin	B-6
Sulphadimethoxine	Probenecid	Xanthinol Nicotinate
Ethambutol	Diazepam	
Ethionamide	Chlofibrate	
Metronidazole	Folic acid	
Diloxanide/Furoate		

It is expected that the quantum of imports would come down after the units go into production.

21. Total imports of major bulk drugs during the last 3 years have been summarised as under, group-wise :—

(Rs. in lakhs)

Sl. No.	Group of drugs	1971-72	1972-73	1973-74
1.	Antibiotics	884.16	615.97	571.82
2.	Anaesthetics/analgesics	90.66	95.23	113.09
3.	Antiamoebic (dysentery)	23.76	35.28	40.55
4.	Anti-cancer	4.77	8.11	8.47
5.	Anti-diabetics : Insulin	32.41	7.05	7.37
	Orals	7.02	7.79	5.29
6.	Anti-epileptics	2.70	5.22	6.23
7.	Anti-leprosy	Nil	Nil	Nil
8.	Anti-malarials	77.21	129.64	64.37
9.	Anti-histaminics	15.76	24.35	18.38
10.	Anti-T.B.	25.64	4.64	10.18
11.	Cardiac	4.70	7.54	10.06
12.	Diuretics	2.76	23.13	12.17
13.	Hormones/Steroids	86.43	78.58	98.17
14.	Immunologicals	12.41	12.25	5.98
15.	Sulphas	211.81	170.77	110.06
16.	Tranquillizers	16.06	14.18	58.70
17.	Vitamins	199.87	184.85	246.37
18.	Barbiturates	8.31	10.57	7.82
19.	X-Ray/Diognostic agents	2.26	6.49	9.50
20.	Catguts	0.15	0.63	Nil
21.	Others	400.33	310.63	306.46
	TOTAL	2109.17	1752.44	1711.03

Exports vs Imports :

22. Drugs and pharmaceutical industry is included in the list of priority industries which carry an export obligation. The individual units in this industry are liable to a cut in their import requirements/entitlements whose export performance is less than 5% of their production during the previous year. The cuts imposed are on a slab system as indicated below :—

Export performance	Cut imposed
1. No exports or export less than 1%	20%
2. Export 1% or above, but less than 2%	15%
3. Export 2% or above, but less than 3%	10%
4. Export 3% or above, but less than 4%	7.5%
5. Export 4% or above, but less than 5%	5%
6. Export 5% or above	No cut.

23. The above cuts apply to the entitlements for imported raw materials required for the manufacture of the products listed below :—

1. Antibiotics Preparations.
2. Emetine preparations.
3. Quinine sulphate.
4. Quinine preparations—others
5. Strychnine preparations.
6. Brucine preparations.
7. Ayurvedic and Unani Medicines.
8. Antacid and Digestive preparations.
9. Cold, Cough and Bronchial preparations.
10. Asthama, Catarrah and Hay Fever preparations.
11. Gripe water.
12. Headache, Neuralgia and Pain Remedies.
13. Disinfectants.
14. Salves, Ointments for Burns, Cuts etc.
15. Tonics, Blood Purifiers and Emulsions.
16. Proprietary and Patent Medicines n.o.s.
17. Botanical drugs and derivatives.
18. Beta Ionone.

24. The cut as mentioned above would not apply to the raw material requirements in respect of otner end-products of this industry. The export obligation, however, does not apply to :—

(i) small-scale units; and

(ii) other units which have not completed 5 years of production.

25. Depending upon the export performance of the individual units this industry also enjoys a preferential treatment in respect of their imports of raw materials. In order to help production for exports, units which export 10% or more of their production are entitled to the following facilities :—

(i) expansion of their export production; and

(ii) import of their requirements from preferred sources of supply.

Industrial units exporting 25% or more of their production are eligible to import a higher quantum of their requirements against free foreign exchange. Normally, DGTD now allows imports of raw materials etc. in equal proportions from both the General Currency Area (GCA) and Rupee Payment Area (RPA), i.e. the Actual Users' import licence values are divided equally, as 50% from the former and the balance of 50% from the latter. In case of units exporting more than 10% of their production, the G.C.A. value is increased to 75% and correspondingly the R.P.A. portion is reduced to 25%, depending upon the availability of the required raw materials from the respective sources. In case of essential raw materials, additional ad-hoc imports are also allowed in deserving cases.

26. According to the statistics compiled by the Basic Chemicals, Pharmaceuticals and Cosmetics Export Promotion Council, the exports of drugs, pharmaceuticals and fine chemicals during the last 3 years have been as under :—

Year	Rs. crores
1971-72	10.33
1972-73	13.53
1973-74	37.54

The details of the exports of drugs, pharmaceuticals and fine chemicals during these 3 years, have been given in Annexure VII. It will be seen therefrom that a number of products viz. Streptomycin, Chloramphenicol, Oxytetracycline, Anti-diabetic drugs other than Insulin, Chloroquin and its salts, some of the sulpha drugs, Salicylic acid, Salicylamide and phyto-chemicals like Emetine, Quinine and its salts, Strychnine and Brucine alkaloids, Berberine Hcl. etc. along with their preparations have also been exported besides a number of other drugs/formulations. The above figures include the exports of medicinal castor oil during these years as under :—

Year	(Rs./crores)
1971-72	0.23
1972-73	2.03
1973-74	21.13

27. Drugs and pharmaceuticals produced in India are now being exported to 80 countrie, including the developed countries like UK, USA, West Germany, USSR, Japan and others, who buy mostly the basic drugs and fine chemicals. Total exports of drugs and pharmaceuticals, excluding medicinal castor oil, accounted for about 5% of the indigenous production.

28. There was a remarkable increase in the export of Quinine salts. Exports in 1973-74 were of the value of Rs. 1.18 crores, as compared to Rs. 0.70 crores during 1972-73, the main buyers being West Germany, Hungary, USSR and Bulgaria.

29. There has also been a substantial increase in the export of crude drugs, exports having gone upto Rs. 7.70 crores in 1973-74, as against Rs. 4.29 crores in 1972-73. Major items were Psyllium husk/seeds and Senna leaves and pods.

30. Annexure VIII would give the details of exports of drugs, pharmaceuticals and fine chemicals effected during the 6 monthly period April/Sept. 1974, as compared to the corresponding periods in the earlier two years i.e. April—September, 1973 and April—September, 1972. The total exports, including medicinal castor oil, during the half yearly periods of 1974, 1973 and 1972, have been as under :—

April—September, 1974 (estimated)	Rs. 25.3 crores
April—September, 1973	Rs. 17.64 crores
April—September, 1972	Rs. 5.07 crores

An analysis of exports during this half yearly period of the three years would bring out the following data which would show that there has been a considerable increase in the export of these items over the year :—

(Rs./Lakhs)

Item	April—Sept. '74	April—Sept. '73	April—Sept. '72
Quinine salts/alkaloids	139.47	55.71	31.36
Antibiotics and their preparations other than Streptomycin, Penicillin, Oxytetracycline and Chloramphenicol	25.21	13.50	9.83
Nux Vomica alkaloids	13.88	12.37	6.47
Certain sulpha drugs	1.12	0.23	0.02
Salicylic Acid	18.02	0.14	0.09
Medicinal Castor oil	1569.89	1229.08	37.68
Salicylamide	4.13	..	..

31. Besides the general export obligation under the Trade Control Policy, certain specific export conditions are of late being imposed now while approving proposals under the Industries (Development & Regulation) Act, for the manufacture of new drugs as well as for expansion, particularly in the case of firms having majority foreign equity participation. The quantum of export stipulation imposed varies between 10% and 60% depending upon the nature of the product and its possible demand in the export market.

32. The data furnished below would show the growing imbalance between import requirements of the industry and the export earnings :—

(Rs./crores)

Exports of drugs, pharmaceuticals and fine chemicals

1963-64	2.00	
1965-66	4.80	
1967-68	4.63	incl. Med. castor oil
1969-70	7.31	,, ,,
1971-72	10.33	,, ,,
1973-74	37.54	,, ,,

Import of drugs and pharmaceuticals etc.

(Rs./crores)

1963-64	13.17
1965-66	13.90
1967-68	26.51
1969-70	26.19
1971-72	35.04
1973-74	37.50

It may be seen that while exports have gone up from Rs. 2.00 crores in 1963-64 to Rs. 37.54 (Rs. 16.41 crores, excluding medicinal castor oil) in 1973-74, imports have gone up from Rs. 13.17 crores in 1963-64 to Rs. 37.50 crores in 1973-74. The production of finished formulations during this period increased from Rs. 120.0 crores in 1963 to Rs. 370 crores in 1973. This would indicate that the industry has to strive hard to reduce the import bill through increased production.

33. **Distribution pattern of drugs**

It would be interesting to review the shares of the various drugs, according to the different therapeutic groups, in their sales through the trade channel. A study of the market survey undertaken by a commercial research group would reveal the following interesting data. The study made by this research group is based on the sales of finished medicinal preparations of about 120 companies effected through the trade channel. These data were worked out on purchase records maintained by 532 chemists spread out all over India. These, however, do not cover the off-take by the non-chemists i.e. the doctors, hospitals, Government agencies etc. The following percentages against the various categories of products during the years 1969, 1971 and 1973 have been worked out :

Category of products	1969	1971	1973
1	2	3	4
1. Antibiotics	20.7	19.3	19.9
2. Vitamins	12.7	12.1	11.7
3. Cough & Cold preparations	5.7	6.0	5.5
4. Haematinics	5.1	5.5	5.3
5. Tonics & Health restorers	4.7	5.0	5.2
6. Hormones	5.1	4.8	4.8
7. Dermatological preparations	3.5	3.9	4.1
8. Analgesics	3.5	3.7	3.8
9. Anti-rheumatics	2.9	3.1	3.1
10. Anti-diarrhoeals	3.2	2.7	3.1
11. Dietetics	3.4	3.1	2.6
12. Enzymes and digestants	2.8	2.7	2.5
13. Cardio-vascular drugs	1.9	1.8	1.8
14. Anti-spasmodics	1.4	1.5	1.8
15. Psyohotherapeutics	1.8	1.6	1.7
16. Opthalmologicals	1.6	1.9	1.7
17 Anti asthmatics	1.4	1.6	1.6
18. Amoebicides	0.9	1.3	1.3
19. Anti-T.B. preparations	1.2	1.5	1.4
20. Antacids	1.2	1.4	1.4
21. Anti-Histaminics	1.2	1.4	1.4
22. Sulphonomides	1.7	1.5	1.3

34. As mentioned earlier, in the computation of the above figures, only the sales effected through the retail trade channel have been taken into account. Significant purchases are also made by the Government agencies, hospitals and doctors, which have not been reflected in those estimates. The low percentage in respect of Sulphonamides and Anti-T.B. preparations could be due to the fact that such preparations are made available in large quantities to the consumers through the hospitals and other Governmental agencies.

35. It would be seen from the above that about 22% of the market share is enjoyed by Vitamins, Tonics and health restorers and haematinics, while about 20% was shared by the antibiotics. There has been a decline in the sales of Sulphas through the trade and an increase in the amoebicidals. In the case of other categories of medicines, the market share has been more or less the same over the years, with minor changes.

Research and Development

36. It is well-known that the drugs and pharmaceutical industry is highly research-oriented and the key role that R&D plays in this industry cannot be over-emphasized. The need for intensive research and development work in any field of industrial activity is of utmost importance, but this is more so in the field of drugs and pharmaceuticals.

37. According to the present estimate, the expenditure on research and development activity incurred by the industry in India, is about Rs. 4.5 crores per annum, about 1.1% of the total turnover by the industry in 1973. The expenditure is woefully inadequate when looked at from the angle of total turnover by this industry, vis-a-vis the expenditure incurred on R&D in the developed countries and the turnover attained. While the expenditure by any individual unit here does not exceed 5% of its turnover, except for Haffkines (14%), the R&D expenses incurred by a number of units in the developed countries range between 12—15% of their turnover. Although some of the foreign units operating here enjoy the benefits of research undertaken by their parent organisations or associated laboratories abroad, it is absolutely essential that these units also take up R&D activity in right earnest.

38. An analysis of the data from 71 pharmaceutical companies in the organised sector revealed that while 54 companies have research and development departments, the remaining 17 companies have made no investments so far in research and development programme.

ANNEXURE-I

Statement showing names of major drugs including Antibiotics, Capacities licenced, Production targets etc.

(Chapter II—Para 13)

Sl. No.	Item	Unit	Target of requirements 1978-79	1983-84	Name of units	Registered/ Licenced Capacity	Production 1970	1971	1972	1973	Letter of Intent	Total of 7 & 12
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
Antibiotics.												
1.	Penicillin . .	MMU	780	1560	I.D.P.L.	140	29.94	65.82	54.21	56.23		
					H.A.L.	84	60.97	55.47	84.56	80.65		
					Alembic	100	49.18	48.13	43.43	57.71		
					Standard	40	41.44	53.47	47.95	52.93	45	
						364	181.53	220.89	230.15	247.52		409
2.	Streptomycin .	T	825	1650	I.D.P.L.	85	15.67	22.00	30.89	24.50		
					H.A.L.	90	65.57	63.10	71.90	71.23		
					Synbiotics	62	76.44	92.80	94.92	82.46	108	
					Alembic	20	...	0.75	1.40	1.66		
						257	157.68	178.65	199.11	179.85		365
3.	Chloramphenicol & its Esters	T	390	780	Parke Davis	20	Nil	9.51	9.70	11.79		
					Boehringer Knoll	30	25.25	34.23	28.66	19.58		
					Dey-Se-Chem	53	12.37	2.81	Nil	15.35		
					Mac Labs.	0.8	0.29	0.49	2.70	0.47	24.2	
					Themis	5			New Unit			
						108.8	37.91	47.04	41.06	47.19		133.0
4.	Tetracycline Hcl. *Includes Chlortetracycline & Dimethyl-Chlortetracycline	T	200	350	I.D.P.H.	25	7.88	11.73	14.52	14.58		
					H.A.L.	1.5	Nil	Nil	Nil	Nil		
					Synbiotics	3	0.214	1.31	3.72	7.04	27	
					*Cyanamid	10	4.31	8.64	7.03	8.63		
					Pfizer	5	Nil	Nil	Nil	Nil		
5.	Oxytetracycline .	T	88	160	Pfizer	9	25.35	29.46	56.59	39.72		
					I.D.P.L.	25	6.05	11.95	3.08	10.63		
6.	Dimethyl-Chlortetracycline	T	23	46	Cyanamid	...	6.82	4.62	7.71	8.78		
7.	Chlortetracycline	T	...	...	I.D.P.L.	70	Nil	Nil	Nil	Nil		
					Cyanamid	...	0.63	1.59	0.75	0.89		
							*1.40			0.44*		
		*Veterinary Quality				148.5	52.65	69.30	73.30	90.71		178.5
8.	Amphotericin .	T	3	6	Synbiotics	1	1.54	0.25	0.55	0.39		1
9.	Neomycin Sulphate .	T	10	16	Synbiotics	0.3	0.742	0.57	0.66	0.31	2.7	
					H.A.L.	2.0	...	Nil	Nil	Nil		5.00
10.	Nystatin . . .	T	3	4.8	I.D.P.L.	10	...	0.62	0.74	0.27	...	10

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
11.	Ampicillin & other Semi Synthetic Penicillins	T	55	100	Ranbaxy Cipla H.A.L. Alembic Uni-chem	5 0.75 5 5 No capacity fixed						15.75
12.	Bacitracin	BU	23	46								
13.	Cycloserine	T	8	16								
14.	Erythromycin Base & Esters	T	30	60	Alembic Themis H.A.L. Abbott	6 4	0.02	0.16	1.05	2.84	 6 4	 20
15.	Griseofulvin	T	20	40	I.D.P.L.	6					...	6
16.	Hamycin	Kgs.	150	240	H.A.L.	250	15.21	nil	nil	nil	...	250
17.	Kanamycin	T	0.8	1.6	Alembic	1					...	1
18.	Oleandomycin	Kgs.	1500	2400								
19.	Doxycycline				Ranbazy I.D.P.L.						2.5 5.0	7.5
20.	Polymyxin	Kgs.	130	260								
21.	Cephaloridine											
22.	Gentamycin											
23.	Rifampicin											
24.	Framycetin											
25.	Lincomycin											
26.	Aureofungin				H.A.L.	0.5	Nil	Nil	Nil	Nil		
	Sulpha Drugs.											
1.	Sulphadiazine	T	230	460	Atul May & Baker Cibatul	180	Nil 55.75 Nil	0.79 53.95 Nil	4.33 51.04 4.35	21.89 42.47 30.09		
							55.75	54.74	59.72	94.45		
2.	Sulphacetamide & derivatives	T	80	160	I.D.P.L. East India Bengal Immunity Albert David	50 18	7.37 13.69 0.04 Nil	19.35 10.75 Nil Nil	32.22 11.42 0.06 Nil	0.8 5.70 Nil Nil		30
							21.10	30.10	43.70	6.50		
3.	Phthalyl Sulphathiazole	T	150	280	M.S.D. I.D.P.L. Ciba May & Baker	3.5	Nil	Nil	Nil	Nil		100 50
4.	Succinyl Sulphathiazole	T	8	19	May & Baker Merck Sharp & Dohme	3.5	— Nil	— Nil	— Nil	Nil Nil		
5.	Sulphamerazine	T	34	35								

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
6.	Sulphathiazole/Sodium	T			May & Baker		Nil	Nil	Nil	Nil		
					Atul Products,	240	21.72	63.17	98.05	159.97		
					Cibatul		127.58	55.07	120.13	156.59		
					Ciba		—	—	—	1.26		
							149.30	118.24	218.18	317.82		
7.	Sulphafurazole	T	6	7								
8.	Sulphamethizole	T	12	13	I.D.P.L.	5			1.09	1.26		
9.	Sulphasomidine/Sodium (including Sulphamoxole)	T	260	465	Ciba		54.74	68.95	80.93	61.79		
					Cibatul		46.43	34.39	97.02	21.66		
					German Remedies	21.6*	Nil	Nil	Nil	Nil		
							101.17	103.34	177.95	83.45		
10.	Sulphaphenazole/Sodium	T	180	350	Cibatul		40.15	46.89	43.72	18.28		
					Ciba		36.11	54.55	40.80	19.89		
					I.D.P.L.		—	—	—	—	50	
11.	Sulphamoxole	T	45	70	German Remedies		7.73	10.91	15.52	38.02		
12.	Sulphaguanidine	T	135	145	I.D.P.L.	250	156.54	210.40	208.64	265.97		
13.	Sulphamethoxy-Pyridazine	T	17	19								
14.	Sulphadimethoxine	T	30	55	I.D.P.L.	30						
15.	Sulphamethaxozole	—	—	—	Roche	18						
					Cipla	5.5						
					I.D.P.L.							
16.	Sulphanilamide	T			I.D.P.L.	150	84.48	136.90	131.69	71.88	150	
17.	Sulphadimidine/Sodium	T	1010	2020	I.D.P.L.	500	126.37	225.79	318.88	328.81	500	
					May & Baker		nil	0.12	nil	0.04		
					Cibatul		nil	nil	nil	nil		
18.	Sulphapyridine	T			May & Baker		17.44	20.12	8.13	11.30		
19.	Sulphacetamide Phthalyl	T			East India		0.35	0.07	nil	nil		
					Albert David		1.76	2.58	0.85	1.35		
					B.I.		nil	nil	0.03	0.26		
					I.D.P.L.	15	—	—	1.44	1.41		

(Combined Capacities for Sulpha Drugs)

	Cibatul		320	Ciba Geigy	95T		May & Baker			210T
	Sulphadizine Sulphathiazole			Sulphaphenazole Sulphathiazole			Sulphadiazine Phthalyl Sulphathiazole			
	Sulphasomidine			Sulphasomidine			Succinyl Sulphathiazole			
	Sulphaphenazole Sulphamethazine			Sulpha methyl Phenazole			Sulphamerazine Sulphapyridine Sulphathizole			
	Anti T.B. Drugs.									
1.	Pas & its Sales	T	1000	1200	Haryana Chemicals	—				400
					A.M. Raja	—				80
					I.D.P.L.	150	nil	36.25	98.69	135.90	250	
					Pfizer	110	95.26	84.54	93.94	119.33		
					Bio Evans	120	92.60	109.51	70.10	56.06		
					Bio Synth	100	95.50	104.40	67.70	51.16		
					Wander	300	182.76	150.84	153.94	135.82		
						780	466.12	485.54	484.37	498.27		

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
	2. Isoniazid (INH)	T	265	530	Cal Chemicals	—	0.05	nil	nil	nil		
					Bengal Immunity	20	5.32	4.98	3.07	1.47		
					Chemo Pharma	35	9.18	20.66	23.99	26.55	65	
					Cipla	10	0.71	1.17	0.28	0.13		
					Bio Evans	9.96	9.96	12.64	15.31	11.72		
					Synbiotics	27	3.40	3.96	4.60	nil		
					I.D.P.L.	20	nil	nil	nil	nil		
					B.C.P.W.	1.6	0.105	0.04	0.05	0.06		
					Pfizer	80	nil	16.62	49.00	50.31		
					Suneeta	40	—	22.92	25.14	6.24		
					Albert David	—	—	nil	nil	nil		
					Warner Hindustan Dev. Corporation of Konkan	50	nil	nil	nil	nil	100	
						293.56	28.715	83.00	121.44	96.48		458.56
	3. Thiacetazone	T	70	140	Bengal Immunity	25	nil	nil	nil	nil		
					Bio Evans	30	nil	0.09	nil	nil		
					Chemo Pharma	25	2.31	0.59	0.40	1.30		
					Unichem	12	2.65	8.16	15.00	14.98		
					Albert David	0.6	0.05	0.04	0.07	0.06		
					Suneeta	30	—	8.12	12.39	10.11		
					I.D.P.L.	—	—	0.95	1.08	8.71		
						122.6	5.01	17.96	28.94	35.16	5	127.6
	4. Ethambutol	T	20	25	Themis	15						
					I.D.P.L.						15	
					Cyanamid							
					Sarabhai						1	
					Suneeta						12	
					P.C. Sharma						5	53
	5 Pyrazinamide	T	12	24	Uni Sankyo	3						3
	6 Morphazinamide	T	1.22	1.75								
	7 Ethionamide	T	12	25	Suneeta						12	
					Themis						8	20
	8 Prothionamide	T			Themis						2	2
	Anti Dysentry Drugs.											
	1 Halogenated Oxyquinolines	T	450	600	East India	112	30.85	33.42	38.24	25.77		
	Iodochloro—				Atul	80	29.40	42.01	30.65	38.88		
					B.C.P.W.	6	0.35	0.45	0.30	0.29		
	Hydoxyquinolines				Albert David		0.13	Nil	Nil	0.38		
					Syn biotics	7.2	1.54	2.16	0.73	0.64		
					Hind Chemicals	7.2	Nil	0.13	0.02	0.15		
					Unichem	25			3.08	6.68		
							62.27	78.17	73.02	72.79		
	2 Dilodo Hydoxyquinolines				Albert David		1.72	2.59	1.19	1.63		
	(Capacities shown against				East India		0.86	0.19	Nil	Nil		
	each unit cover both Di-				May & Baker	4.2	4.32	1.57	5.35	4.57		
	iodo and iodo-Oxy-				Synbiotics		2.94	0.29	0.73	1.70		
	quinolines)				Bio Evans	2.9	2.93	2.22	2·20	1.47		
					B.C.P.W.		0.03	0.01	0.02	0.07		
					B.I.		0.17	0.21	..	Nil		
					Therapeutic	120	—	4.10	2.55	4.40		
					I.P.C.L.	8	—	0.20	0.73	3.56		
						398.6	12.97	11.38	12.77	17.40		393.6
	3. Di-Brome Hydoxyquinoline				Sandoz	28.8	14.35	14.63	11.17	10.26	11.2	40

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
4.	Bisbenzoxaldine				Sandoz		6.46	0.44	3.15	6.18		
5.	Emetine & Dehydroemetine	Kgs.	900	1470	Burroughs Wellcome	250	164+	132.20+	16.69+	23.83		750
					Whiffens	500	Nil	1.10				
6.	Metronidazole	T	50	100	May & Baker	0.602	0.80	5.30	6.92	7.67	0.602	
					Indo Pharma	4						
					I.D.B.L.						30	
					Suneeta						10	
					Unichem						6	
					Cipla						12	
					K.A. Reddy						10	73.204
7.	Diloxamide/furoate	T	35	55	Boots	12						
					Ranbaxy						24	
					Cipla						2.5	38.5
	Anti Leprotics Drug.											
1.	Diamino-diphenyl Sulfone (DDS and derivatives)	T	30	50	B.W.	10.8	7.07	1.23	7.64	7.09		
					B.C.P.W.	6.9	1.16	1.08		1.07		
					Albert David	—	Nil	Nil	Nil	Nil		
					B.I.	—	Nil		Nil	Nil		
							8.23	2.31	7.64	8.16		17.7
2.	Clofazimine	T										
	Anti Diabetics.											
1.	Insulin	MU	3000	6000	Boots	1500	807.04	733.01	631.79	898.03	—	1500
2.	Tolbutamide	T	75	100	Hoechst	72	40.93	28.99	58.07	57.62		
					B.C.P.W.	1.2	Nil	Nil	Nil	0.05		
					Albert David	3	Nil	Nil	Nil	Nil		
					Bio Evans	0.96	Nil	Nil	Nil	Nil		77.16
3.	Chlorpropamide	T	40	70	Pfizer	6.5	6.22	11.97	12.93	9.08		
					Albert David	1.0	Nil	Nil	Nil	Nil		
					B.C.P.W.	1.2	0.13	0.08	0.45	0.35		
					Bengal Immunity	0.6	—	—	—	—		
					I.D.P.L.	—	—	—	—	—	15	24.3
4.	Phenformin	T	15	30	B.I.	1	0.30	0.03	Nil	Nil		
5.	Glybenclamide	T			Hoechst						0.2	
					I.D.P.L.						5.0	7.2
	Anti Malarials.											
1.	Quinine Salts				Govt. Factory Madras	—	21.19	11.69	12.73	8.71		
					West Bengal	—	27.34	24.52	16.91	20.31		
					Cipla	—	0.22	0.04	0.11	0.18		
2.	Amodiaquin	T	55	116	Parke Davis	36	24.06	16.98	25.74	9.89		
					Albert David	1	Nil	Nil	0.05	Nil		
					Suneeta	6			0.50	0.95		43
3.	Chloroquin & its Salts	T	150	225	Bayer	12	13.89	22.20	22.72	10.32	24	
					Bengal Immunity	10	1.88	Nil	1.11	2.63		
					Saneeta	18	—		0.75	2.25		
					I.D.P.L.						80	
					Themis						48	
							15.79	22.70	24.58	15.20		1
4.	Primaquin	T	1.5	2.5								

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
	Anti Filarials											
1.	Diethylcarbam azine Citrate	T	45	95	Burroughs Wellcome	2	4.38	6.57	7.63	6.61		
					I.D.P.L.	30	3.12	8.10	0.61	Nil		
					Uni UCB	24	3.72	2.59	2.99	1.04		
							11.22	17.26	11.23	7.65		56
	Anaesthetics:											
1.	Procaine HCL	T	200	300	Hoechst	100	24.41	39.74	67.39	42.74		
					Hico Products	150	Nil			Nil		
					I.P.C.L.	50	Nil			0.03		
					Ammar G. AZIZ	—					75	375
2.	Xylocaine/Lignocaine	T	14	30	Suhrid Geigy	1	1.95	3.20	3.23	3.05		
					Unichem	2	0.24	0.95	0.73	1.17		
							2.24	4.14	3.90	4.22		3
3.	Ether BP/Anaesthetic	T	530	850	Alembic	435	266.83	108.80	348.40	347.00		
					Hyd. Chemicals		12.78	104.00	N.A.	Nil		
					B.C.P.W.		2.70	2.70	3.65	1.69		
							282.31	215.50	352.05	348.69		435
4.	Ethyl Chloride	T	150	250	Alembic	144	45.01	27.50	25.20	22.30		
5.	Halothane											
6.	Carbocaine											
7.	Marcaine											
8.	Ketamine Hcl.											
	Analgesics, Antipyretics & Anti Gout.											
1.	Aspirin	T	1900	3800	Andhra Sugars	—	—	—	—	—	500	
					Alta	960	696.09	755.70	788.68	744.90		
					Martin & Harris	300	46.55	122.27	184.96	76.92		
					Indosal	100	19.02	48.76	28.22	Nil		
					G.M. Swamy						90	
					Haryana Chemicals						500	
							761.66	926.73	1001.86	821.82		2450
2.	Sodium Salicylate	T	600	1200	Alta Labs.,	420	214.87	29.95	381.96	204.01		
					Indosal	80	Nil					
					Calcutta Chemicals		1.94	— 0.55	—	—		
					Nila Products		0.97	0.2	—	—		
					G.M. Swamy		—	—	—	—	50	470
3.	Phenacetin	T	500	800	I.D.P.L.	350	104.08	185.83	136.69	136.85		50
					East India	50	—		—	—		
					Calcutta Chemicals	12.18	—	—	—	—		
4.	Paracetamol	T	400	800	Mohta						100	
					Chemo Pharma	48	10.33	9.50	2.39	0.83		
					I.D.P.Y.	85	Nil	0.33	10.66			
					I.P.C.L.	15	Nil	Nil	1.92	9.08		
					Cipla	—	1.12	Nil	Nil	Nil		
					Burroughs Wellcome	3	23.47	5.51	7.22	0.87		
					Themis	120	1.70	Nil	Nil	—		
					Duphar	10	1.15	0.54	0.97	0.28		
					Therapeutic	—	—	4.00	5.19	7.56		
					East India	50	—	—	—	—		
						331	37.77	19.88	28.31	18.62		

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(1
5. Salicylamide	.	T			Alta	120	15.00	16.00	26.00	21.00		
					Albert David					2.20		
6. Salicylic Acid	. .	T			Alta Labs.,	600	437.90	1019.98	1615.24	1324.32		
									219.00	227.00	IP Grade	
					Indosal	175	2.64	39.53	Nil	Nil		
					Calcutta Chemicals	—	0.15	Nil	Nil	Nil		
					Haryana Chemicals	—	—	—	—	—	600	
					G.M. Swamy	—	—	—	—	—	350	1725
7. Methyl Salicylate	.	T			Alta	250	87.85	103.98	155.89	195.00		
					Calcutta Chemicals	—	Nil	0.15	Nil	Nil		
					G.M. Swamy						50	300
8. Analgin	. . .	T	400	800	I.D.P.L.	460	26.87	67.8	77.63	136.72	240	400
9. Amidopprine	.	T			I.D.P.L.	40	3.45	5.89	3.82	2.86		40
10. Pethidine	. . .	Kgs.	1200	2400	Gluconate	750	198	216	310	240		750
11. Phenylbutazone	.	T	200	300	Themis	50						
					Jim	50						
					Suhrid Geigy	30	21.18	11.07	8.93	11.70		159
					Indo Pharma	4						
					P.C. Sharma	25						
12. Oxyphenyl Butazone	.	T	50	100	Suhrid Geigy	12			8.59	7.23		12
13. Indomethacin	. .	T	12	24	Themis	8						
					I.D.P.L.						5	13
14. Probenecid	. .	Kgs.	1200	2100	Suneeta	12000						12T
15. Allopurional	. .	T			I.D.P.L.						2	2
16. Dextropropoxyphene	.	T			Uni Chem	6						6
17. Trichlorophos Sodium		T			Abbott							
18. Ibuprofen	. .				Boots	6						
					Gipla	2	..	..	..	..	..	
Anthelmentics												
1. Piperazine & its salts.		T	118	230	I.D.P.L.	50	21.90	28.58	43.73	66.53	65	
2. Bephanium Hydoxy-Napthoate	. .	T	15	30	B.W.	5						
3. Treibendazole	. .											
4. Niclosamide	.											
5. Tetramizole	. .											
6. Pyrantal Pamoate/ Tartarte	. . .											
7. Mesulphen	. .	T			Bayer		0.12	1.45	nil	nil		
Rarbiturates												
1. Phenobarbitone	.	T	34	70	I.D.P.L.	15	3.76	8.97	9.76	9.18	15	
2. Anylobarbitone	.	T	10	20								
3. Secobarbitone	. .	T	10	20	I.D.P.L.						10	
4. Diallylbarbitone	.	T			I.D.P.L.						0	
5. Thiopentone	. .	T	3	5								
Anti-Depressants												
1. Imipramine	. .	Kgs.	900	1800								

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
2. Amitryptyline		Kgs	600	800	Themis						200	200
3. Methaqualone		T	20	40								
4. Chlordiazepoxide		T	6	12	Ranbaxy Roche	3 0.19						
5. Diazepam		T	0.5	1	I.D.P.L. Cipla Ranbaxy Roche	.. .. 4.00 ..	.. ..	.. ..	.. ..	.. ..	1 0.7	 1 .. 5.7
6. Chlorpromazine		T	12	24	May & Baker	2.5			1.11	2.73	..	2.5
7. Phenoth-azines & its Derivatives		T	2	4	May & Baker	0.5			1.29	2.05	..	0.5
8. Meprobamate		T	50	60	Suneeta Geoffrey Manners	30 1.8		13.6	23.75 1.42	4.72 2.13		31.8
9. Haloperidol												
10. Dexebin												
11. Thiothixene												
12. Sintamil		Kgs.			Ciba						310	310
13. Nitrazepam		Kgs.			Cipla						250	250
14. Trifluoperazine Hcl.												
Anti-Hypertensives and CVC drugs												
1. Methyl-Dopa		T	50	100	Suneeta I.D.P.L. Themis						12 10 12	 34
2. Guanthidine		Kgs.	35	70	Ciba	252	1	155	nil	nil		252
3. Prenylamine Lactate		Kgs.	1600	3200	Hoechst						800	800
4. Isoxopurine		Kgs.	1000	2000	Dupher						500	500
5. Clofibrate		T	2	4	Themis Ranbaxy Cipla Bio Evans ACCI	2 4 1 4				1.0	 10	 21
6. Mephentermine		Kgs.	200	400								
7. Propanalol												100
8. Salbutamol		Kgs.			Glaxo						1	1
9. Practolol		T			Cipla Themis						1 5	 6
Anti-Histamines.												
1. Pheniramine		T	6.5	13	Hoechst	4	1.92	2.06	3.87	3.44		4
2. Chlorpheniramine		T	16	32	Uni-Sankyo Indo Pharma	2 4						6
3. Diphenhydramine		T	16	32	Unichem Parke Davis	3 6	0.82 2.55	2.45 1.60	0.46 1.74	1.42 0.82		9
4. Mepyramine Maleate					May & Baker	2	—	—	0.74	0.69		2
Vitamins.												
1. Vitamin A		MMU	80	150	Roche	15	19.88	23.52	27.81	26.79	15	
					Glaxo	30	17.09	18.66	21.72	20.59		60
							36.97	42.18	49.53	47.38		
2. Vitamin B1 Hcl. & Mononitrate		T	100	200	I.D.P. L.	60	5.39	15.74	19.47	27.39	60	120

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
3.	Vitamin B2 & derivatives	T	24	48	I. D. P. L.	15	1.45	2.25	1.63	1.21	9	24
4.	Vitamin B6	T	50	400	I. D. P. L. Themis Sarabhai						50 20 12	82
5.	Vitamin B12 (Cyano & Hydroxo)	Kgs.	300	600	MSD Themis Alembic Glaxo Synbiotics	111 50 20 6 13.2	98.70 29.98 6.44 0.59 5.15	115.13 8.90 9.17 nil 5.35	142.37 56.84 11.05 nil 8.03	123.60 42.45 3.17 nil 9.46		
						233.2	140.84	138.55	218.29	178.68		253 2
6.	Folic Acid	T	7.5	15	I.D.P. L.	3.5	0.40	1.04	1.57	2.12	4	
7.	Panthenol & Pantothenates	T	60	90	Searle I. D. P. L.	5.0	—	—	0.34	0.60	40	45
8.	Vitamin C & Salts	T	900	1800	Sarabhai H. A. L. Suneeta D. R. Gandhi	120 125 125	194.6 — —	241.87 — —	254.56 — —	261.58 — —	150	
						370	194.06	241.87	254.56	261.58		520
9.	Vitamin D2 D3	Kgs.	1000	2000	Duphar	1000	91.87	71.07	141.4	75.99		1000
10.	Vitamin E	T	9	18	Roche E. Merck	— 4	..	..	..	5.52		
11.	Vitamin K	Kgs.	1140	2280	Atul Products Glaxo	450	386	432	442	366.04		
12.	Vitamin P	T	5	7	Ciba E. Merck	50 4		nil	nil	nil		54
13.	Nicotinic Acid	T	600	1200	Chemo Pharma Cipla Synbiotics B.C.P.W. I.P.C.L. Therapeutic	65 12 6.16 1.2 15	19.41 6.39 nil 0.20	11.89 22.73 nil nil	6.46 3.86 .. .. 0.02 ..	1.80 13.54 nil 0.33 0.24 0.19	75	
14.	Nicotinamide (Capacities shown against each individual Unit are combined for both Nicotinic Acid and Amide)				Chemo Pharma Cipla Synbiotics B.C.P.W. I.D.P.L. I.P.C.L Bio Evan Warner Hindustan Suneeta East India H.C. Shah Dev. Corpn. of Konkan	20 20 25 48 10	9.52 5.46 nil nil 0.25 nil .. 41.23	6.67 6.90 nil nil 1.26 nil .. 49.48 16.34 ..	5.76 5.02 nil 0.03 8.56 0.15 .. 29.84 16.75 ..	36.08 3.47 nil 0.01 14.92 nil 0.27 30.55 ..	800 100 600	
Diuretics												
	Hydrochlorthiazide	T	40	80	East India Ciba M.S.D.	0.5 2 3	.. 0.36 0.86	.. 0.43 0.02	.. 0.60 0.04	.. 0.58 0.05		
2.	Hydroflumethiazide	T	40	80		(*Includes Chlorthiazide also)						
3.	Polythiazdie	T	16	23								
4.	Frusemide	T	3.5	7	Hoechst I.D.P.L.	1.2				0.173	10	11.2
5.	Acetazolamide	T			I.D.P.L.	25						25
6.	Spiranolactone	Kgs.			Searle	28			36.55	41.07		
7.	Bendrofluazide											

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
Anti-parkinsonians												
1. L-Dopa		T	1	2	Ranbaxy	2						
2. Amantadine												
Vasodilators												
1. Ephedrine		T	45	90	Boehringer Knoll B.C.P.W. Mehta Pharm	18	0.23 nil 0.29	0.09 nil 0.02	4.45 nil nil	4.47 nil nil		
2. Theophylline/Aminophylline		T	60	120	Khandelwal	31.4	..	..	..	..		
3. Xanthinol Nicotinate		T	6	12	German Remedies Cipla	12 3	..	..	..	6.52		
Hormones & Steroids												
1. Ethisterone		Kgs.	480	1000	Wyeth		2.38	1.70	nil	nil		
2. Nor-Ethisterone		Kgs.	192	400								
3. Progestrone & Salt		Kgs.	192	400	Ciba Cipla Wyeth	102	16.70 305.05 522.05	19.38 27.50 17.40	11.44 67.02 246.50	22.49 299.87 527.60		
4. Norgestrol		Kgs.	48	100								
5. Mestrenol/Ethinyl Estradiol		Kgs.	288	580	Ciba Wyeth	6	3.16 0.20	1.61 6.62	0.66 0.69	2.35 0.67		
6. Testosterone Esters		Kgs.	680	1400	Ciba Wyeth Cipla Searle	30 50	54.80 283.71 51.20 nil	24.30 108.88 175.00 7.50	12.80 404.55 4.36 nil	18.64 363.67 14.27 nil		
7. Methyl Testosterone			192	400	Searle	15	41.95					
8. Lynestranol			150	300	Ciba	199.2	72.53	57.36	41.92	61.99		
Cortico Steroids												
1. Cortisone		Kgs.	6700	13000	Glaxo M.S.D.		5.29 nil	8.66 nil	12.61 nil	7.14 nil		
2. Hydrocortisone			4500	9000	Glaxo Wyeth M.S.D.		37.56 nil nil	13.53 757.36 nil	41.38 294.58 nil	52.01 183.89 nil		
3. Prednisone			100	200	Glaxo M.S.D. Wyeth		11.47 nil 516.55	2.68 nil 58.38	3.49 nil 8.95	3.40 nil 10.75		
4. Prednisolene			1500	3000	Glaxo Wyeth M.S.D.		nil nil nil	nil nil nil	nil 594.97 nil	nil 836.90 nil		
5. Triamcinbone/Acetonide			90	180								
6. Dexamothasone		Kgs.	150	300	M.S.D.		7.52	13.94	3.94	18.25		
7. Betamethasone		Kgs.	80	90	Glaxo		64.36	78.26	93.09	133.80		
Others												
1. Adrenaline Salts		Kgs.	96	190	Burroughs Wellcome	48	..	30.08 (1970-71)	37.61 (1971-72)	15.00 (1972-73)		
2. Nor Adrenaline		Kgs.	12	20								
3. Oxytocin		MU	240	480								
4. Isoprenaline												

1	2	3	4	5	6	7	8	9	10	10	12	13
	Drugs of Vegetable Origin											
1.	Atropine 2. Homatropine 3. Hyoscine 4. Hyosyamine	Kgs.	75	120	Mehta Pharma		0.87	Nil	Nil	Nil		
5.	Butyl Hyoscine Hydro-bremide	Kgs.	75	120								
6.	Digoxin	Kgs.	150	240	Sandoz B & W. Hind		Nil 8.28 0.01	Nil 9.82 Nil	23.15 6.52 Nil	8.71 4.60 Nil		
7.	Erogotamine		75	120								
8.	Caffeine & Salts	T	160	350	B.C.P.W. Mehta Pharma Smith Stani-street Hind Chemicals	60 4	15.78 0.07 1.25	10.59 0.016 1.05	18.41 0.03 0.10	22.30 Nil 0.30 Nil.		
9.	Morphine & Salts	T	1600	3200	Govt. Factory Ghazipur		1.00	0.56	0.75	0.66		
10.	Codeine & Salts	T	20	40	Govt. Factory Ghazipur		5.58	3.25	7.25	5.17		
11.	Narcotine & Salts											
12.	Papawerines	T	6	12								
13.	Reserpine	Kgs.	20	40	Mehta Pharma		Nil	Nil	Nil	Nil		
14.	Strychnine & Brucine	T	60	100	Smith Stanin-street Mehta Bio Evans B.C.P.W.	15	4.54 9.20 1.82	1.33 8.54 0.84 Nil	1.65 11.41 4.64 Nil	1.75 13.63 4.02 Nil		
15.	Quinidine Sulphate	T	15	30	Cipla Govt. Factory Tamil Nadu./ West Bengal		0.25 0.13	0.24 0.05	0.16 0.07	0.15 0.12		
	Sera & Vaccines											
1.	Tetanue Antitoxin	MU	30000	60000	Bengal Immunity Bio Evans Deys B.C.P.W. Haffkine Chowgale		3046.2 3152 31.68 80.07 480.98 —	4445.4 4487 Nil 80.11 1068 Nil	8223.2 889.10 Nil 97.43 1876.20	6201.53 4686.00 Nil 187.64 1687.00 Nil	The data in respect of Biological product are not complete.	
							6791.63	10080.51	16090.91	12745.17		
2.	Diptheria AT	MU			Bengal Immunity Haffkine Bio Evans (Toxoid) Kgs. B.C.P.W.		584.61 68.55	497.22 149 302 0.80	562.69 331.44 200 Nil	438.08 355.00 340 0.20		
							617.16	949.02				
3.	D.T.P. (Triple Vaccine)	M Doses	20	40								
4.	B.C.G. Vaccine	,,	66	130								
5.	Polio Vaccine	,,	20	40				Lit	Lit	Lit		
6.	Tetanus Toxoid	,,	32	70	Bio Evans B.C.P.W. Glaxo Bengal Immunity	3465 8192.8 2123 243.44	5853 17.47 1021 437.99	6465 13.92 —	5145.00 17.39 Nil 1497.00			

1	2	3	4	5	6	7	8	9	10	11	12	13
7.	Diphtheria Toxoid											
8.	Gas Gangrene											
	Anti-Epileptics											
	Phenyl Hydantxoin & derivatives . .	T	12	24								
	Miscellaneous Drugs											
1.	Calcium Gluconate .	T	400	800	Albert David		1.48	1.64	1.50	1.48		
					Sandox		71.91	111.81	120.63	112.66		
					Alembic	60	24.17	14.92	17.30	19.30		
					Calcutta Chem		Nil	Nil	Nil	Nil		
					Anil Starch	150	48.60	43.40	60.70	72.60		
					Baropharm		8.36	5.38	0.03	11.45		
					Nila Products		Nil	Nil	Nil	Nil		
2.	Ferrous Gluconate .	T	120	240	Baropharm		1.84	2.06	0.34	4.19		
					Nila Products		6.20	7.75	8.97	2.13		
					Sandoz		15.83	17.20	31.84	4.50		
					Albert David		Nil	Nil	Nil	0.22		
3.	Ferrous Succinate .	T	25	50								
4.	Ferrous Fumarate .	T	50	100	Rallis	1.2						
					Sandoz	20						
					Unichem	12						
					Chemo Pharma	N.A.						
5.	Ferrous Sulphate .	T	240	400								
6.	Nikethamide & Salts .	T	25	30	East India		1.35	0.09	Nil	Nil		
					B.C.P.W.		0.26	0.06	0.12	0.18		
					Atul Products		6.62	3.05	2.70	4.25		
					Standard		Nil	Nil	Nil	Nil		
					Ciba							
7.	Furazolidine . .	T	30	60	Indo Pharma	4						
					I.P.C.L.	9						
					Power Cable						12	
8.	Nitrofurantoin . .	T	45	90	Indo Pharma	3						
					I.P.C.L.	9						
					S.K.F.						31	
					I.D.P.L.						10	
					Sarabhai						4	
					Day-Se-Chem						24	
					Power Cables						5	
9.	Nitrofurazone . .	T			Indo Pharma	4						
					I.D.P.L.						1	
10.	Nalidixic Acid . .		--	—	Ranbaxy						10	
					P.J. Menezes						2.5	
11.	Azothioprine . .		—	—								
12.	Iron Chaline Citrate .		—	—								
13.	Trimethoprin . .		—	—	B.W.	3.6						
					Cipla	1.1						
					I.D.P.L.						2	
14.	Sod. Cromoglycate .	T	—	—	Cipla						0.2	
	Anti-Micotics											
1.	Methotrexate . .	Kgs.	200	400								
2.	Cyclophesphamide .	Kgs.	200	400								
3.	Hydroxy Urea											
4.	6-Mercaptopurine											
5.	Testolactone											
6.	Thiotepa											
7.	Mustine Hel											

1	2	3	4	5	6	7	8	9	10	11	12	13
8.	Chlorambucil											
9.	Melphalan											
	Radio & X-Ray Contrast Media:											
1.	Iodipamide	Kgs.	100	200								
2.	Di & Triazine Salts											
3.	Sodium Meglumine Iothalomate											
4.	Iodoxyl											
	Enzymes:											
1.	Cellulase . .	T	9	15								
2.	Papain . . .	T	75	120								
3.	Pancreatin . .	T	30	50								
4.	Diastase . . .	T	45	80								
5.	Lipase . . .	T	6	10								
	Plasma Substitutes :											
1.	Dextran . . .	M. Lts.	1	1.6								
2.	Polivinyl Pyrolidone .	T	38	60								

ANNEXURE II

(Chapter II—Para 11)

Bulk Drug production in the Small Scale Sector

S.No.	Name of the bulk drug	Name of firms	Production	Total
1.	Paracetamol	1. Poona Pharm. Chem. Industries	2640 Kgs. (1972-73)	
		2. Mujherat Chemicals	N.A.	
		3. Eagle Pharmaceutical Works	2916 Kgs. (1973-74)	
		4. Trichem Laboratories	1388 Kgs. (1973-74)	
		5. Unique Pharmaceutical Labs.	714 30 Kgs. (1972-73)	
		6. British Pharmaceutical Works Labs.	806 Kgs. (1972)	
		7. Suly Chemicals	21000 Kgs. (1973)	
		8. Chandra Bhagat Chemicals	2200 Kgs. (1972-73)	
		9. Farmson Pharmaceuticals Pvt. Ltd.	40000 Kgs. (1973-74)	
		10. Liger Chemicals	8000 Kgs. (1973-74)	
		11. Pharma Synth Chemicals	5921 Kgs. (1973)	
		12. Suchem Laboratories	2800 Kgs. (1973)	
		13. Atomplant Industries	N.A.	
		14. Aceto Chemicals	13900 Kgs (1973)	102285 30
2.	Diethyl Charbamazine Citrate	1. Chemipharm	3135 Kgs. (1973-74)	
		2. Trichem Laboratories	348 Kgs. (1972-73)	3483
3.	Dilodohydroxyquinoline	1. Chemipharm	5364 Kgs. (1973-74)	
		2. Mujherat Chemicals	N.A.	
		3. Heni Chemical Industries	N.A.	
		4. Eagle Pharmaceutical Works	4819 Kgs. (1973-74)	
		5. Mulraj G. Dungarsey and Co.	3000 Kgs. (1974)	
		6. British Pharmaceutical Labs.	880 Kgs. (1973)	
		7. Universal Chemicals	1225 Kgs. (1973)	
		8. Chandra Bhagat Chemicals	2790 Kgs. (1973-74)	
		9. Suchem Laboratories	2411 Kgs. (1973)	
		10. Sunny Industries Pvt. Ltd.	504 Kgs. (1973-74)	
		11. Neogy Laboratories	6700 Kgs. (1973)	
		12. Hooghly Chemical Industries Pvt. Ltd	1200 Kgs. (1972-73)	28803
4.	Piperazine and its Salts	1. Chemipharm	3273 Kgs. (1973-74)	
		2. Trichem Laboratories	3555 Kgs. (1973-74)	
		3. Mulraj G. Dungarsey & Co. Pvt. Ltd.	5000 Kgs. (1974)	
		4. British Pharmaceutical Labs.	1577 5 Kgs (1973)	
		5. Universal Chemicals	50 Kgs. (1971-72)	
		6. Chandra Bhagat Chemicals	439 Kgs. (1973-74	
		7. Suchem Laboratories	150 Kgs. (1973)	14035.5
5.	Vitamin B 2-5 Phosphate Sodium	1. Nivedita Chemicals Pvt. Ltd.	558 Kgs. (1973-74)	558
6.	Phenacetin	1. Nivedita Chemicals Pvt. Ltd.	918 Kgs. (1972-73)	
		2. Trichem Laboratories	8370 Kgs. (1972-73)	
		3. British Pharmaceutical Labs.	1775 Kgs. (1973)	
		4. Pharmasynth Chemicals	4932 Kgs. (1973)	
		5. Suchem Laboratories	2080 Kgs. (1973)	
		6. Aceto Chemicals Pvt. Ltd.	22600 Kgs. (1973)	40675
7.	Calcium Lactate	1. Chemipharm	195 Kgs. (1973-74)	
		2. Crystal Chemicals	980 Kgs. (1973-74)	1175
8.	Chlorpheniramine Maleate	1. Chemipharm	54 Kgs. (1973-74)	54
9.	Diphenhydramine Hydrochloride	1. Chemipharm	1137 Kgs. (1973-74)	1137
10.	Menadione	1. Chemipharm	65 Kgs. (1972-73)	65
11.	Methaqualone	1. Chemipharm	310 Kgs. (1973-74)	310
12.	Methanamine Mandelate	1. Chemipharm.	3605 Kgs. (1973-74)	
		2. Pharmasynth Chemicals	811 Kgs. (1973)	4416
13.	Sulphadiazine	1. Chemipharm	750 Kgs. (1973-74)	
		2. Trichem Laboratories	837 Kgs. (1973-74)	1587
14.	Suocinyl Sulphathiazole	1. Chemipharm	195 Kgs. (1973-74)	195
15.	Papain	1. True Food Corporation	30000 Kgs. (1973-74)	
		2. Enzo Chem. Labs. Pvt. Ltd.	18000 Kgs. (1972-73)	48000

1	2	3	4	5	6
16.	Nicotinic Acid/amide	1. Eagle Pharmaceutical Works	725 Kgs.	(1973-74)	
		2. Mulraj G. Dungarsay Pvt. Ltd.	1573 Kgs.	(1972-73)	
		3. Sulphara Pharmaceuticals & Chemicals	9448 Kgs.	(1972-73)	
		4. British Pharmaceutical Labs.	160 Kgs.	(1973)	
		5. Dekka Chem. India	800 Kgs.	(1973)	
		6. Atomplant Industries	454 Kgs.	(1973)	
		7. Inter Chem.	3894.3 Kgs.	(1973)	
		8. Pharmasynth Chemicals	3113.7 Kgs.	(1973)	
		9. Pharma Indiana Laboratories	7860.4 Kgs.	(1973-74)	
		10. Suchem Laboratories	394 Kgs.	(1973)	
		11 Shroffs Industrial Chemicals Ltd.	382 Kgs.	(1972-73)	
		12. Basichem	684 Kgs.	(1973-74)	
		13. Biochem Agencies	N.A.		29428.5
17.	Chloramphenicol	1. Trichem Laboratories	520 Kgs.	(1973-74)	
		2. Unique Pharmaceutical Labs.	62.6 Kgs.	(1973-74)	
		3. British Pharmaceutical Works	1175.8 Kgs	(1973)	
		4. Pharmasynth Chemicals	7917 Kgs.	(1973)	9675.4
18.	Isoniazid	1. Eagle Pharmaceutical Works	661 Kgs.	(1973-74)	
		2. Mulraj G. Dungarsey & Co. Pvt. Ltd.	1950 Kgs.	(1973)	
		3. Pharmasynth Chemicals	626 Kgs.	1972	
		4. Bio Chem	N.A.		
		5. Dr. Karanths Pharma Chemical Industry	7370 Kgs.	(1973)	
		6. Syntho Chem.	N.A.		
		7. Katha & Allied Industries Pvt. Ltd.	7150 Kgs.	(1973)	17757
19.	Berberine Hcl.	1. Mulraj G. Dungarsey and Co. Pvt. Ltd.	25 Kgs.	(1973)	25
20.	Oxyphenbutazone	1. Unique Pharmaceutical Labs.	408.80 Kgs.	(1973-74)	408.8
21.	Phthalyl Sulphathiazole	1. British Pharmaceutical Labs.	1360 Kgs.	(1972)	1360
22.	Diazepam	1. Nitson Laboratories	45 Kgs.	(1973)	45
23.	Sulphamethizole	1. Nitson Laboratories	1600 Kgs.	(Feb. to March 1974)	1600
24.	Ferrous Fumerate	1. Universal Chemicals	1088 Kgs.	(1973)	
		2. Basi Chem.	42870 Kgs.	(1973-74)	43958
25.	Aspirin	1. Gujarat Chemical Industries	N.A.		
26.	Magnesium Trisilicate I.P.	Hansa Chemicals	50000 Kgs.	(1973-74)	50000
27.	Imipramine Hydrochloride	Inter Chem.	17 Kgs.	(1973)	17
28.	Thiacetazone	1. Pharmasynth Chemicals	7020 Kgs.	(1973)	
		2. Basichem Industries	7310 Kgs.	(1973-74)	14330
29	Phenyl Butazone	1. Pharmasynth Chemicals	1752.5 Kgs.	(1973)	
		2. Syntho Chem.	N.A.		1752.5
30.	Chlorpromazine Hcl.	1. Pharmasynth Chemicals	13.5 Kgs.	(1973)	13.5
31.	Salicylamide	1. Pharmasynth Chemicals	86 Kgs.	(1972)	86
32.	Dried Aluminium Hydroxide Gel.	1. Sovin Chemicals	39240 Kgs.	(1973)	
		2. India Alkalies Ltd.	350 Kgs.	(1973)	39590
33.	Glycero Phosphates (Sodium, Potassium, Calcium etc.)	1. Unsar Pharmaceuticals	51300 Kgs.	(1973-74)	51300
34.	Meprobamate	1. Basichem Industries	886 Kgs.	(1973-74)	886
35.	Tolbutamide	1. Dr. Karanths Pharma	310 Kgs.	(1973)	310
36.	Caffeine	1. Associated Drug Co. Pvt. Ltd.	25400 Kgs.	(1973-74)	25400
37.	Iodo Chlorophydroxyquin	1. Sunny Industries Pvt. Ltd.	271 Kgs.	(1973-74)	
		2. Neogy Laboratories	16780 Kgs.	(1973)	17051

ANNEXURE—III

Position of some bulk drugs in the Organised and Small-scale Sectors vis-a-vis Fifth Plan Targets

(Chapter—II—Para—15)

Item	Unit	Total production in small-scale sector	Total production in the organised sector	Total indigenous production	Capacity approved in the organised sector	Fifth Plan targets
1		2	3	4	5	6
1. Paracetamol	T	102.28	18.62	120.90	431	400
2. DCC	T	3.48	7.65	11.13	56	45
3. Halogenated-8-hydroxyquinoline.	T	45.94	100.5	146.44	427.4	450
4. Piperazine & salts.	T	14.04	66.53	80.57	115	118
5. Vitamin B2	T	0.558	1.21	1.768	24	24
6. Phenacetin	T	40.67	136.85	177.52	432.18	500
7. Nitrofinic Acid/amide	T	29.48	101.40	130.88	1769	600
8. INH/Isoniazid	T	17.75	96.48	114.23	458.56	265
9. Oxyphenbutazone	T	0.409	7.25	7.659	72	50
10. Pthalyl Sulphathiazole	T	1.360	Nil.	1.360	153.5	150
11. Diazepam	Kgs.	45	..	235—	5700	500
12. Ferrous Fumerate	T	43.95	..	43.95	33.2	50
13. Aspirin	T	N.A.	821.82	821.82	2450	1900
14. Phenyl Butazone	T	1.75	11.70	13.45	159	200
15. Thiacetazone	T	14.33	35.16	49.49	127.5	70
16. Salicylamide	T	0.086	21.62	21.70	123	—
17. PAS & its salts	T	N.A.	498.27	498.27	1510	1000
18. Tolbutamide	T	0.310	57.67	57.98	77.16	75

ANNEXURE IV

Production of Bulk Drugs during 1952, 1957, 1960, 1965, 1970 & 1973

(Chapter II Para 17)

Sl. No.	Item	Unit	1952	1957	1960	1965	1970	1973
1	2	3	4	5	6	7	8	9
I. *Antibiotics :*								
1.	Penicillin	MMU	..	17.5	39.70	103	182	247
2.	Streptomycin	T	..	..	..	100.7	158	179.
3.	Tetracyclin	T	..	1.93	2.220	21.79	53	90.
4.	Chloramphenicol	T	..	1.5	3.819	29.38	38	47
5.	Amphotericin	Kgs.	..	..	..	..	1542	39(
6.	Erythromycin	Kgs.	..	..	..	..	24	2846
7.	Neomycin Sulphate	Kgs.	..	..	..	..	742	310
II. *Anti Dysentry Drugs.*								
1.	Halogenated Oxyquinolines	T	4.84	20.19	21.619	70.07	90	100
III. *Anti Diabetic Drugs:*								
1.	Tolbutamide	T	..	..	..	16.76	41	57.
2.	Chlorpropamide	T	..	..	..	1.79	6	9.
3.	Insulin	MMU	..	..	..	513 75	807	8
IV. *Anti-Leprosy Drugs :*								
1.	DDS and its derivatics	T	0.83	2.49	7.413	3.55	8	8.
V. *Anti Pyretics & Anagesics :*								
1.	Acetyl Salicylic Acid	T	..	..	76.312	413.40	762	821.
2.	Phenacetin	T	..	..	16.558	3.52	104	136
3.	Paracetamol	T	..	..	..	..	38	18.
4.	Analgin	T	..	..	..	..	27	136
5.	Sod. Salicycate	T	3.12	118.05	319.46	N.A.	N.A.	204.0
6	Pethidine Hcl.	Kgs.	..	..	..	..	198	240
VI. *Anti T.B. Drugs :*								
1.	INH	T	1.08	14.82	29.047	56.32	29	96.
2.	PAS & its Salts	T	..	42.89	82.988	338.90	466	498
3.	Thiacetazone	T	..	..	..	..	5	35.
VII. *Anaesthetics :*								
1.	Procaine Hcl.	T	..	..	..	49.17	24	51.
2.	Xylocaine/Lignocaine	T	..	..	..	0.448	1.72	4.
VIII. *Synthetic Hormones:*		Kgs.			163	813	1997	25.
IX. *Anti Malarials:*		T	..	0.06	..	13	40	26
1.	Chloroquin & Amodiquin							
X. *Alkloids & Allied Drugs:*								
1.	Caffeine	T	2.780	5.28	12.668	15.23	17.11	22.
2.	Emetine Hcl.	Kgs.	..	72	188	278	165	
3.	Ephedrine	Kgs.	1.18	17	23	3228	519	447
4.	Quinine	T	..	..	9.291	47.79	49.02	29.

1	2	3	4	5	6	7	8	9
5.	Strychnine & Brucine	T	8.48	4.64	14.324	21.30	15.57	19.40
6.	Reserpine	Kgs.	..	0.27	9.03	N.A.		
XI.	*Sulpha Drugs :*							
1.	Sulphadiazine	T			14.008	107.71	56	94.45
2.	Sulphapyrdidine	T			13.134	19.06	17	11.30
3.	Sulphadimidine	T			..	..	126	328.81
4.	Sulphathiazole	T			75.236	45.27	149	317.82
5.	Sulphanilamide	T	41.87	114.32	..	..	84	71.88
6.	Sulphasomidine	T			27.816	62.56	101	83.45
7.	Sulphaguanidine	T	..	..	..	..	157	265.97
8.	Sulphaphenazole	T			..	..	76	38.1
9.	Other Sulpha Drugs	T			..	..	20	
XII.	*Vitamins:*							
1.	Vitamin A	MMU		..	..	14.5	23.5	37 47.38
2.	Vitamin B-12	Kgs.		..	..	5.22	43.7	141 178.68
3.	Vitamin C	T		..	..	..	93.79	194 261.58
4.	Nicetinic acid/amide	T	0.94	0.18	0.213	57.47	82	101.40
5.	Vitamin B-2	T		..	..	..	..	1.451 1.21
6.	Vitamin B-1	T		..	..	..	..	5.39 27.39
7.	Vitamin D-2 and D-3	Kgs.		..	..	..	..	92 75.99
8.	Vitamin B-6	Kgs.		..	..	..	1351	.. ..
9.	Folic Acid	T		..	..	..	..	0.40 2.12
XIII.	*Other Drugs:*							
1.	Calcium gluconate/Lactobionate	T			1351	61.415	130.14	155 217.49
2.	Ferrous gluconate	T				18.142	25.651	23 11.04
3.	Nikethamide	T	0.35	3.24	3.108	8.690	8	5.08
4.	Diethyl carbamazine citrate	T				..	4.88	11 7.65
5.	Meprobamate	T				..	3.74	Nil. 2.13
6.	Amidopyrin	T						3 2.86
7.	Phenobarbitone	T						4 9.18
8.	Pethidine Hcl.	Kgs.						198 2.40
9.	Diphenyl Hydramine Hc.	T						3.374 2.25

ANNEXURE V

STATEMENT SHOWING THE IMPORTS OF BULK DRUGS DURING 1971-72 TO 1973-74 WHICH ARE ALSO MANUFACTURED INDIGENOUSLY

(Chapter II—Para 17)

Sl. No.	Name of the Drug	Accounting Unit	1971-72		1972-73		1973-74	
			Quantity	Value in Rs.	Quantity	Value in Rs.	Quantity	Value in Rs.
1	2	3	4	5	6	7	8	9
1.	Pethidine Hcl.	Kgs.	323.784	70,101	280,918	67,847	183.39	8,76,277
2.	Procaine Hcl.	,,	23,781	6,86,794	12,680	4,54,015	15,633	5,53,851
3.	Analgin (metamizol)	,,	1,30,966	56,65,850	1,42,670	54,89,223	2,19,094	64,78,675
4.	Phenyl Butazone	,,	22,209.2	10,10,878	24,776.01	9,83,577	1,190.26	65,209
5.	Oxy Phenbutazone	,,	2,366.3	6,26,843	5,919.2	15,48,032	9,845.6	28,67,153
6.	Emetine	,,	—	—	—	—	800	4,424
7.	Phenacetin	,,	13,650	1,70,556	—	—	—	—
8.	Chloramphenicol	,,	65,635	1,68,78,618	64,470.5	91,11,847	41,000	49,24,126
9.	Chloramphenicol Palmitate	,,	19,048	45,79,718	35,652	49,09,112	20,890	26,82,694
10.	Chloramphenicol Succinate	,,	400	1,80,860	400	81,295	3,100	10,46,004
11.	Chlor-tetracycline	,,	55	30,992	447.6	1,23,316	180	66,196
12.	Oxy-tetracycline	,,	54,190	1,07,57,567	1,517.3	2,83,453	Nil	Nil
13.	Tetracycline Hcl.	,,	44,365.5	1,16,41,190	20,126	86,15,109	54,025	73,59,808
14.	Penicillin G Sodium	M.U.	1,00,00,000	19,96,986	Nil	Nil	Nil	Nil
15.	Penicillin G Potassium	,,	3,00,00,000	3919,674	99,90.030	11,71,851	5,18,149	70,845
16.	Streptomycin Sulphate	Kgs.	83,703.4	1,70,09,884	99,205.74	16,96,496	51,946	63,41,191
17.	Neomycin	,,	2,554.61	7,79,524	2,616·7	778,007	4,458.025	15,13,919
18.	Erythromycin (Bulk)	,,	2,577.82	1,18,61,613	14,421	1,14,10,128	9,007	66,39 081
19.	Ampicillin (Bulk)	,,	2,776,038	21,03,551	6,837.5	47,18,379	24,592.81	1,60,69,030
20.	Insulin Crystallin Plain	M.U.	471.14	20,75,640	152.004	705,0411	15.0026	7,35,556
21.	Tolbutamide	Kgs.	12,884	2,93,694	6,201	155,662	1,648	56,196
22.	Chlorprepamide	,,	2,444,5	1 42,156	1,948	1,27.612	756	50,66
23.	Phenformin Hcl.	,,	1,554.06	2,12,728	29,55.29	4,48,689	2,584.05	3,49,349
24.	Chloroquin's Salts (Bulk)	,,	52,648.53	76,83,309	99,335.64	1,27,05,977	48,052.17	69,34,201
25.	Mepyramine Maleate	,,	697.5	87,198	361	54,606	556	1,00,030
26.	Diphenydramine Hcl.	,,	1,718	95,647	1,535.642	73,830	1,401	74,116
27.	Promethazine (Base & Hcl)	,,	174.3	26,159	585	88,028	125	26,97
28.	Promethazine B. Chloro-Theophylinate	,,	95	27,603	26.28	6,600	23.85	9,208
29.	Isoniazid (INH)	,,	3,100	93,000	1,300	32,500	Nil	Ni
	(A) PAS & Its salts	,,	71,000	8,89,903	—	—	—	—
30.	Digoxin	Gms.	3,453	1,53,712	2,201	1,03,797	3,582	1,53,879
31.	Caffeine	Kgs.	57,150	14,38,277	25,000	8,00,493	Nil	Nil
32.	Hydrochlorthiazide	,,	25	2,029	63.81	3,510	400	20,000
33.	Spironolactone	,,	18.5	2,31,492	1	10,634	2	24,000
34.	Prednisone	,,	Nil	Nil	9.68	44,095	1,650	5,803
35.	Prednisolone	,,	Nil	Nil	20,918	86,733	Nil	Nil
36.	Dexamethasone	,,	99.45	37,99,504	47.598	20,22,947	9 00,858	32,19,410
37.	Ethisterone	,,	188.672	3.72,615	238.43	422,143	246.31	8,59,111
38.	Hydrocortisone	,,	89.48	3,67,561	100.6	3,06,155	23.8	55,297
39.	A drenaline & its Salts	,,	20.83	1,00,264	22	25,846	40	35,557
40.	Diptheria Antitoxin (Bulk)	,,	281	1,00,112	1,177.46	4,00,171	548.540	2,33,295
41.	Tetanus Antitoxin (Bulk)	,,	3,529.5	8,89,633	3,677.4	7,38,855	810	1,93,600
42.	Phthalyl Sulphacetamide	,,	1,925	84,552	2,300	92,301	2,000	97,379

1	2	3	4	5	6	7	8	9
43.	Sulphathiazole	Kgs.	25,267	8,21,386	2,975	74,375	Nil	Nil
44.	Succinyl Sulphathiazole	,,	2,000	81,356	Nil	Nil	1,500	60,550
45.	Sulphaguinadine	,,	50,000	13,75,000	1,00,850	16,16,764	60,000	10,08,000
46.	Sulphadimidine	,,	1:48,500	86,02,990	1,24,900	29,68,111	43,500	10,74,359
47.	Sulphadiazine	,,	43,410	28,25,633	1,035	55,545	Nil	Nil
48.	Sulphasomidine	,,	13,120	6,16,047	54,949	22,37,980	18,137.55	9,63,452
49.	Sulphapiemazole	,,	14,545	12,77,347	8,687	10,10,130	1,879	2,01,974
50.	Sulphamethizole	,,	3,525	3,19,473	12,357	9,71,348	11,293	6,99,961
51.	Meprobamate	,,	—	—	—	—	194.2	4,273
52.	Pronlorpoazine Maleate & Ethane Sulphate	,,	32.5	14,479	55.4	25,958	126.5	71,748
53.	Folic Acid	,,	1,612.921	9,36,666	Nil	Nil	500	2,18,384
54.	Penthenol	,,	5,541.3	7,15,406	6,758	6,42,116	7,195	7,93,013
55.	Nicotinamide	,,	465.7	22,567	22,160	10,12,137	Nil	Nil
56.	Vitamin 'B1'	,,	35,718.88	56,98,913	14,216	16,19,012	26,626.5	24,95,213
57.	Vitamin B2	,,	2,169.7	4,70,023	5,189	11,01,399	11,250	24,15,822
58.	Riboflavin 5 Phos-Sodium	,,	1,172.9	7,77,033	Nil	Nil	625	3,70,633
59.	Vitamin B 12	Gms.	448	1,07,379	Nil	Nil	15.77	2,34,973
60.	Vitamin C	Kgs.	1,33,633.2	33,93,950	2,80,625	1,04,64,494	3,06,000	1,12,64,591
61.	Vitamin D	MV	52,92,280.42	77,172	11,76,555	53,371	1,88,100	37,299
62.	Vitamin E	Kgs.	5,121	7,98,760	30,90,760	4,45,791	5,629.008	8,60,683
63.	Vitamin K	,,	83	6,809	48	12,311	19	2,149
64.	Vitamin P	,,	5,038.2	7,52,847	3,770.5	4,61,889	5,265	7,51,890
65.	Phenobarbitone	,,	236.5	16,075	130	9,987	Nil	Nil
66.	Phenobarbitone Sodium	,,	331.3	24,915	5,750	1,75,812	Nil	Nil
67.	Ephedrine	,,	2,694.2	21,28,449	9,687.40	16,66,161	12,967.425	27,14,882
68.	Metronidazole	,,	7,152.4	8,31,183	16,255.3	21,65,815	25,583.78	31,97,012
69.	Niketharnide (ceramine)	,,	32	1,280	187.5	13,137	2,388	1,13,311
70.	Piperazine Hexahydrate	,,	12,020	88,082	6,800	58,022	1,06,950	8,37,684
71.	Diazepam	,,	94.5	26,785	638.05	1,51,598	3,110.31	7,69,351
72.	Fursemide	,,	1,183.95	29,13,859	1,293.2	18,52,577	1,406.63	7,95,795
73.	Calcium Lactabionate	,,	82	5,441	31.75	2,321	Nil	Nil
74.	Calcium Lactate	,,	4,525	20,537	3,975	20,356	Nil	Nil
75.	Chloropromazine Hcl.	,,	2,207.17	4,13,542	1,836.50	3,09,835	2,455.51	3,93,834
76.	Guanthidine Sulphate	,,	10	11,160	2	3,782	10	18,201
77.	Clofibrate	,,	668.38	3,06,052	1,319	5,02,653	5,210.3	4,14,244

ANNEXURE VI

(Chapter II—Para 19)

Imports exceeding Rs. 10 lacs During 1973-74

S. No.	Item	Quantity	Valu
		Ton	Rs. lac
1.	Analgin	219.09	64.
2.	Oxy-phanyl-butazone	9.85	28.
3.	Chloramphenicol & estes	65	86
4.	Tetracycline/Hcl.	54	73.
5.	Streptamycine Sulphate	51.95	63.
6.	Griseofulvin	4.82	17.2
7.	Neomycin	4.46	15.1
8.	Framycetin	0.694	12.2
9.	Erythromycin	9	66.
10.	Chloroquin/Salts	48.06	60.
11.	Ergot alkaloids	11.63	27.
12.	Dexamethasone	90.08kg.	32.
13.	Triaminolore	39.83	17.
14.	Nor-ethysterone	89.85kg.	25.
15.	Phthalyl Sulphathiazole	121.99	40.
16.	Sulphaguanidine	60	10.
17.	Sulphadimidine	43.5	10.
18.	Sulphamethoxy Pyridazine	18.82	17
19.	Thioridazine (Melleril)	11.7	53
20.	Pentothenates, Na/ca	25.99	14
21.	Vitamin B1	26.62	24.
22.	Vitamin B2	11.25	24.
23.	Vitamin B6	23.82	32.
24.	Vitamin C	506	112.
25.	Polyvinyl Pynolidone	34.72	12
26.	Ephedrine	12.97	27
27.	Ethionamide	3.56	10.
28.	Glucose anhydrous	717.56	25.
29.	Isoxuprine	210.32kg.	10
30.	Methyl Dopa	3.6	18
31.	Metronidazole	25.58	31
32.	Amitriptyline	555	10.
33.	Ampicillin	24.59	160
34.	Isoptine	549.kg.	12.
35.	Centamycin Sulphate	65.63kg.	42.
36.	Nogestrol	27.64kg.	14.
37.	Pyrazinamide	4.26	11
38.	Purinethol	502	11.

Imports between Rs. 5 and Rs. 10 lacs During 1973-74

S. No.	Item	Quantity	Val
1	2	3	
		Ton.	Rs. la
1.	Pethidine Hcl.	183.39	8.
2.	Procaine Hcl.	15.633	5.
3.	Diloxanide/Furoate	4.97	7.

1	2	3	4
4.	Cyloserine D Tartrate	486kg.	6.54
5.	Cyclophosphamide	140	7.34
6.	Insulin, Plain	150m.u.	7.36
7.	Chlorpheniramine maleate	1.88	5.17
8.	Aminophyllline	11.65	6.97
9.	Ethysterone	246.3kg.	8.59
10.	Diosaganiu	4.12	7.50
11.	Sulpha-merazine	11.43	5.36
12.	Sulphasomidine	18.14	9.63
13.	Sulphamethizole	11.29	7.00
14.	Penthenol	7.19	7.93
15.	Vitamin E	5.63	8.61
16.	Vitamin P	5.26	7.52
17.	Avapyrazine	650	5.81
18.	Bisumuth Salts	3.34	6.65
19.	Dydrogesterone	10.75	6.39
20.	Furazoldone	11.51	6.11
21.	Piperazine Hexahydrate	107	8.37
22.	Diazepam	3.11	7.69
23.	Furosemide	1.41	7.96
24.	Thiabendazole	2.8	5.44
25.	Doxycycline	158kg.	5.17
26.	L-Dopa	1.38	5.88

1	2	3	4	5
541.6318	Vaccine Yellow Fever	1.2	..	11.1
541.6329	Bacterial Vaccine n.e.s.	45.3	90.1	56.5
541.6331	Bacteriological Products n.e.s.	1.0	.	..
541.7001	Ayurvedic & Unani Medicines	1536.4	1959.5	1193.1
541.7002	Homeopathic Medicines	66.8	298.8	69 6
541.7003	Acetarsol B.P.C. (Stovarsol)	..	6.5	..
541.7004	Acetyl Salicylic Acid/Aspirin	633.7	823.4	692.5
541.7005	Antacid & Digestive Prepns.	34.6	17.1	29.8
541.7006	Antidiabetic Drugs other than Insulin	631.2	3112.7	4162.1
541.7007	Anti Histonines	1.9	9.9	173.4
541.7011	Anti Malerial Chloroquine & Chloroquine Phesphate	17.0	66.1	25.6
541.7012	Anti Malerial Quinoline derivatives n.e.s.	390.9	31.0	..
541.7015	Asthma, Cattarh & Hay Fever prepns.	37.8	30.5	7.1
541.7017	Calcium PAS	..	12.1	..
541.7021	Chemical, Medicinal Contraceptive Foam Tablets	44.8	10.4	168.9
541.7022	Chemical & Medicinal Contraceptive Jellies Paste, Cream etc.	..	1.4	..
541.7023	Cold, Cough, Bronchial prepns. except salves ointments & vaccines	81.8	62.0	143.9
541.7025	Dehydrocholic Acid	17.4	..	1.0
541.7026	Diethyl Carbamazine Cirtus Acidus	..	..	5.0
541.7028	Gripe water	145.9	135.6	187.8
541.7031	Headache, Neuralgia & Pain Remedies	319.2	28.9	170.2
541.7034	Iron Almonium Citrate	..	..	70.2
541.7036	Jodine Tincture	50.3	10.6	7 7
541.7041	Leptazol B.P.	..	..	6.7
541.7042	Magnesium Trisilicate	157.7	154.1	137.6
541.7046	Milk of Megnesia	..	9.2	..
541.7052	Potassium Glycerophosphate	..	..	2.0
541.7055	Phthalyl Sulphathiazole	19.6	65.0	31.7
541.7058	Sulphacitamide	..	..	0.7
541.7063	Sulphanilamide	..	..	16.3
541.7064	Sulphathiazole	..	..	214.2
541.7065	Sulphadiazine	16.0	..	..
541.7066	Sulphamerazine/Sulphamethyldiazine	..	..	0 6
541.7067	Sulpha Drugs n.e.s.	137.1	17.9	21.2
541.7068	Salicylamide	17.1	..	..
541.7071	Salves & Ointment for Burns Cuts etc.	110.3	81.1	96.1
541.7072	Salves & Ointments for Cough, Cold & Bronchial prepns.	590.7	924.3	734.4
541.7073	Sodium P.A.S.	16.0	..	14.7
541.7076	Tonics, Blood Purifiers, Emulsion Appetisers etc.	132.8	28.1	71.1
541.7081	Proprietory & Patent Medicines	22175.9	5985.5	6863.4
541.7082	Botanical Drugs, Derivatives & Synthetic Equivalent prepns.	21.5	120.5	62.9
541.7083	Drugs, Animal Origin, Synthetic Equivalent prepns. n.e.s.	11.4	..	6.5
541.7084	Organic Acids & prepns. n.e.s.	34.0	3.3	..

1	2	3	4	5
541.7095	Drugs, Medicines, Chemicals Containing Spirit n.e.s.	2007.9	962.6	232(
541.7099	Other Medicaments	69712.6	55500.0	41301
541.9101	Adhesive Bandages	872.3	84.9	647.
541.9102	Adhesive Tape (Medicinal)	247.9	112.7	151.
541.9103	Poultice of Kaolin	4.1	20.1	2
541.9104	Lint Medicated	363.9	469.9	403.
541.9105	Plaster of Paris	723.8	265.1	87.
541.9109	Bandages n.e.s.	13916.1	6189.1	2605.
541.9901	Dental Cement & other Dental Fillings	148.3	81.6	105.
541.9902	First Aid Boxes Kits	..	219.3	
541.9905	Sterile Surgical Catgut etc.	27.9	38.4	421.
658.5601	Wadding & Articles of Wadding/Absorbent Cotton	6365.5	859.6	24.
512.1308	Chloroform	10.3	..	
512.2304	Menthol	1361.8	321.7	533.
512.3104	Ether Solvent/Ethyl Ether	..	..	1.
512.4323	Beta Ionone	4031.8	8103.0	958
512.5106	Beanzl Benzoate	38.6	4.5	2
512.5107	Bismuth Compounds of Monoacids	197.5	..	
512.5142	Undecylenic Acid	639.2	170.1	242.
512.5301	Calcium Gluconate	..	2.5	4.
512.5302	Citric Acid	..	103.0	
512.5308	Methyl Salicylate	245.9	81.9	12.
512.5312	*Potassium Citrate*	215.6	48.3	202.
512.5314	Salicylic Acid	197.6	20.8	2.
512.5316	Sodium Salicylate	322.2	309.6	11.
512.6301	Calcium Glycerophosphate	32.2	..	51.
512.7413	Phenacetin	..	..	250
512.8512	Dehydroxy Quinoline	..	1.8	29
512.8517	Hydroxy Quinoline Salts	34.9	..	
512.8527	Alpha Picoline	..	79.1	571
512.9103	Papain Pure	554.6	11.2	9
514.1601	Potassium Iodide	..	187.4	
514.1609	Iodides, Oxyiodies, Iodates, Periodates others	..	0.1	
514.9200	Hydrogen Peroxide	..	7.9	
899.1801	Empty Gelatine Capsules	88.4	90.8	
599.2100	Disinfectants	66.1	912.9	128
422.5000	Medicinal Castor Oil (compiled from the customs lists)	211308.3	20364.2	231
	Re-Export			
541.7099	Other Medicaments	44.9	219.5	
		37,54,24.8	13,52,71.2	10,3

ANNEXURE—VIII

(Chapter II—Para 30)

Export During

(In '000 Rs.)

	Apr./ Sept. '74 (Est.)	Apr./ Sept. '73 (Act.)	Apr./ Sept. '72 (Act.)
1	2	3	4
Drugs, Pharmaceuticals & Fine Chemicals			
Salt and other derivatives of nicotine	..	640.1	182.7
Vitamin B 1	..	..	42.2
Vitamin B Complex	14.5	4.8	3.8
Vitamin C	..	..	1.7
Provitamin, Vitamin natural or reproduced n.e.s.	3.8	92.1	91.3
Chloramphenicol & its prepns.	..	72.4	445.0
Erythromycin	..	..	1.5
Oxytetracycline & its prepns.	..	1566.0	2307.4
Penicillin & its prepns.	..	63.9	4.9
Streptomycin & its prepns.	..	488.8	356.4
Other Antibiotics & their prepns.	2521.4	1350.3	983.5
Cocaine alkaloid, salt & derivatives	..	..	17.0
Ephedrine Hydrochloride	..	152.2	351.5
Ergot Alkaloid	..	20.0	..
Salt other derivatives of ergot	..	..	1.5
Emetine alkaloids	83.0	10.8	8.5
Salt other derivatives of emetine	..	..	33.7
Quinine alkaloids	..	1661.6	..
Salt and Derivatives of quinine n.e.s.	3099.4	1986.5	2063.7
Quinine Sulphate	10847.6	1922.9	1072.7
Rauwolfia alkaloids & prepns.	..	14.6	90.2
Strychnine alkaloids/salts.	192.0	403.9	373.3
Salt & other derivatives of nux vomica alkaloid/Brucine	1196.7	833.1	274.2
Berberine Hydrochloride	186.6	352.3	286.4
Vegetable alkaloids	..	260.9	240.3
Hormones—others	.	35.4	..
Digoxin	..	..	261.2
Blood Plasma	45.7	..	5.9
Liquid Extract of Liver	5.5	0.7	4.1
Ferrous Sulphate	56.8	..	..
Organo Therapeutic glands or other organs & their extracts—others	..	5.0	6.6
Antitoxins	..	..	4.3
Tetanus Serums	..	..	1.6

1	2	3	4
Antibacterial Serums & Antiserums n.e.s.	..	203.3	232.1
Vaccine Cholera	..	..	0.4
Serra Vaccine other	71.9	..	..
Bacterial Vaccine n.e.s.	..	34.9	44.2
Bacterialogical products n.e.s.	..	1.0	..
Ayrvedic & Unani medicines	613.5	354.5	709.7
Homeopathic Medicines	10.9	38.3	135.5
Acetyle Salicylic Acid/Aspirin	..	195.3	433.8
Antacid & Digestive prepns.	..	6.0	8.9
Anti Diabetic drugs other than insulin	527.6	630.0	515.8
Anti Histamines	..	0.7	9.8
Anti malarials chloroquine & chloroquine phosphate	287.0	17.0	2.8
Asthma, Catarrah & hay fever prepns.	..	30.0	8.8
Chemical, medicinal contraceptive, foam tablets	..	44.7	0.3
Chemical & medicinal contraceptive Jellies, paste, creams etc.	..	..	2.4
Cold, cough & pronchial prepns. except salves, ointments & vaccines	..	35.2	21.4
Dehydrochyic Acid	..	17.4	..
Gripe Water	69.4	42.2	79.2
Headache, neuralgia & pain remedies	475.2	19.3	23.3
Iodine Tincture	..	1.4	0.4
Magnesium Trisilicate	64.4	43.5	93.9
Milk of Magnesia	..	..	9.2
Phthalyl Sulphathiazol	..	..	65.0
Sulphadiazine	..	16.0	..
Sulpha Drugs n.e.s.	112 5	23.7	0.2
Salves & Ointments for burns, cuts etc.	45.0	50.4	26.7
Salves & Ointments for cough, cold & Bronchial prepns.	..	365.0	702.7
Tonics, blood purifiers, emulsions, appetisers	57.9	47.5	14.4
Proprietory & Patent Medicines	726.2	2663.9	1757.1
Botanical drugs, derivatives & synthetic equivalent prepns.	..	..	1.1
Drugs, medicines, chemicals containing spirit n.e.s.	..	1131.4	291.9
Wadding and Articles of wadding/ Absorbent cotton		..	231.1
Adhesive Bandages		69.2	14.0
Adhesive Tape (Medicinal)		94.2	24.0
Poultice of Kaoline		..	20.1
Lint Medicated	16847.8	127.5	434.4
Plaster of Paris		352.4	27.4
Bandages n.e.s.		4658.5	1210.7
Dental Cement & Other dental fillings		36.1	9.7
Sterile Surgical catgut etc.		..	30.8
Calcium Compounds/prepns.	106.2	..	..
Harmless medicines	40256.6	..	..
Drugs Intermediates	463.8	..	..
Other medicaments	7194.4	27919.2	23664.9

1	2	3	4
Menthol	1113.7	..	..
Beta Ionone	2089.5	1554.0	4937.5
Benzyl Benzoate	0.7	36.5	..
Bismuth Compounds of Monoacids	1193.9	..	..
Undecylenic Acid	269.2	40.4	116.1
Citric Acid	..	..	241.0
Methyl Salicylate	..	103.4	39.9
Sodium Citrate	50.6	..	..
Potassium Citrate	145.8	152.5	31.8
Salicylic Acid	1802.8	14.2	9.3
Sodium Salicylate	44.2	234.2	233.7
Calcium Glycerophosphate	..	10.0	..
Acriflavin	..	..	12.1
Alpha Picoline	..	..	126.6
Papain Pure	133.6	139.9	0.7
Potassium Iodide	..	..	185.5
Iodides, Oxyiodides, Iodates & Periodates—others	..	..	0.1
Hydrogen Peroxides	..	..	8.0
Paracetamol	430.4	..	..
Empty Gelatine Capsules	..	..	31.1
Disinfectants	5.3	59.2	615.5
Medicinal Castor Oil	156989.2	122908.1	3768.3
Soluble Sodium Saccharine	1064.1	..	..
Cineole	286.9	..	..
Phenolphthalein B.P.	286.0	..	..
Salicylamide	413.8	..	..
Fine Chemicals	551.7	..	..
	253056.5	176460.9	50732.4

CHAPTER III

PUBLIC SECTOR

1. This chapter is devoted to the second term of reference of this Committee. This term of reference require that the Committee recommends the measures necessary for ensuring that the public sector attains a leadership role i the manufacture of basic drugs and formulations and in research and development.

2. The public sector has to play an important role in the industrial development of the country. Subject to th overall consideration of resources, the programme in the public sector envisages further expansion in high priority field to fulfil the gap and correct existing imbalances in the industrial structure to meet the social needs of the country The Industrial Policy Resolution, 1956, takes into account the need to prevent monopoly and concentration of economic power in the hands of a small number of individuals.

3. The Committee notes that the public sector has achieved an overall production of substantial capacity particularly in the field of synthetic drugs, and has demonstrated the competence of this sector to handle the growing needs of the country in this highly technology-intensive area of drug production.

4. In order that the public sector may enter the field of manufacture of basic drugs and formulations in a big way, as is recommended in this chapter, with a view to making essential medicines available to large masses of our people at reasonable prices, it will be necessary to remove some of the constraints and deficiencies in the public sector units.

5. The Committee has suggested measures necessary to make the public sector more efficient, in respect of organisational set-up, and management patterns, taking into consideration the deficiencies, difficulties and disabilities from which the public sector units are suffering at present. The Committee has also suggested the areas in which the public sector should expand so that it can effectively serve the objectives and attain a commanding height in the manufacture of bulk drugs and formulations. Measures have been suggested to bring about technological improvements and for appropriate organisation of research and development in the field of drug industry. The importance of utilizing various public sector laboratories and institutions has also been dealt with. In view of the fact that this sector must grow in magnitude to fulfil national needs, the Committee has suggested the establishment of National Drug Authority (NDA) a central organisation which will lay down and coordinate the policies of manufacturing programmes, as well as the sale and distribution systems of the products produced in public sector units. The composition and functions of the Authority has been discussed in Chapter IV.

6. Pattern of production of the domineering units in the private sector, which consist predominantly of multinational subsidiaries or their branches or their equity partners in India, indicates that the primary objective of these units is trade based almost entirely in the economically preferable area of formulations from bulk drugs, largely imported from their principals, rather than on the production of the bulk drugs themselves. Government, therefore, decided that, in the interests of the health and well-being of the people of this country, more units for the production of drugs be started in the public sector. It was perhaps felt that health care was a national charge and the ethics of production of drugs should have essentially the character of meeting national needs as distinct from trade and commercial angle. Further, such needs should be met by a determined effort to produce bulk drugs from primary raw materials and intermediates. The Planning Commission, in addition to recommending the development of chemical industry in general (drug in their basic form are chemicals) also emphasized that high priority should be given to manufacture, within the country, of bulk synthetic drugs rather than the formulation of imported drugs.

7. This emphasized the desirability of the setting up of a large drugs and pharmaceuticals complex in this country and resulted in the establishment of a public sector enterprise, Indian Drugs and Pharmaceuticals Limited (IDPL), where production started in 1968. Earlier, Hindustan Antibiotics Ltd., Pimpri, started production in 1955. The Committee on Public Undertakings said in their 22nd report :

> "The setting up of the drug manufacturing units and surgical instruments factory in the public sector was intended to serve the triple objectives, namely to bring down the prices by large scale production of high quality life-saving drugs, to provide facilities for medical relief to the people on a mass scale in consonance with the declared objectives of the Government in this regard and finally, not only to achieve self-sufficiency but also to produce an exportable surplus and earn foreign exchange."

8. Despite production of about Rs. 370 crores worth of pharmaceuticals during 1973, it is estimated that modern drugs reach only about 20% of our people. This would imply that the majority of people, particularly in the rural areas and economically weaker sections of the society derive little advantage from the modern systems of medicines and to that extent their suffering remains unabated. This immediately throws into focus the magnitude of inadequacy of our national effort in this vital area of not only social but also economic consequence to our people. It is thus clear that production of allopathic drugs, in terms of the magnitude of the needs of the country has barely begun in India and that the field is wide open for enlightened leadership to make bold efforts and take up the challange. on a national scale, and meet this vital problem by proper planning.

9. The National Committee on Science and Technology (NCST) and the Task Force appointed by the Planning Commission, have, during the last two years carried out studies of the existing product pattern in pharmaceutical and drugs industry. The Committee feels that the basic data used by the NCST and the Task Force conforms to existant pattern of market needs rather than the real social needs of the country. The Committee is of the view that there is urgent need to institutinalize data collection and base the national production targets in terms of the needs indentified by such a system. However, for the present, the Committee accepts the projection of the Task Force for drawing up the more immediate production plans. The NCST and the Task Force identified the needs of the nation over the next 5 to 10 years. Both the groups concluded that it is necessary to maintain a sustained growth rate of at least 15% in this industry with high emphasis on the production of bulk drugs. They have also suggested the need to fix targets and adjudge the growth rate in quantitative terms and not in terms of rupee value. This Committee wishes to emphasize the necessity of fixing growth targets and judging the growth rate in terms of individual quantities. This is necessary because of the changing value of rupee. Presentation of growth in terms of rupee value can, as it has been done in the past, present a distorted picture and induce an unjustified sense of achievement and complacency.

10. The above two Committees have rightly emphasized the need to dove-tail the development progammes of the drug industry with those of the chemical industry on which the former is largely dependent. Besides supporting this plea, the Committee is of the opinion that extensive development in the field of critical plant materials, as will be indicated later in this report, should be given high priority.

11. In respect of chemicals, needed as raw materials for the production of bulk drugs, Hindustan Organic Chemicals (H.O.C.). Indian Petrochemicals Corporation Ltd. (IPCL) and such other units in the public sector as may be concerned now or in the future, with the production of vital solvents like alcohols, organic acids, ester, anhydrides, etc. basic chemicals like benzene, toluent, xylenes, napthalene and related intermediates, pyridines, etc. ; mineral acids would need to be materially strenghened in terms of an annual growth rate of at least 15%. This has been emphasized in the relevant NCST report. It is essential that all these products, arising out of the efiorts of either the public sector or the private sector units, shoud meet the priority needs of the bulk drugs industry.

12. As has been mentioned elsewhere in this report, formulation activity represents the high pay-off sector of the pharmaceutical industry and bulk drugs manufa ture given comparatively low profits. Inevitably, therefore, entrepreneurs who enter the pharmaceutical industry, usually prefer formulation activity. An analysis of the working of a number of drug manufacturing units in this country has revealed that the ratio of capital invested to sales turnover in the formualtion sector averages out at about 1 : 2.6 with an upper limit of as high as 1 : 7.75. It is estimated that a purely formulation unit recovers the entire invested capital in a 2-4 year period. On the other hand, in bulk drug production, under the best of cirmdumstances, sales turnover to capital ratio does not usually exceed the 1 :1 figure and in many cases, in the early development stages, this ratio is much lower.

13. It is evident, therefore, that a manufacturer whose basic philosophy is materially trade oriented, would usually try to remain in the formulation sector and keep the less paying basic drug manufacture at the lowest level of production priority.

14. It has been estimated by NCST that in order to register a formulation production growth rate of 15% leading to a total production of Rs. 700 crores from the present production of about Rs. 370 crores, at the end of the Fifth Plan period, capital requirements will be of the order of only Rs. 100 crores. Where as that group has also estimated that for achieving a targetted production of the value of Rs. 200 crores worth of bulk drugs from the present Rs. 75 crores, additional investment requirements will be au high as Rs. 150 crores. The conclusions are obvious.

15. It is not, therefore, surprising that for the past many years, foreign or foreign-equity holding companies have, by and large, resisted the governmental suggestions to enter the basic drug production in a big way. Experience has shown that even when these units undertake the manufacture of bulk drugs, they tend to linger long at the very initial phase of manufacture of bulk drugs from penultimate or near-penultimate intermediates imported often at high cost essentially from their principals abroad.

16. An analysis of the effort invested in the production of bulk drugs by the different sectors of the industry p vides some revealing data. In 1973, the organised sector of the drugs and pharmaceutical industry in India, produ a total of 5300 tons of bulk drugs. These included natural products, synethetic drugs, steroids, antibiotics, etc. total value of this production was about Rs. 70 crores.

17. The figures for bulk drug production in the small scale sector, in terms of tonnage, are not available. H ever, their total production is rated at about Rs. 5 cror es in terms of money value and could be estimated at ab 500 tonnes including a fairly high percentage of synthetic bulk drugs. It is interesting that out of the productio 500 tonnes by the small scale sector, only about 3% was produced by the foreign and foreign majority units in sector and about 97% by the Indian units.

18. Analysis of the production figures of 5300* tonnes produced in the organised sector reveals that :

(i) The public sector units produced about 1500 tons of bulk drugs valued at Rs. 24 crores;

(ii) The Indian and the Indian-majority units manufactured 3200 tons of bulk drugs valued at Rs. 27 cr and.

(iii) The foreign and foreign-majority equity units produced about 600 tons of bulk drugs valued at Rs. crores.

19. The above figures would indicate that whereas the public sector and the purely Indian and Indian majo sectors produced large tonnage of drugs of relatively lower value, the foreign and foreign-majority units opera in general, selectively in the area of low tonnage high rupee-value bulk drugs. They contributed less than 12% the total production of bulk drugs in the organised sector and recovered as much as about 27% of the turn-ove rupee value.

20. In contrast to the efforts of the various units in bulk drugs production, it is interesting that a hundred s sixteen units comprising 25 totally foreign or foreign-majority equity firms and 91 other units with either relati minority foreign equity or totally Indian units, the "organised" sector, accounted in 1973, for about Rs. 296 cro (80%) of the total turnover. Over half of this was shared by the 25 firms with total foreign or majority foreign eq and other half was accounted for by the remaining 91 units including about Rs. 20 crores worth of formulati produced in the public sector. Out of the remaining Rs. 74 crore turnover (20%), 9 fully foreign or foreign-majo companies in the small scale sector, accounted for over about Rs. 18 crores (24%), and the remaining nearly 2 units shared between them a turnover of about Rs. 56 crores. Analysis of about 486 units in the small scale sec listed in the publication on Indian Pharmaceutical Industry for 1973 compiled and published by Developm Council for Drugs and Pharmaceuticals, Govt. of India, reveals that 260 companies, constituting over 52 % these listed units, had an individual turnover of rupees one to five lakhs. These figures indicate that the large majo of the remaining over 2000 units operate only as tiny tablet or tincure makers with no showing whatsoever the overall economics of the pharmaceuticals and drugs industry.

21. These relative figures, both for bulk drugs production and formulations, lead to the inescapable conc sion that the multinationals have not only concentrated their effort in the production of formulations, but even their minor effort in bulk drug production, they have limited their activities only to low-tonnage high-rupee-va bulk drugs. Some of which are, of course, essential and technology intensive such as steroids, vitamins A, B etc. It is evident that it is the Indian and Indian majority sector, and in particular the two public sector units, t have made the major contribution in the critical area of bulk drug production, which constitutes the base plank the pharmaceutical industry.

22. There are three broad areas at present under which the various drugs may be considered :

(i) Those derived from higher plants;

(ii) Those derived from micro-organisms, lower plants and animal sources; and

(iii) Synthetics.

23. Drugs derived from plant sources will include in this report, an important insecticide e.g. extract of P thrum flower heads. The latter has added to its importance recently because of the threat of the spread of ma ria in this country and because the malarial parasite -carrying mosquito has become resistant to most of the ava able synthetic insecticides.

24. In the order of importance, plants of medicinal value may be listed as follows :

1. Pyrethrum-as source for mosquitecides.

*These figures do not include the turnover of immunological agents in Govt. institutions or private sec units and of Insulin, Non-pharmacopoeial grade salicylic acid and ether.

2. (a) Dioscorea species e.g. *D. delteides, floribunda and D. composita.* (b) *Salanum khasianum* } *D.* as source of intermediates for the synthetsis of therapeutically active steriods including antifertility steroids.

3. Cinchona for quinine and quinidine.

4. Poppy for opium alkaloids e.g. morphine, codeine and noscapine.

5. Ergot of Rye, (*Clariceps purpurea*) for ergot alkaloids, ergotamine, ergometrine, etc.

6. Digitalis species *D. lanata* and *D. purpurea* for cardiac glycosides e.g. digoxin, digitalin, etc.

7. Ipecac for the production of emetine.

8. Dubosia and atropa species (A. belladonna and A. accuminate) for atropine and hyoscine.

9. Tea dust and tea waste for caffeine.

10. Nuxvomica for strychnine and brucine.

11. Glycyrrhiza for new anti-inflammatories and a possible anticarcinogenic agent.

12. *Vinca rosea* for the anti cancer alkaloids vincristin, vinblastin, etc.

13. Lemon grass for carotenoids for the preparation of Vitamin A.

14. Rauvolfia for hypertensive and CNS active total alkaloids and reserpine.

25. Of the above fourteen plant materials, eight, namely, dioscorea species (or solanum species), cinchonaf, poppy, ergot, digitalis, ipecac, dubosia (or atropa) species and lemon grass are the sources for essential drugs identified by this Committee.

26. Five of the above plant materials, namely, pyrethrum, cinchona, poppy, ergot of rye and ipecac have been and continue to be cultivated entirely by the various State agencies. Three groups of plant materials, namely, dioscorea species and solanum khasianum, digital is and atropa species are under various stages of cultivation (experimental-commercial) partly under State auspices and partly by the private sector industry.

27. Tea waste and tea dust are obtained from privately owned tea plantations and rauvolfia, nuxvomica and vinca are collected almost entirely from the areas where these grow naturally. Only marginal effort has been made in the State sector for the experimental cultivation of glycyrrhiza. Lemon grass is wholly cultivated in the private sector.

28. The relative importance of these plant materials needs hardly to be emphasized. These have been taken note of by the NCST : the magnitude of needs of most of these for the future have been estimated and the area of land and other facilities required for their economic cultivation have also been worked out and due recommendations, made by NCST.

29. This Committee is of the view that the biologically valuable materials derived from the above plant sources are not likely to be replaced by any cheaper or less toxic substitutes in the foreseeable future. The Committee, therefore, strongly endorses the recommendations of the NCST in this matter. The NCST's recommendations (Annexure I) indicate a large layout of cultivable land for these plant materials. It is estimated that about 4400 hectares will need to be brought under cultivation, in stages, for pyrethrum, dioscorea, ipecac, ergot, atropa species, glycyrrhiz, etc. It is necessary that acquiring land for this purpose, at the State level, should be appropriately incorporated in the afforestation policies and land reforms by the State Governments.

30. The Committee feels that the existing area of 8,000 hectares available for cinchona plantation needs urgent attention for improvement in the variety of the cultivated cinchona species (Java variety is reported to produce 16-17% total alkaoids whereas the Indian variety produces an average of only 3.5-4% alkaloids), as also in the production technology by the Governments of West Bengal and Tamil Nadu. It is necessary to expand this plantation to a larger area. There is need for doubling the area for ipecac (productivity has gone down from 30,000 kg. of ipecac and is reported to be 18,000 kg. at present) in West Bengal and of consolidating the existing areas under poppy in the poppy growing States of U.P., Bihar and Madhya Pradesh and the processing of opium at the Ghazipur factory.

31. Technologies for the processing of the above plant materials for their respective end-products (except for ergot and vinca for which active work is already a foot under the auspices of the CSIR) are all available though there is need to streamline these processes for better economic productivity. The Committee notes that appropriate technological skill for all these is already available in the country. While attributing the present shortfalls of production of the various products outlined above to inadequacy of effort in cultivation, the Committee feels that if updating of production technologies had gone apace for the items already under production, and this was perfectly possible within the country) the present production should have been much better.

32. In view of the vital and growing importance of the products derived from the above plant materials and the fact that cultivation of these plants, is technology, finance and labour intensive with comparatively low returns, this activity should be taken up in a determined and businesslike manner under the public sector. In case of a State enterprise, equity might be floated for participation by Indian nationals or Indian private companies. Such joint units should be managed by trained personnel. Past experience has demonstrated the preference of the private sector entrepreneurs, in respect of cultivation, only for such plant materials as may produce the high activity, low bulk and high money value intermediates of final bulk drugs e.g. dioscorea species for the expensive steroids, digitalis for the expensive digoxin and lemon grass for Vitamin A. Incidentally, land requirements for these specific items are also relatively low.

33. Drugs derived from lower plants/micro-organisms and animal sources may be sub-divided into (i) antibiotics (ii) products from animal tissues such as insulin, pancreatin, trypsin, chymotrypsin, etc. and (iii) immunological agents, namely, sera, vaccine, antitoxins and toxoids.

34. Antibiotics account for the most important products of this class. Licensed capacities as also production of the more important antibiotics in 1972 and 1973 are given in Annexures II and III, which also reflect the estimated needs of the four essential antibiotics namely, penicillin, the tetracyclines, chloramphenicol and streptomycin, for the years 1978-79 and 1983-84, as projected by the Task Force. Relevant figures in the annexures indicate that as at present, of the total licensed capacity for bulk production for penicillin, 62% (224 MMU) is in the public sector and 38% (140 MMU) is in the Indian and Indian majority sectors. Foreign and foreign majority units have not participated in the production of this antibiotic.

35. Licensed capacity for streptomycin (257 tonnes), in 1973 was shared between the public sector units (175 tonnes, equivalent to 68%) and the Indian and Indian majority units (82 tonnes, equivalent to 32%). Foreign majority units did not participate in the production of this antibiotic either.

36. Licensed capacity for tetracyclines in 1973, which stood at a total of 149 tonnes, included licensed capacity for 70 tonnes of chlorotetracycline which was originally programmed for production in the public sector and remained un-utilised till 1973. In effect, the total capacity for marketable tetracyclines stood at 79 tonnes of which capacity for 52 tonnes was in the public sector and 27 tonnes largely in the foreign majority units.

37. Licensed capacity in 1973 for the production of chloramphenicol was 109 tonnes and lay entirely in the private sector.

38. The public sector produced about 137 MMU of penicillin accounting for about 61% utilization of the licensed capacity and the Indian and Indian majority sector produced about 111 MMU, equivalent to about 79% utilization of the licensed capacity.

39. Production of streptomycin in the public sector amounted to about 96 tonnes equivalent to about 55% of their licensed capacity, whereas the Indian and Indian majority private sector units contributed 84 tonnes representing 102% utilization of their licensed capacity.

40. Public sector produced about 25.0 tonnes of tetracyclines and accounted for the utilization of about 48% of its installed capacity for saleable tetracyclines (its licensed capacity of 70 tonnes for the non-marketable chlortetracycline is not included in this calculation). The private sector, consisting very largely of foreign majority units produced about 65 tonnes of tetracyclines representing 240% utilization of their licensed capacity.

41. Production of chloramphenicol was entirely in the private sector and was of the order of 47 tonnes, representing about 43% utilization of the licensed capacity.

42. Annexure II shows that import for penicillin was negligible whereas there were substantial imports for the other three antibiotics. These figures indicate that with near 100% utilization of licensed capacities, we should have been able to meet and even exceed our present national needs for all these antibiotics.

43. Recent production figures of I.D.P.L. are indicative of the realization by this unit that with appropriate care, utilization of the installed capacities can be materially improved. Over the 12 month period ending October 1974, streptomycin production registered an increase of about 18% and that of tetracycline an increase of about 80% compared with the corresponding production figures for the 12 month period ending October, 1973 (Annexure IV). It is necessary that this unit should immediately utilize the 70 tonnes capacity, originally created for the production of chlortetracycline, for the production of tetracycline and oxytetracycline.

44. In respect of other major antibiotics, namely erythromycin and ampicillin which were imported to the extent of Rs. 1.6 crores in 1972-73 and more than Rs. 2.2 crores in 1973-74, the Committee is of the opinion that the public sector units must undertake their production also. In respect of erythromycin, against a licensed capcity of 10 tonnes in 1973, production amounted to about 3.0 tonnes, and for ampicillin, against a licensed capacity of 16 tonnes, a beginning has now been made for its production by H.A.L. It is relevant to note that the public sector unit (HAL) has been granted a capacity of six tonnes for erythromycin and 5 tonnes of semi-synthetic penicillins including ampicillin. It is understood that IDPL have included the production of erythromycin, ampicillin and deoxy-oxytetracycline to the extents of 10, 10 and 5 tonnes, respectively, in their production programme. Projections for erythromycin and ampicillin requirements are 30 and 35 tonnes respectively for 1978-79 and 60 tonnes and 100 tonnes respectively for 1983-84.

45. While reviewing the production programme of the public sector units producing antibiotics, the Committee felt that there was considerable overlap in their spectrum of products and that this contributed to some extent to their inability to concentrate and specialise on a given line of products. The Committee, therefore, feels that the public sector units should divide, between themselves, the responsibilities for the production of individual items so that they may attain the required level of specialisation and sophistication in their respective lines of effort. The Committee hopes that this would lead to better economic working for the production of antibiotics in the public sector units whereby each of the public sector units does not duplicate the production pattern of another unit. In general, the narrow spectrum antibiotics such as penicillin, streptomycin, and penicillin derivatives, could be assigned to HAL while broad spectrum antibiotics such as tetracycline, derivatives of tetracycline and other newer antibiotics should be allocated to IDPL.

46. The Committee notes that the present licensed capacity for the production of penicillin, streptomycin and tetracycline is about 660 tonnes (each MMU of penicillin is calculated to be equivalent to 0.7 tonne) and estimated requirements for 1978-79 amout to 1675 tonnes.

47. In view of the growing importance of erythromycin, semi-synthetic penicillin and deoxy-oxtetracycline and the fact that the public sector units are already engaged in the production of penicillin and oxytetracycline, the starting materials for the two latter antibiotics, the Committee feels that even though these drugs do not figure in the essential drugs list, the public sector must carry the major responsibility for the production of these and other useful antibiotics as may appear in therapeutics from time to time.

48. Drugs from natural sources include such important items as Vitamin B12, products derived from slaughter-house waste like insulin, pancreatin, trypsin, pepsin, etc., and immunological agents including sera, vaccines, antitoxins and toxoids.

49. Vitamin B12 and some of the enzymes like diastase, amylase, lipase, cellulase, etc. belong strictly to the class of essential materials that lend themselves to production involving fermentation processes. Of these, only Vitamin B12 is listed in the essential drugs list and this is the major therapeutically useful item in this group. Vitamin B12 is being produced indigenously and some capacity is at the moment available for diastase also. Against a total licensed capacity for Vitamin B12 of 233 kg., production in 1973 was of the order of 179 kg. Estimated requirements for Vitamin B12 have been placed at 300 kg. in the year 1978-79 and 600 kg. in 1983-84. Considering the low figure for present imports, it would seem that the installed capacity could, with appropriate planned expansion, meet the national requirements.

50. Enzyme production has heavy economic implications outside the field of drugs and pharmaceuticals. The Committee would like to stress the need for the creation of active centres for enzyme production to be preceded by the setting up of a strong centre for R & D in enzymology and enzyme technology as recommended by the NCST. The Committee does not, however, consider it necessary to make any specific recommendations in this regard because the use of enzymes as drugs is only marginal.

51. In respect of slaughter house products e.g. insulin, pancreatin, trypsin, heparin, etc. effort at their production is only marginal at present. Insulin is manufactured from imported pancreas in quantities of about 900 M.U. against a licensed capacity of 1500 M.U. Estimated requirements are 3000 M.U. in 1978-79 and 6000 M.U. in 1983-84. A joint team of scientists working under the auspices of CSIR and ICAR at the Vallabh Bhai Patel Chest Diseases Research Institute, Delhi, the Haffkine Institute, Bombay and the Central Drug Research Institute, Lucknow are right now engaged in working out the production details and ecomonics of a process for the production of insulin from sheep, hog and ox pancreas. It is felt that since production of insulin and other slaughter-house waste products is bound up with upgrading of abattoirs in the larger cities and because of the need to set up the primary extraction units for such products in the immediate vicinity of slaughter houses (the tissue degenerates rapidly with time and must be collected and frozen and preferably processed immediately after an animal is slaughtered), this entire work of development of these sensitive products may be allocated to the Biochemicals units at S.V.P. Institute, Delhi in collaboration with the Haffkine Institute and other institutions where adequate scaling up facilities exist.

52. Sera, vaccines, antitoxins and toxoids are produced in this country in governmental institutions and the private sector (Annexure V). These include vaccines against samll pox, cholera, antitetanus serum and tox antidiphtheria serum and toxoid and antirabic vaccine and triple antigen and oral polio vaccine etc. This Commit feels that the institutional centres such as Haffkine Institute, Bombay, Central Research Institute, Kasauli, Past Institute, Shillong, King Institute, Guindy, Pasteur Institute, Connoor, Vaccine Institutes at Bangalore, Calcu Shillong, Namkum (Bihar), etc., and the private Indian units should be sterngthened to meet the domestic ne and even for export in terms of the projections for the Fifth and Sixth Five Year Plan.

53. Synthetic Drugs represent today the king-pin of the entire drugs and pharmaceutical industry. Earl attempts to copy and then improve on nature launched the era of modern chemotherapy quite early in the hist of modern drug development. As distinct from products drawn from natural sources, the area of synthet provides the promise of possibilities of molecular design to combat the diverse variety of pathological conditi with logic. Such possibilities of design can of course only follow, with a degree of certainty, the resolution of p siological and the corresponding pathological processes in specific molecular terms. Even though possibilities such molecular resolution lie right now in a twilight area because of inadequacies in the presently available exp mental methods of molecular biology, some progress on correlation between molecular structure and physiologi acitivity, does permit a fair degree of logical approaches in chemotherapy. The spectacular array of synthetic dru now available for the treatment of disease, dominate the entire spectrum of the means of treatment in modern thera

54. The simpler synthetic analgesics, hypnotics, antipyretics, antiprotozoal agents, etc., were followed by powerful antibacterial sulfa drugs and then came the whole variety of drugs effective on the diseases of, or clos related to cardiovascular system, the central nervous system, hormonal imbalances, etc. And, today synthetic dr dominate the entire field of therapeutics and their role is bound to grow with advances in methods of experimer molecular biology and chemistry.

55. Because of their vary nature, synthetic drugs are directly derived from fine chemicals indus and depend for their production on a variety of chemicals, which arise in most cases, from down-stre products of the chemical industry itself. It is for this reason primarily that all over the world, synthe drugs industry forms, in a high percentage of cases, a subsidiary of the organic chemical industry

56. In India, chemical industry is still at the stage of development. The need for drugs cannot, however, postponed and production of synthetic drugs has to go on.

57. The Committee noted with satisfaction that in addition to HOC and IPCL, the recovery of chemicals fr coal tar at Durgapur had been undertaken on a fairly large scale. The Committee is of the opinion that appropri units for preparing basic intermediates from the down-stream products of the Durgapur Plant would help substa tially in the setting up of a bulk drug manufacturing unit in the Eastern region. In the context that new units shou be established mainly on considerations of economic viability, Durgapur holds good promise.

58. The multi-national units of the drugs and pharmaceutical industry have dominated, in this country, the field of synthetic drugs and by far the largest component of their formulation activities lies in this area. Mo of these multinational units, both in the small and large sectors, have concentrated their activities on the produ marketed by their overseas parent organisations and have almost completely cornered the Indian market for th respective products. They have also built up enormous markets on the sale of a large variety of other formulatio e.g. tonics, combinations of vitamins etc. Even where purely Indian units in the medium and the small scale sect produce equivalent formulations, they face the greatest difficulty in obtaining the relevant bulk drugs from the mu tinationals, but more particularly in facing high pressure and costly sales practices of the latter.

59. In the last few years, there has been a further tendency in multinational units to introduce newer produc of similar activities with marginal differences. Since such products are patented, they are usually priced high ar allowed to be formulated for a period of 2 years by importing the basic bulk drug from their principals at a hi price. The Committee is of the opinion that while considering the licensing of the manufacture of new drugs, de loped abroad the main consideration should be that the proposed new drugs has distinct advantages over the exi ing range of drugs. The Committee further recommends that the therapeutic character of such new drugs shou be scrutinised by a Committee of experts.

60. From the early days of our independence, the Government of India have been endeavouring to persua the multinational units to produce bulk synthetic drugs in this country and share these with other formulators. Re ponse of the multinationals during the earlier years was negative, or, poor. However, in recent years some of t multinational units did enter the field of bulk drug production obviously because of the emergence of the publ sector. Even so, they were usually, highly selective and chose low-tonnage, high money-value bulk items and start to manufacture these, frequently from penultimate or near-penultimate intermediates imported, usually, from the corresponding principals, at high costs. This position is only slightly better today.

61. As against the poor performance of multinational units in the field of bulk drugs, the effort of the private Indian and Indian majority sector has been a great deal more impressive and satisfying. Some of these units sell their entire production of bulk d. .g. to formulators or share these with other formulators. There are of course several units in this sector also whose entire bulk drug production activity is limited for their captive use

62. The Committee noted that when public sector entered the field of production of synthetic bulk drugs - 1968, there was need to modify production technologies to conform to economic compulsions of a competing economy. The public sector has met this chellange effectively. They have revised the technology for their production of almost all the products and worked out the technology for several other products. Their initial licensed capacity was rated to produce 851 tonnes covering 16 items. The revised licensed capacity for the production of 20 bulk drugs *stood* at 1988 tonnes. In 1973, they produced 1212 tonnes of 17 bulk drugs (Annexure VI). Out of this production, the public sector distributed about 600 tonnes in 1973, to other formulators. This represent about 50% of their total production of bulk drugs. This commendable performance of the public sector technologists is reassuring. It is clear that technological competence has developed to an appropriate level in the public sector to permit entrusting this sector with heavier responsibilities with confidence.

63. Formulation activity of synthetic bulk drugs production in the public sector has, however, been at a low ebb. There is need clearly for the public sector to upscale this activity materially by increasing the range of products to include injectibles, storile ointments etc.

64. This Committee has identified 44 drugs derived purely from synthetic sources, as essential drugs. Requirements of these essential drugs for the Fifth & Sixth Five Year Plan periods are given in Annexure VII.

65. Out of these 44 synthetic drugs, 7 are produced exclusively in the public sector and 6 others are produced both in the public and private sector. Out of the remaining 31 drugs, 20 drugs are produced in varying quantities in the private sector only. Licensed capacity and production figures for 1973 are also given in Annexure VII. These figures reveal big gaps in the production of our present requirements of synthetic bulk drugs even though the licensed capacities are substantially high. Furthermore, production of a fair number of these drugs is carried out at present from imported intermediates.

66. As has been indicated earlier in this chapter, the public sector manufacture 13 out of 44 essential synthetic drugs. These thirteen drugs formed the bulk of their production of 17 items which the public sector unit at Hyderabad produced in 1973. Quantities so produced are given in Annexure VI. The annexure also lists the projected requirements of these drugs for 1978-79 and 1983-84 as estimated by the Task Force. Out of these 13 items, 7 items, namely, Sulfadimidine, Vitamin B1, Vitamin B2, Folic acid, Phenobarbitone/sodium, Analgin and Piperazines are being manufactured exclusively in the public sector and 6 items namely Nicotinamide, Thiacetazone, PAS, Paracetamol, Sulfacetamide and Diethyl carbamazine citrate are also manufactured in the private sector.

67. Licensed capacity for the 7 essential items producted in the public sector is about 803 tonnes and total production of these amounted to about 572 tonnes in 1973. Imports for these 7 items of 1972-73 stood at about 305 tonnes.

68. Projected requirement for 1978-79 for the production of these 7 items add up to 1683 tonnes and proposed expansion programmes in the public sector for the production of these items is of the order of 1696 tonnes for 1978-79.

69. It would thus be clear that with full utilization of the existing and projected capacities, the public sector would meet the entire projected needs, for these items of the country by 1978-79. Projected figures of the Task Force, for these seven items for 1983-84 stand at 3383 tonnes.

70. The Committee recommends that the public sector must take the responsibility of expanding the production of these seven important drugs to meet the increasing requirements of the nation and free the country from import of these drugs. It is clearly understood that this additional production representing over four-fold increase over the present capacity during the next ten years, will need to be achieved by judicious expansion of the present capacities and by setting up of new production units where necessary.

71. The Committee notes that out of the remaining six items, projected requirements for 1978-79 for Thiacetazone and Diethyl carbamazine citrate would be adquately met by the capacities already licensed for these two drugs if the licensed capacities are fully utilized. The Committee recommend that first option for the production of the remaining 3 items namely, Nicotinamide, Paracetamol and PAS, should be given to the purely Indian sector and, if, however, it is found necessary, this may be shared between the public sector and the private Indian sector; the exact quantum of production of the individual items being determined by mutural consultation between the concerned public sector unit/units and the private Indian sector units. In respect of sulfacetamide, the Committee feels that this drug should be produced in the public sector to meet the projected requirements.

72. The Committee recommends that in addition to the above, the following eight drugs, appearing in the essential drugs list and which are currently largely imported (Annexure VIII) should also be produced in the public sector in quantities projected for the V & VI plan periods taking into account the quantities for which capacities have already been licensed.

1. Nitrofurantoin, 2. Nitrofurazone, 3. Fursemide, 4. Pyridoxine Hydrochloride, 5. Theophylline, 6. Phthalyl sulfathiazole, 7. Aminophylline, 8. Calcium pantothenate.

73. Public sector already holds letters of intent for the production of Nitrofurantoin, Nitrofurazone, Fursemide, Pyridoxine hydrochloride, Calcium pantothenate, Phthalyl sulfathiazole, Aminophylline and theophylline in quantities given in Annexure VIII.

74. The Committee understands that the public sector manufacturing units and national research laboratories have already developed laboratory scale technology for the production of nitrofurantoin, nitrofurazone, fursemide and pyridoxine hydrochloride and some of these technologies are in the test operation stage at the pilot plant level. The Committee further understands that the public sector and a national laboratory (NCL) have the necessary technology for the production of Phthalyl sulfathiazole, Aminophylline and Theophylline and a national laboratory (RRL, Jorhat) had developed a laboratory scale technology for Calcium pantothenate. The Committee recommends that immediate steps be taken to coordinate the work already done on these drugs in the above mentioned laboratories to upscale these processes through pilot plant and prototype large scale production within the next 24 months. Should it be found necessary, for reasons of time, or if any of above technology is found not to conform to economic working, the Committee recommends that such technology be imported by the concerned public sector unit on a priority basis. The Committee also recommends that licences should be immediately given on a priority basis to the public sector for import of raw materials for these drugs wherever import is necessary. In respect of Pyridoxine, the Committee notes that the country is spending substantial foreign exchange. The Committee feels that it is necessary that the production of this important item should be expedited, particularly because of its short supply in the international market. The Committee recommends that the available indigenous technology should be assessed within the next six months by the concerned Ministry/NDA and necessary decision in respect of import, or otherwise, of the technology, should be taken as early as possible.

75. Metronidazole is being produced in a quantity of 7.7 tonnes against a licensed capacity of 0.6 tonnes from the pentultimate imported 2-methyl 1-4-nitroimidazole in the private sector by a wholly foreign company against a requirement of 33 tonnes as judged from the import figures of 25.5 tonnes in the year 1973-74. One Indian unit holds a licence for the production of 4 tonnes but it does not appear to have started production so far. Projected requirements of this drug stand at 50 tonnes for 1978-79 and 100 tonnes for 1983-84. The Committee understands that a public sector unit has completed the laboratory scale studies for its production starting from the basic stage of glyoxal. The Committee recommends that the production of this important drug should be undertaken in the public sector and high priority should be given to immediate upscaling of the laboratory process, and, if necessary, the relevant technology may be imported.

76. Chloroquin is at present produced in the private sector in some quantity (about 15 tonnes in 1973). A foreign unit and one Indian unit prepare it from the late imported intermediates *viz.*-7chloro-4-hydroxyquinoline and novaldiamine. Another Indian producer of this drug, however, produces it from the basic stage *viz.* m-chloroaniline. The import figure of 99 tonnes in 1972-73 for this important drug emphasize the need of producing it in the country from basic indigenous materials. Against a total licenced capacity of 40 tonnes available today, projected needs for 1978-79 are estimated at 150 tonnes and for 1983-84 this figure stands at 225 tonnes. The Committee is strongly of the opinion that while facilities should be provided to purely Indian units to reach their licensed capacity for chloroquin, public sector must undertake its production in a big way and fulfil the targets for 1978-79 and 1983-84.

77. Against a licensed capacity of 294 tonnes for INH, production was of the order of 96 tonnes in the private organised sector for 1973 and there were practically no imports. The rest of the need was met by the small scale sector. As at present, there would appear to be no need to create any additional capacity for the production of INH.

78. Licensed capacities, actual production figures and imports, as in 1972-73, in respect of the 20 items produced only in the private sector, at present, are shown in Annexure VII. Corresponding projected figures, in respect of these items for 1978-79 and 1983-84 are also given therein.

79. Out of these 20 items, licensed and/or installed capacities of Methyl salicylate, Lignocaine, Dapsone, Vitamin D2/D3, Tolbutamide and Mephentermine sulfate approximate to the projected requirements for the year 1978-79, though actual production in several cases does not reach anywhere near the licensed capacity. There is need that the licensees be required to work upto the licensed capacities. No additional capacities for these items would be necessary at present.

80. Halogenated-8-oxy-quinolines, Acetyl salicylic acid, Pethidine and Vitamin C are also largely under-produced at present (compared to the licensed/installed capacities--Annexure VII). Projected requirements of these drugs for 1978-79 and particularly 1983-84 are of the order of 200—300% of the presently licensed capacity. The Committee recommends that expansion of production of these items, to conform to national requirements for 1978-79 and 1983-84 should be handled entirely in the public sector and the Indian-private sector.

81. There appear to be no, or in a few cases, small installed capacities for the production of the relatively low-tonnage essential drugs, namely, Primaquin, Chloropromazine, Succinyl choline chloride, Thiopental, Adrenaline, Nor-adrenaline, Oxytocin, Chlorpheniramine maleate and hydrochlorthiazide. The Committee recommends that the items (some of these are highly technology intensive) should be produced in the public sector to meet the national requirements. The Committee notes that ephedrine is being manufactured at present by a foreign unit from imported phenyl acetyl carbinol in a quantity far short of their licensed capacity of 18 tonnes. The Committee understands that a national laboratory (CDRI) has evolved a fermentation process for the production of this intermediate and its conversion by synthetic methods into ephedrine. The Committee further understands that up-scaling of this work is being carried out in collaboration with an Indian unit in the private sector. The Committee recommends that in order to meet the estimated needs for 1978-79 of 49 tonnes, ephedrine hydrochloride may be manufactured in the private Indian sector, who may also expand, if necessary.

82. There are a number of other drugs, not included in the essential drugs list, that are either imported into the country in fairly large quantities or are high sales items. These include sulpha-methoxazole, indomethacin, ethamutol, diazepam, chlordiazapoxide, secobarbitone, trimethoprim, methyl dopa, etc. The Committee is of the opinion that whereas it is desirable that public sector units may participate in the production and formulation of this class of drugs, production of each such item should however by examined on merits by N.D.A.

83. Raw materials and intermediates required for the production of essential synthetic drugs are dealt with in Chapter VI. Recommendations of the Committee in respect of their production in various sectors of the industry and also for their distribution are also given therein.

84. Existing and recommended capacites for the production of the essential synthetic drugs, identified by the Committee for production in the public sector, are shown in Annexure IX.

85. The Committee recommends that at least 60% of bulk drugs produced by the public sector units should be formulated by the public sector industry itself. In the disposal of the remaining 40%, first preference should be given to meet the needs of the Indian sector particularly small scale units.

86. In terms of the above recommendations, the public sector will be required to manufacture 34 items of bulk drugs in quantities indicated against these for the Fifth Five Year Plan. It would be necessary, of course, to make allowance for setting up additional capacities.

87. Seven items (Annexure IX—items 1—7) which are produced only in the public sector at present and for which the total licensed capacity is about 800 tonnes, will be required in quantity of about 1680 tonnes in 1978-79. Production capacity for about 880 tonnes should be set up for these seven drugs.

88. For three drugs (Annexure IX—items 8—10) namely, Nicotinamide, Paracetamol and PAS, the present licensed capacity in the public and the private sector, is 1335 tonnes and estimated requirement for the year 1978-79 is 2000 tonnes. As has already been recommended, the remaining about 665 tonnes of these three drugs may be produced in the private Indian sector, or, shared between the private Indian sector and the public sectors. For the purpose of the present calculations, it is assumed that 60% of the required additional about 665 tonnes, which is equivalent to about 400 tonnes will have to be produced in the public sector. Requirements of the additional quantity of sulphacetamide (Annexure X—item 11) will be produced in the public sector.

89. Eight drugs (Annexure IX, items 12—19) for which the total licensed capacity in the country as on date is of the order of about 57 tonnes are expected to be required in a total quantity of about 380 tonnes in 1978-79. No figures have been estimated by the Task Force for nitrofurazone. Considering, however, that this drug is required in small quantities, its requirement for 1978-79 is mostly estimated at 10 tonnes. The capacity to be set up in the public sector, in terms of the recommendations made above, would add upto about 320 tonnes.

90. Annexure IX (items 20—34) lists the remaining 15 drugs for which the present total licensed capacity is about 2210 tonnes. These are expected to be required in 1978-79 in a quantity of about 3520 tonnes. In terms of the above recommendations, the balance of about 1310 tonnes should be met by the public sector.

91. This would mean that public sector will have to raise its capacity by about 3000 tonnes. It is estimated that the public sector will require an additional outlay of about Rs. 51.0 crores, in terms of the 1973 prices, to ensure the production of the above 34 bulk drugs.

92. It has also been recommended above that the public sector should formulate 60% of its total production of bulk drugs and this amounts to about 1800 tonnes. In terms of the 1973 prices, it is expected that to formulate these 1800 tonnes of bulk drugs, the capital required for this formulation activity will be about Rs. 18 crores.

Problems of Public Sector and Recommendations

93. During the course of its visits to the public sector units, the Committee found that whereas one of the unit (the Synthetic Drugs Plant of IDPL) had made commendable progress, working of the two antibiotic-producing units at Pimpri and Rishikesh needed immediate attention. The performance of HAL at Pimpri has been satisfactory except for a decline during the years 1972 and 1973, and their productivity had gone down inspite of the better yielding strains and even, in many respects, better technology available to them. The Rishikesh plant has yet to make the grade—allowing even for the low yielding strains available to them. The Committee felt that there was urgent need to bring home to the management and the technologists at both these plants that they could not be allowed to function at their present low-level of productivity. The fact that the employees of public sector units enjoy certain privileges, should make the employees more responsible in their work and behaviour. A spirit and system of accountability to the industry and therefore to the nation must develop from top to bottom. Moreover, the management should see that the workers are increasingly involved in the functions and operations of the Public Sector so that they feel that they are a part and parcel of the industry and management. Bureaucratic behaviour at the top and irresponsible attitude at the lower level should be deprecated. This would generate a healthy industrial relationship which is the best way of increasing production.

94. The management should have a degree of freedom to act in every respect, subject to the overall supervision by the Government/NDA and to the general guide-lines laid down from time to time in respect of Public Sector Parliament being the supreme body has the right and duty to check up the activities of Public Sector.

95. In general, the Committee feels that the present structure need substantial changes so as to achieve the objectives set for the public sector in terms of our socio-economic goals.

96. The Committee noted that even though the public sector had served to an extent to safeguard against irrational pricing by the private sector, the existing system had not made material difference in the pattern of either the production or distribution of drugs which are at the moment governed largely by marketing mechanics. There is need to revise these to conform to our social needs.

97. The Committee recommends that working of the public sector plants at all levels should be carefully reorganised in respect of every step whether it involves purchase and standardization of raw materials, processing of raw materials and production of bulk drugs or formulations, their storage and distribution, etc. The Committee feels that there is need to attend immediately to removing all deficiencies in the plants. The Committee is also of the view that with intelligent and devoted attention to detail, these deficiencies could be overcome without involving heavy financial commitments. The Committee feels that each unit should operate strictly on economic basis.

98. The public sector units are facing difficulties in procurement of raw materials required for the production of essential drugs. The Committee recommends that the raw materials and intermediates produced or manufactured indigenously, essentially those manufactured in other public sector units. e.g. H.O.C. and I.P.C.L., and such other units as may come into existence hereafter, must be made available to the public sector engaged in drug production on the basis of the highest priority. Auxiliary items such as rubber caps, glass ware and packaging materials should also be available to these units on highest priority to make them more effective and efficient.

99. The Committee notes that both the units (IDPL & HAL) have fair sized R&D laboratories and that they need to be strengthened. It is well known that for all R&D efforts, there is a lower critical minimum in men and materials necessary to produce meaningful results. Whereas all the three laboratories at Pimpri, Rishikesh and Hyderabad have some every competent scientists/technologists for their R&D effort, there is need to bring this number up to a level of meaningful productivity. The Committee recommends that each one of these units should take immediate steps to strengthen their R&D effort by reasonably liberal allocations in men, equipment and materials. The Committee recognize that modern R&D, in this sophisticated field, is expensive in terms of investments. The Committee, is however, convinced that a sound R&D base is the best insurance for the growth of the drugs and pharmaceutical industry.

100. Besides recommending the strengthening of R&D laboratories at each plant, the Committee is strongly of the view that as between these three units, avoidable duplication of effort must be discouraged and the results (even the raw research data) of each unit must be available to the related unit in other R&D laboratories. This recommendation is based on the philosophy that as between the two units in the public sector (IDPL & HAL) there should be no secrets. Indeed, any improvements, in a strain, a process or a plant developed in the R&D laboratory of one unit, should be freely available for the use to the other unit.

101. The Committee further recommends that both the public sector units must establish the closest liaison with the other R&D laboratories such as the CSIR, ICMR, ICAR, etc., and the State institutions like the Haffkine Institute, the IITs, Universities, etc. The Committee feels that such coordination is vital for development. The Committee cannot but emphasise the need for such coordination by NDA. The Committee recommends that appropriate facilities should be created in the identified institutions, wherever necessary, to permit time-bound completion of individual projects.

102. The Committee wishes to emphasise that the primary task of the R&D laboratories of the public sector units and their associates should be to constantly upgrade technologies for achieving greater economies in the production of on-stream products and innovate technologies for products proposed to be manufactured in the immediate future.

103. The Committee recommends strongly that the Public Sector should set an example in respect of R&D in this area and must, to begin with, set aside at least 5% of their net turn-over for this purpose.

104. To enable the pharmaceutical industry in general, and the public sector in particular, to fulfil its objectives, it is essential that equipment, instruments and appliances of high precision should be made available to them expeditiously. The Committee notes that there has been commendable progress made in the manufacture of such equipment by private sector, particularly in Gujarat, Maharashtra and West Bengal. A number of firms are manufacturing sophisticated equipment of desired specifications. The engineering and designing units deserve encouragement from the public sector units.

105. In respect of such essential technologies, or the high yielding strains of antibiotics producing microorganisms as may not await indigenous development, for economic reasons, the best available technology, or antibiotic producing microbial strains, must be purchased on the following terms :

(i) The technology or an antibiotic producing microbial strain should as far as possible, be the best available in the world market.

(ii) The technology, or an antibiotic producing microbial strain, should be purchased centrally so that it is available to all the concerned units in the public and to such other units in the private sector, as the Government/NDA may identify in national interests.

(iii) Import of technology must not be linked up with import of machinery.

(iv) The technology or an antibiotic producing microbial strain may be purchased on the basis of one-time lumpsum payment or, where necessary, on the followig terms.

(a) Royalty payment for a period not exceeding 5 years which may vary between 2—5% of the net sale value of the bulk drug, the quantum being dependent upon the essentiality of the drug and the intricacies involved in the manufacturing technology.

(b) Lumpsum payment, to be made in instalments; the final payment to be made only after successful implementation of commercial production in India.

The public sector is today poised to absorb any imported technology and then improve it through R&D.

106. Under Section 100 of the Patents Act, 1970, it is stated that the Central Government and any person authorised in writing by it, may use a patented invention for the purposes of the Government. Use for the purpose of the Government has been defined in Section 99 of the said Act to include the making, using, exercising or vending for the purposes of the Central Government, a State Government or a Government undertaking. Government should, therefore, under the powers vested in it, permit the public sector undertakings to use the inventions for the purposes of the Government. The effect of this will be that the mere fact that a patent has been filed or—a patent has been granted will not debar public sector undertakings from manufacturing and distributing the products so patented. The Committee feels strongly that allowing the freedom to the public sector units to use desirable patents would not only constitute an exciting challenge to the scientists and technologists, to innovate and establish, production technologies, ordinarily forbidden to them by patent laws, but also would obviate payment of high royalties for really worthwhile patents.

107. The Committee recommends that early steps may be taken, with a time bound programme to expand capacities where possible and instal new capacities when necessary for enabling the public sector to fulfil the production obligations incorporated in the recommendations of this Committee. The Committee is of the opinion that while planning these additional tasks due care should be taken that location of sites for new units for bulk drug production is dictated by reasons of economy. This must of course be done in the overall context that within the desired constraints of economic functioning, there is, as far as possible, reasonable dispersal of the new units in different regions of the country. As an example, it has been suggested elsewhere in this chapter, that a unit for bulk drugs—production requiring large bulk volumes of chemicals arising from products of coal tar distillation may be set up around the Durgapur complex.

101. The Committee further recommends that both the public sector units must establish the closest liaison with the other R&D laboratories such as the CSIR, ICMR, ICAR, etc., and the State institutions like the Haffkine Institute, the IITs, Universities, etc. The Committee feels that such coordination is vital for development. The Committee cannot but emphasise the need for such coordination by NDA. The Committee recommends that appropriate facilities should be created in the identified institutions, wherever necessary, to permit time-bound completion of individual projects.

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105. In respect of such essential technologies, or the high yielding strains of antibiotics producing microorganisms as may not await indigenous development, for economic reasons, the best available technology, or antibiotic producing microbial strains, must be purchased on the following terms :

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107. The Committee recommends that early steps may be taken, with a time bound programme to expand capacities where possible and instal new capacities when necessary for enabling the public sector to fulfil the production obligations incorporated in the recommendations of this Committee. The Committee is of the opinion that while planning these additional tasks due care should be taken that location of sites for new units for bulk drug production is dictated by reasons of economy. This must of course be done in the overall context that within the desired constraints of economic functioning, there is, as far as possible, reasonable dispersal of the new units in different regions of the country. As an example, it has been suggested elsewhere in this chapter, that a unit for bulk drugs—production requiring large bulk volumes of chemicals arising from products of coal tar distillation may be set up around the Durgapur complex.

108. The Committee also recommends that wherever possible public sector units for drugs and pharmaceuticals should also produce bulk intermediates which may not either be produced indigenously or may be produced in insufficient quantity. The Committee notes that ordinarily it is not feasible for any country to produce all the bulk drugs and intermediates that it may need. It is however necessary and wise that such dependence is reduced to the minimum.

109. The Committee recommends that additional formulation units be set up in the country immediately. One such unit is recommended to be set up in the Eastern Zone by developing M/s. Smith Stanistreet and Co. Ltd., which is at present being managed by IDPL. The Committee recommends that this unit be now taken over by IDPL. While making this recommendation, the Committee recognizes the limitations of Smith Stanistreet in the shape of old and outdated plant. These limitations will need to be met by preferably transferring the available assets to a new site and starting a modern formulation plant. The Committee feels that the proposed and the existing formulation units should feed groups of neighbouring states. Eventually, there will be need to set up a formulation unit preferably in each State.

110. The Committee recommends that distribution systems in the public sector should make use of unconventional agencies such as primary health centres, panchayats, dispensaries, post offices, petrol and kerosene sales-depots, etc., for the distribution of household remedies. The Committee recognized that logistics of a wide distribution system of this nature will have to be worked out carefully by NDA. The Committee feels that there is need to evolve a wide distribution system suited to our own socio-economic ecological conditions. Marketing arrangement of the products of public sector is week. They should pay greater attention to the maintainance of close liaison with the medical profession.

111. The Committee feels that all the pharmaceutical public sector units now in existence should have strong boards of directors consisting of more non-official membersincluding academicians, technologists, management experts and representatives of workers/employees. This board should supervise a functional whole-time internal board consisting of the Managing Director, (ii) a Finance Director, (iii) a Technical Director, (iv) a Commercial Director, (v) a R&D Director, (vi) a Planning and Public Relations Director. The Committee also recommends that each individual unit should have a similar functional board, headed by the general manager of the unit, for conducting the affairs of the unit.

SUMMARY OF RECOMMENDATIONS

(1) With a view to streamlining the operations and achieving the basic objectives of producing and distributing essential drugs to the largest number of people as economically as may be possible, the Committee recommends the establishment of a National Drug Authority (NDA) which will also lay down and co-ordinate the policies.

(Chapter—III. Para. 5)

(2) In appreciation of the fact that ill health has major socio-economic implications, the Committee feels that in a welfare state, availability of prophylactics and curatives should receive the highest priority on par with food and shelter. Production and distribution of drugs should, therefore, constitute an important social resposibility of the state.

The Committee is of the opinion that trade aspects of this vital industry should be divorced from the ordinarily accepted principles of trade for profit. Indeed, the Committee feels that trade aspects in this field should be limited only to the extent that the industry generates resources for its own growth and expansion through R & D, where necessary, to meet the increasing needs of the nation.

In order to achieve the above objectives, the Committee feels that leading role for production and distribution of drugs and pharmaceuticals should vest with the State. The Committee makes the following recommendations for providing to the public sector a leading role in the production and distribution of essential drugs and pharmaceuticals.

The public sector should be given the major role for the production of capital and technology intensive bulk drugs such as are needed in high tonnage quantities and where large scale production would be economically preferable.

(Chapter—III. Para. 6).

(3) The Committee feels that the basic data used by the NCST and the Task force appointed by the Planning Commission conforms to the existing pattern of market needs rather than the social needs of the country. There is urgent need to institutionalise data collection and base the national production targets in terms of the needs identified by such a system. The Committee also emphasise the necessity of fixing growth target and judging the growth rate in terms of individual quantities.

(Chapter III. Para 7)

(4) It is essential that raw materials for the production of bulk drugs arising out of the effort of either the public sector or the private sector units should meet the priority needs of the bulk drug industry.

(Chapter III. Para 11)

(5) In the order of importance, the Committee has identified 14 plants having medicinal value, out of which 8, namely, dioscorea species, cinchona. poppy, ergot, digitalis, ipecac, dubesia (or atropa), and lemon grass are the sources for essential drugs identified by this Committee.

(Chapter III. Para 24 & 25)

(6) The Committee strongly endorses the recommendations of the NCST for increased cultivation of the 14 plant materials and also production of active Principles obtainable therefrom with updated technology.

(Chapter III. Para 29 & 30)

(7) In view of the vital and growing importance of the drugs derived from the identified plant materials, cultivation of these plants, which is technology, finance, and labour intensive, should be taken up in a determined and business like manner under the public sector/joint sector.

(Chapter III. Para 32)

(8) IDPL should utilize the capacity that was originally created for the production of chlor-tetracycline, for the production of tetracycline and oxy-tetracycline.

(Chapter III. Para 43)

(9) Although such antibiotics as Erythromycin, Ampicillin etc. have not been identified as essential drugs, the Committee feels that it may be desirable to produce these in the public sector because of their heavy imports. Ampicillin in Deoxy-oxytetracycline may be produced in the Public sector particulary because the starting material for ampicillin and deoxy-oxytetracycline are already being produced in the public sector.

(Chapter III. Para 44 & 47)

(10) Public sector units should between themselves divide the responsibilities for the production of individual items so that they may attain the required level of specialisation and sophistication in their respective lines of effort.

(Chapter III. Para 45)

(11) The Committee stresses the needs for the creation of active centres for enzyme production to be preceded by the setting up of a strong centre for R & D in enzymology and enzyme technology.

(Chapter III. Para 50)

(12) Considering the importance of insulin production and utilization of the products available from the slaughter houses, the work of development of the sensitive items may be allocated to the bio-chemical units at S. V. P. Chest Institute, Delhi, Haffkine Institute Bombay and other institutions like CDRI where facilities for such work exist.

(Chapter III. Para 51)

(13) The production of immunological agents at the State-owned institutions and in the private Indian Sector should be upscaled and streamlined to meet the needs of the country and also for exports.

(Chapter III. Para 52)

(14) The Committee noted that recovery of chemicals from coal-tar distilation products has been undertaken at Durgapur on a fairly large scale. New units should be established for the manufacture of bulk drugs at Durgapur to utilize the available downstream products.

(Chapter III. Para 57)

(15) While considering the licensing of new drugs manufactured abroad, the main consideration should be that the proposed new drugs have distinct advantages over the existing range of drugs, for which therapeutical character should be scrutinized by a Committee of experts.

(Chapter III. Para 59)

(16) Public sector has developed technological competence in the field of synthetic drugs and can be entrusted with the heavier responsibilities with confidence.

(Chapter III. Para 62)

(16A) The Committee has identified 44 drugs derived purely from synthetic sources as essential drugs.

(Chapter III. Para 64)

(17) The public sector should take the responsibility of expanding the production of analgin, piperzine, phenobarbitone, sulphadimidine, folic acid, vitamin B1, and vitaman B2, upto the quantities envisaged for the Fifth and Sixth Plan periods.

(Chapter III. Para 70 & 87)

(18) The Committee recommends that the first option for the production of nicotinamide, paracetamol and PAS salts should be given purely to the Indian sector and if necessary, their production may be shared with public sector. In respect of sulphacetamide, the increased requirements should be met by the public sector.

(Chapter III. Paras 71 & 88)

(19) The following eight drugs, appearing in the essential drugs list and which are currently largely imported, should be produced in the public sector in quantities projected for the Fifth and Sixth Plan periods, taking into account the quantities for which capacities have already been licened :—

1. Nitrofurantoin
2. Nitrofurazone
3. Fursemide.
4. Pyridoxine Hydrochloride
5. Theophylline
6. Phthalyl sulfathiazole
7. Aminophylline
8. Calcium pantothenate

(Chapter III. Paras 72 & 89)

(20) Immediate steps should be taken to co-ordinate the work already done in respect of developing production technologies of the eight drugs mentioned in 19 above, in the National laboratories and the Public sector, to upscale their processes through pilot plant and proto-type large scale production within the next 24 months. If technology for any of the above drugs is found not to conform to economic working, such technology should be imported by the concerned public sector unit on priority basis. Licences for import of raw materials for these drugs, wherever necessary should also be given on a priority basis.The Committee feels that the production of Vitamin B6 in particular should be expedited and recommends that the available indigenous technology should be assessed within next six

months by the concerned Ministry/NDA and necessary decision to import or otherwise of the technology should be taken as early as possible.

(Chapter-III. Para 74)

(21) Production of Metron-dazole should be undertaken in the public sector and high priority should be given to upscale the laboratory process and, if necessary, the relevant technology may also be imported.

(Chapter-III. Para 75)

(22) While facilities should be provided to purely Indian units to reach the licenced capacity for the production of Chloroquin, public sector should also undertake its production in a big way and fulfil the targets for 1978-79 and 1983-84.

(Chapter-III. Para 76)

(23) No additional capacities for the manufacture of Methyl salicylate, Lignocaine, Dapsone Vitamin D2/D3, Tolbutamide and Mephentermine sulfate would be necessary at present and the existing licence-holder should be asked to work up to the licensed capacities.

(Chapter-III. Para 79)

(24) Expansion in the capacities for Halogenated-8-oxyquinolines, Acetyl Salicylic acid, pethidine, aspirin, and vitamin C should be handled entirely between the public sector and Indian units to meet the national requirements.

(Chapter-III. Para 80)

(24) Public sector should also take up the manufacture of Primaquin, Chlorpromazine, Succinyl choline chloride Thiopental, Adrenaline, Noradrenaline, Oxytocin, Chlorpheniramine moleateand Hydrochlorthiazide. The Committee also recommends that Ephedrine should be manufacture in the Indian sector and the Indian sector should be given the necessary licence to produce such quantity as may be required for the V & VI Plan Period.

(Chapter III. Para 81)

(26) The Public Sector may produce sulphamethoxazole, indomethacin, ethambutol, diazepam, chlordiazepoxide, secobarbitone, trimethoprim and methyl dopa etc., which are currently largely imported.

(Chapter-III. Para 82)

(27) At least 60% of the bulk drugs produced by the public sector should be formulated by the Public Sector Industry itself. In the disposal of the remaining 40%, first preference should be given to the Indian sector, particularly the small scale sector units.

(Chapter-III. Para 85)

(27A) The public sector should be required to manufacture 34 items of bulk drugs in quantities indicated against these for the Fifth Five Year Plan by setting up additional capacities.

(Chapter-III. Para 86)

(28) To ensure the production of 34 bulk drugs in quantities indicated in these two paras, the public sector will require an outlay of Rs. 51 crores in 1973 value of the rupee. For formulating, 60% of their total production of bulk drugs, they will require another about Rs. 18 crores at the 1973 value of rupee.

(Cpahter-III. Para 91-92)

(29) Healthy industrial relation at all points in the production and management of the public sector should be developed to achieve the desired results.

(Chapter-III. Para 93)

(30) The management should have a degree of freedom to act in every respect subject to the overall supervision by Government/NDA.

(Chapter-III. Para 94)

(31) The present system of production and distribution of drugs needs revision to conform to our social needs.

(Chapter-III. Paras 95-96)

(32) Working of the public sector plants at all levels should be carefully reorganized in respect of every step including purchase and standardization, production of bulk drugs and formulations, their storage and distribution etc. Each unit should operate strictly on economic basis.

(Chapter-III. Para 97)

(33) Raw materials and intermediates produced or manufactured indigenously in the Public Sector and such other units which may come into existence hereafter should be made available to the Public Sector units engaged in drug production on the basis of highest priority.

(Chapter-III. Para 98)

(34) The R & D Laboratories of all the Public Sector drug manufacturing units should be strengthened immediately by reasonably liberal allocations in men, equipment and materials. A sound R & D base is the best insurance for the growth of the drugs and pharmaceutical industry.

(Chapter-III. Para 99)

(35) Avoidable duplication of R & D efforts must be discouraged and the results available at each unit must be made available to the other related unit. There should be no secrets between the Public Sector units. Any improvement in a strain or a process or a plant developed in the R & D laboratory of one unit should be freely available for use by the other units.

(Chapter-III. Para 100)

(36) Public Sector units must establish the closest liaison with the other R & D laboratories of the National Laboratories, State Institutions and other Educational Institutions under the supervision of NDA. Appropirate faclities should be created in the identified institutions wherever necessary, to permit time-bound completion of individual projects.

(Chapter-III. Para 101)

(37) Public Sector should set an example in respect of R & D activity in the drugsfield and to begin with should set aside at least 5% of their net turn-over for this purpose.

(Chapter-III. Para 103)

(38) Public Sector should engage the indigenous engineering and designing units to meet their requirements of equipments, instruments and appliances of high precision.

(Chapter-III. Para 104)

(39) To achieve increased production of Antibiotics expeditiously high yielding strains of micro organism and the associated balancing technology should be allowed to be purchased as per conditions mentioned in para 105.

(Chapter-III. Para 105)

(40) Public sector units should be allowed to use the Patents/invention as permissible under Section 99 and 100 of the Patents Act 1970.

(Chapter-III. Para 106)

(41) Early steps should be taken, with a time-bound programme to expand capacities and also instal new capacities, wherever necessary, to enable the Public Sector to fulfil the production obligations as recommended by this Committee.

(Chapter-III. Para 107)

(42) Wherever possible Public Sector units should also produce bulk intermediates.

(Chapter-III, Para 108)

(43) Additional formulation units should be set up in the country immediately. M/s. Smith Sanistreet, which is presently managed by IDPL should be taken over by IDPL and strengthened and converted into a modern pharmaceutical unit.

(Chapter-III. Para 109)

(44) Distribution systems in the Public Sector should make use of unconventional agencies such as Primary Health Centres, Panchayats-Dispensaries, Post Offices, Petrol and Kerosene Sales Depots, etc. for the distribution of house-hold remedies. There is need to evolve a wide distribution system suited to our own socio-economic, ecological conditions.

(Chapter-III. Para 110)

(45) All pharmaceutical units in the Public Sector should have strong Boards of Directors as indicated in para 111.

(Chapter-III. Para 111)

ADDITIONAL RECOMMENDATIONS AND SUGGESTIONS

(1) Items which are part of the approved production programme of public sector units or items in respect of which public sector has the capacity to produce should ordinarily not be licensed to private sector units. However, in order to ensure that such a reservation of items does not result in shortages, or increased need for imports, an annual implementation programme should be drawn up in the first quarter of the calender year. This programme will have to be kept under review; and on the basis of such a review twice a year, appropriate adjustments should be made in the items to be licenced to units outside the public sector.

(2) Capital requirement for achieving the targetted figures for 1978-79 both for bulk and formulation (60 % of bulk) production of antibiotics is estimated at Rs. 15 crores in terms of 1973 prices .

(3) The Public sector may farm out to the purely Indian sector, particularly the units run by technocrat entrepreneurs, its needs for relatively low-cost tonnage intermediates. And, for this public sector should accept the responsibility to provide the basic technology to the entrepreneurs.

(4) The public sector should be so planned that its constituent units for bulk production of basic drugs and their intermediates are set up in different parts of the country subject to the desirability of centralizing single-raw material or single/similar technology line products at one place for reasons of economy; the choice of the site for a unit being dictated only by economic compatibilities.

(5) The State Governments and the Government of India should obtain all the governmental and corporation needs of such of the drugs as are produced in the public sector from this sector at prices that may be fixed by a body of cost accountants, in consultation with the concerned public sector unit and the BICP. The ruling principle for determination of prices should be that the drugs must reach the largest number of people and profitability should be limited only to ensure progressive growth of the industry for meeting the increasing needs of the nation, with its own resources.

(6) The existing public sector units should consolidate their technological gains and give first priority to the expansion of production of the items for which they have the necessary know-how skills. The magnitude of this expansion should be limited only by the magnitude of the estimated national needs in the next ten years. Simultaneously efforts must be made to improve, by innovation, the technologie or such other products as may already be within the production programmes of the public sector units and for which the present technologies need improvement.

(7) Urgent steps should be taken to ensure employment of competent technologist and management experts and provide necessary in-job training facilities for different cadres.

Constant appraisal and updating of the economics of in-plant operations as also of management procedures and practices and speedy implementation of improvements, as and when these occur, should be assured at both the plant and management levels.

(8) In respect of the import of technologies concurrent purchase of equipment should be avoided. In every case of import of technology, the R & D units of the industry, and their collaborators should be associated from the very beginning. This would ensure that sophistication from the stage of import upwards may be brought about indigenously. Each imported technology should be freely available to all the relevant public and Indian sector units.

ANNEXURE I

RECOMMENDATIONS OF NATIONAL COMMITTEE ON SCIENCE AND TECHNOLOGY ON CULTIVATION OF MEDICINAL/INSECTICIDAL PLANTS

(Chapter III—Para 29)

Name	Estimated demand		Present production		Present imports		Land needed for cultivation (ha.)
	Plant part (tonnes)	Product	Total Plant (tonnes)	Active material (tonnes)	Quantity (tonnes)	Cost (lakhs)	
1	2	3	4	5	6	7	8
1. Chrysanthamum (Cinararifolium)	300	3T	25	20	NA	3.5 (1965)	1000
2. Dioscorea species	500	25T	250	8	0	0	400
3. Atropa belladone & A. acuminate	70	800 Kg.	10	—	NA	NA	200
4. Claviceps purpurea	25	500 Kg.	Experimental	—	7	15.1	600
5. Glycyrrhiza	1000	5	—	—	—	14	1200
6. Cephaelis epecacuanha	8–10	600 Kg.	—	—	—	—	NA
7. Papaver somniferum	2500	3000 Kg.	—	—	2.0	7.17	1000
							4400

ANNEXURE II

LICENCED CAPACITY, PRODUCTION AND IMPORT OF ESSENTIAL ANTIBIOTICS

(Chapter III - Para 34)

Sl. No	Name of the antibiotics	Unit	Licenced capacity as on 1-12-74	Production		Imports				Estimated Demand	
				1972	1973	1972-73 Qty.	Value in Rs. lakhs	1973-74 Qty.	Value In Rs. lakhs	1978-79	1983-84
1.	Penicillin	MMU	364.0	230.15	274.52	9.9	12.0	0.5	0.7	780.0	1560.0
2.	Streptomycin	Tonnes	257.0	199.11	179.85	99.2	137.0	51.9	63.4	825.0	1650.0
3.	Tetracyclines	"	148.5	73.30	90.27	22.0	90.1	54.2	74.2	303.0	556.0
4.	Chloramphenicol	,,	108.8	41.06	47.19	102.0	141.0	64.9	86.5	390.0	780.0

ANNEXURE IV

Comparative Production of I.D.P.L. during the year October 1973 and October 1974.

(Chapter III— Para 43)

Sl. No.	Product	Unit	Production of IDPL Nov. '72 Oct. '73	Nov. '73 Oct. '74
1	2	3	4	5
1.	Penicillin	MMU	65.22	63.65
2.	Streptomycin	Tonnes	38.69	46.23
3.	Tetracyclins.	Tonnes	22.11	39.60

ANNEXURE V

Manufacture of Sera Vaccines

(Chapter III—Para 52)

Manufacturing Units—

(a) Government Units	(b) Private Sector Units.
(1)	(2)
1. Central Research Institute, Kasauli.	1. Biological Evans.
2. Haffkin Institute, Bombay.	2. Glaxo Laboratories.
3. Pasteur Institute, Shillong	3. Bengal Immunity.
4. Bovincial Hygiene Institute, Lucknow (U.P.)	4. Curewell.
5. Vaccine Institute, Belgaum.	5. B.C P.W.
6. Vaccine Depot, Shillong.	6. Chowgule.
7. Govt. Vaccine Depot, U.P.	7. Duphar-Interfran.
8. M.P. Institute, Nagpur.	8. South India Research Institute Pvt. Ltd.
9. Public Health Lab. Travancore-Cochin.	*9. Vaccine Institute, Baroda (S.S.).
10. Vaccine Institute and Lab. Calcutta.	*10. Serum Institute of India, Poona.
11. King Institute, Guindy.	11. Vaccine Institute, Nagpur.
12. Vaccine Institute, Bangalore.	*12. West Bengal Vaccine Institute, Calcutta.
13. Vaccine Institute, Namkarim*	
14. Public Health Central Labs.,* Hyderabad.	
15. Public Health Institute, Bangalore.	*to be added to Govt. Sector.
16. Lymph Depot, Gwalior.	
17. Pasteur Institute, Coonoor.	
18. Drug Research Lab., Jammu.	

Types	Actual Production (1972)	Targets (fifth Plan) (1978-79)
(1)	(2)	(3)
Diptheria AT	894 Mega Units.	4000 Mega Units
Tetanus AT	16091 Mega Units.	30000 Mega Units.
DTP (Triple Antigen)	N.A.	20 M. doses
BCG. Vaccine	N.A.	66 M. doses
Polio Vaccine	N.A.	20 M. doses
Tetanus Toxiod	N.A.	32 M. doses

ANNEXURE VI

Details regarding the Licence capacities, Production in 1973 in Public Sector and the targets suggested by the Task Force.
(Chapter III—Para 62)

(In Tonnes)

Sl. No.	Name of the Product	Original Licenced capacity	Present Licenced capacity as on 31-3-74	Letter of Intent for addition capacity/ Expansion	Production in 1973	Demand Target by 1978-79	Demand Target by 1983--84
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1.	Amidopyrine	40	40	—	2.86	20	40
2.	Analgin	10	160	240	186.72	400	800
3.	Phenacetin	100	350	50	85	500	800
4.	Piperazine salts	50	50	65	66.53	118	230
5.	Diethyl Carbamazine Citrate	30	30	—	—	45	95
6.	Isoniazid	20	20	—	—	265	530
7.	Acetazolamide	25	25	—	—	—	—
8.	Phenobarbitone and Sodium salt	10	15	15	9.18	34	70
9.	Sulphacetamide and Sodium salt	50	50	30	0.80	80	160
10.	Sulphadimidine and Soidum salt	280	500	500	328.81	1010	2020
11.	Sulphaguanidine	130	250	—	265.97	133	145
12.	Sulphanilamide	50	150	—	71.83	—	—
13.	Folic acid	1	3.5	4	2.12	7.5	15
14.	Nicotinamide	20	20	—	14.92	600	1200
15.	Vitamin B1 and derivative	30	60	60	27.39	100	200
16.	Vitamin B2 and derivative	5	15	9	1.21	24	48
17.	Paracetamol	—	85	—	—	400	800
18.	PAS and its salts	—	150	250	135.90	1000	1200
19.	Sulphamethizole	—	5	7	1.26	12	23
20.	Sulphacetamide Phthalyl	1	10	—	1.41	—	—
21.	Allopurinol	—	—	2	—	—	—

1	2	3	4	5	6	7
22	Thiacetazone.	..	..	5	8.71	70
23	Deallyl barbitone	..	..	10	..	..
24	Secobarbitone	..	..	10	..	20
25	Sulphadimethoxine	..	..	30	..	30
26	Sulphaphenazole	..	..	50	..	180
27	Pyridoxine Hcl	..	..	50	..	50
28	Nitrofurantoin	..	..	10	..	45
29	Nitrofurazone	..	..	1	..	..
	Total	851	1988.5	1398	1212.52	5143.5

ANNEXURE VII

Licensed Capacity, Production, Imports and Targets of essential Synthetic Drugs

(Chapter III—Para 65)

(Qty. in Tonnes)

Sl. No.	Item	Licenced capacity as on Nov '74	Total Production in 1973	Production in Public Sector	Total Imports 1972-73	Estimated Targets 1978-79	1983-84
1	2	3	4	5	6	7	8
1.	Acetyl Salicylic Acid	1360	821.82	..	..	1900	3800
2.	Analgin	160	136.72	136.72	142.69	400	800
3.	Adrenaline	0.048	0.015	..	0.021	0.096	0.190
4.	Halogenated-8-Hydroxy Quinoline	427.4	10.50	..	..	450	600
5.	Chlorpheniramine	6.0	..	..	1.81	16	32
6.	Chlorpromazine	2.5	2.73	..	0.05	12	24
7.	Calcium-pentothenate*	5.0	0.60	..	19.20	60	90
8.	Chloroquin saltes	40	15.20	..	99.33	150	225
9.	Dapsone	17.7	8.16	..	..	30	50
10.	Ephedrine Hydrochloride	18	4.47	..	3.69	49	90
11.	Fursemide	1.2	0.17	..	1.29	3.5	7.0
12.	Hydrochlorthiazide*	5.50	.63	..	0.064	40	80
13.	Isoniazid	293.5	96.51	..	1.3	264	530
14.	Lignocaine Hcl	3.0	4.22	..	Nil	14	30
15.	Methyl salicyate	250	195.0	..	N.A	N.A	N.A
16.	Mephenteramine Sulphate	3.6	1.7	..	..	0.2	0.4
17.	Metronidazole	4.6	7.67	..	16.25	50	100
18.	Nitrofurantoin	12.0	..	..	N.A	45	90
19.	Nitrofurazone	4	..	..	N A	N A	N A
20.	Nicotinamide	224.3@	85.31	14.92	22.16	600*	1200@
21.	Oxytocin	..	..	..	N.A.	240MMU	480MMU
22.	Pethidine	0.75	0.24	..	0.28	1.2	2.4
23.	Par	331.0	18.62	..	..	400	800
24.	Phthalyl Sulphathiazole	3.5	..	..	83.21	150	280
25.	Piperazine & Salts	50	66.53	66.53	12.10	118	230
26.	Para-amino-salicylic acid (Sodium)(PAS)	780	498.27	135.90	..	1000	2000
27.	Primaquin Diphosphate	..	..	..	0.12	1.5	2.5
28.	Phenobarbitone & its Sodium Salt	15	9.18	9.18	5.88	34	70
29.	Pyridoxine Hydrochloride	..	..	..	14.25	50	100
30.	Sulphadimidine & Sodium Salt	500**	328.85	328.81	124.00	1010	2020
31.	Sulphacetamide & its Salt	68	6.50	0.80	..	80	1600
32.	Succinyl Choline Chloride	0.005	0.053	..	N.A.	N.A.	N.A.
33.	Tolbutamide	77.1	57.67	..	6.20	75	100
34.	Thiacetazone	122.6	35.16	8.71	..	70	140
35.	Theophylline	31.4	..	..	15.00	60	120
36.	Aminophylmine						
37	Thiopontal Sodium	..	..	..	1	5	10
38.	Vitamin B1 & derivatives	60.00	27.39	27.39	14.21	100	200

1	2	3	4	5	6	7
39.	Vitamin B2 & Derivatives	15.00	1.21	1.21	5.1[illegible]	24
40.	Vitamin C	370.00	261.58	..	218.09	900
41.	Vitamin D2/D3 (Calciferol)	1.0	0.076	..	1.17	1.0
42.	Folic Acid	3.5	2.12	2.12	..	7.5
43.	Diethyl Carbamazine Citrate	56.0	7.65	..	..	45
44.	Nor-adrenaline	N.A.	N.A.	..		0.012

*Includes capacity and production of Panthenol and Pantothenates.

† Includes capacity of Chlorthiazide also.

@This includes Capacity of Nicotinic Acid also.

**Some non-specificcapacity with private companies.

ANNEXURE VIII

Essential Synthetic Drugs not yet produced in the country

(Chapter III—Para 72)

Sl. No.	Name of the Product	Unit (Tonnes)	Imports		Estimated Targets		Letter of Intent with I.D. P.L.
			1972-73	1973-74	1975-76	1983-84	
1.	Nitrofurantoin	Tonnes	N.A.	N.A.	45.0	90.0	10.0
2.	Nitrofurazone	,,	N.A.	N.A.	N.A.	N.A.	1.0
3.	Fursemide	,,	1.3	1.4	3.5		10.0
4.	Pyridoxine Hcl.	,,	14.3	23.8	50.0	10.0	50.0*
5.	Theophylline	,,	15.0	N.A.	60.0**	120.0**	250.0**
6.	Phthalyl Sulphathiazole	,,	82.3	122.0	150.0	290.0	100.0†
7.	Aminophylline	,,	18.9	14.6	**	**	**
8.	Calcium Pantothenate	,,	19.2*	26.0*	60.0	90.0	40.0

*Includes both calcium and sodium-pantothenates.

**Includes Aminophylline also.

†Includes Caffeine and Aminophylline also.

ANNEXURE IX

Additional Capacity proposed, in respect of essential drugs for Public Sector

(In Tonnes)

Product	Total licensed capacity 1973	Production 1973	Target requirement for 1978-79	Proposed additional capacity in public sector
1	2	3	4	5
1. Analgin	160	137	400	240
2. Sulfadimidine	500	329	1000	500
3. Vitamin B1	60	27	100	40
4. Vitamin B2	15	1.2	24	9
5. Folic Acid	3.5	2.12	7.5	4.0
6. Phenobarditone	15.0	9.2	34	19
7. Piperazine	50.0	67	118	68
	803.5	572.52	1683.5	880.0
8. Nicotinamide	224	85.3	600	226
9. Paracetamool	331	18.66	400	41
10. PAS	780	498.3	1000	132
11. Sulfacetamide	68	6.5	80	7
	1403.0	608.7	2080	40
12. Nitrofurantoin	12	..	45	3.
13. Nitrofurazone	4	..	10	
14. Fursemide	1.2	0.17	3.5	2.
15. Pyridoxine HCl.	..	..	50	6(
16. Theophylline 17. Aminophylline	31.4	..	60	28.
18. Phthalyl Sulphathiazole	3.5	0.60	150	146.
19. Calcium Pantothenate	5.0	0.60	60.0	55.(
	57.1	0.77	378.5	321.
20. Metronidazole	4.6	7.7	50	45.
21. Chloroquin	40.0	15.2	150	110
22. Halogenated-8-oxyquinolines	427.4	100.5	450	22
23. Acetyl salicylic acid	1360	822	1900	5
24. Pethidine	0.75	0.24	1.2	0.
25. Vitamin C	370	262	900	53
26. Primaquin	..	..	1.5	1.

1	2	3	4	5
27. Chlorpromazine	2.5	2.75	[illegible]	[illegible]
28. Succinylcholine chloride	0.005	..	.	.
29. Thiopental	..	..	.	.
30. Adrenaline	0.048	0.015	0	0.015
31. Nor-adrenaline	..	..	0.012	0.012
32. Oxytocin	..	..	240 mu	240 mu
33. Chlorpheneramine maleate	6.0	..	16	10
34. Hydrochlorthiazide	5.5*	0.63	40	34.5
	2216.8	1211.0	3524.6 +240mu of Oxytocin	1307.0 +240mu of Oxytocin

*Includes capacity of Chlorthiazide also.

CHAPTER IV

NATIONAL DRUG AUTHORITY OF INDIA

The Committee believes that health care has direct relationship with the socio-economic growth of the cou and a welfare state should treat production, procurement, and distribution of essential drugs, as a social responsib just as important as ensuring supply of food and shelter.

With a view to tackling the problem of large scale production and distribution of drugs, the Committee commends the creation of a statutory body which may be called the National Drug Authority of India (N.D.A

The N.D.A. should perform the following functions :—

(1) Continuously assess national needs for essential drugs in the context of diseases prevalent in the coun

(2) Plan, programme, co-ordinate and monitor the production of all essential bulk drugs and their formulati and lay down the relevant priorities ;

(3) Plan, co-ordinate and allocate production responsibilities to identified individual units in respect of b drug production and formulations;

(4) Plan, procure and allocate all raw materials, intermediates and accessories either through indigen production or by local purchase or by import, where necessary. N.D.A. should evolve a workable procedure purchase/import of drugs in consultation with concerned agencies.

(5) Allocate production responsibilities to identified individual units for all raw materials, intermediates a accessories including equipment required for drug production.

(6) Centrally import, where necessary, bulk drugs, intermediates, raw materials, equipment and accessories a distribute these to the concerned units of the industry.

(7) Evolve and implement economic distribution system for all essential drugs and formulations produced the country or imported, making use of workers in primary health centres, post offices and after public distribut agencies particularly for identified household remedies.

(8) Recommend price maxima in consultation with the Bureau of Industrial Costs and Prices (B.I.C.P.).

(9) Plan, allocate priorities and co-ordinate R & D activities by integrating all R & D facilities in men a materials that may be available at State units, State sponsored autonomous laboratories, the relevant laborato of research agencies supported by public funds e.g. Council of Scientific and Industrial Research (CSIR), Indi Council of Medical Research (ICMR), Indian Council of Agricultural Research (ICAR) ; etc., Universities, Indi Institutes of Technology and other institutions, and encourage all these units and laboratories in all possible ways providing additional facilities, where necessary, to carry out time-bound R & D programmes, giving highest prior to process innovation and upgrading of technology.

(10) Pool all available resources, facilities in men and materials by mobilising the industrial scientists an technical experts, the national institutions and other laboratories by statute, if necessary.

(11) Any new drugs, or process innovations evolved, in any one of the institutions mentioned above shall l the property of N.D.A. and should be made available to the identified units of the industry for their exploitatio

(12) Establish an upto-date data bank for technologies, Patents, R & D information etc., and act as a doc mentation centre and provide all relevant information to the different units of the industry.

(13) Act as sole importer of any technology, that may need to be imported, and ensure its distribution to t participating unit/units.

(14) Ensure horizontal transfer of technology already available within the country and such technologies a may be developed/imported in future.

15) Carry out continuous and systematic analysis of the relevant data to formulate policies necessary for implementing the above recommendations.

In order to discharge the above and such other functions as may be relevant to the implementation of the basic philosophy of socialising drug production and distribution, the N.D.A. should be free from day-to-day governmental interference and should have the powers to function without operational constraints.

Composition : The N.D.A. should have a Governing Board consisting of two Members of Parliament, one expert each on commercial finance and business managements, two eminent technologists, a scientist, a social scientist, a marketing expert, a labour leader and 3-5 representatives of the public and Indian private sector industry. It should have a full time Chairman who should be of the rank of Secretary to the Government of India with such powers as may be necessary to ensure economic and efficient functioning of the organisation. He should be of proven ability as an eminent technologist or a technologist-cum-management expert with wide operational experience and social commitment.

Finances : The N.D.A. should be funded by a cess of 2% levy on total value of sales of all units of the industry. This 2% cess will be on par with excise duty, except for the fact that it will be earmarked for N.D.A. only. The sum of money so collected should take care of (i) the legitimate expenditure of the organisation excluding expenditure involved in business, transactions such as distribution of raw materials, intermediates, bulk drugs and formulations etc., which will be self-financing, (ii) R & D expenditure barring that incurred in individual units of the industry, (iii) upgrading of drug standardisation systems at the centre and in the states and (iv) setting up and maintenance of a central toxicological laboratory for the Central Drug Control Authority.

CHAPTER—V

DEVELOPMENT OF THE DRUG INDUSTRY AND THE INDIAN SECTOR

The Committee has discussed in this chapter the third term of reference which calls for recommendations for promoting the rapid growth of the drugs industry particularly of the Indian and small scale sectors of the industry taking into account the need for a balanced dispersal of the industry. Examination of this term of reference in correct perspective would be greatly facilited if the historical developmentof the drug industry in the country is studied and the current status of the various sectors of the industry, namely, the foreign sector (unit with any measure of foreign equity) and the Indian sector including the small-scale sector indentified. It also requires to be considered what the expectations of government were in the context of its various Policy Resolutions on the development of the drug industry, the extent to which achievements in this field conform to the expectations of Government and the imbalances or distortions that have crept into the growth of the industry either because of loopholes in the policies or their defective implementation.

2. Two decades ago, a limited number of Indian companies were manufacturing conventional drugs such as tinctures and other spirituous preparations, sera and vaccines etc. Synthetic drugs, antibiotics and steroids were introduced into this country after the Second World War. It is worth recailing how within a few years after the country became independent, foreign companies built up substantial business in this country.

3. Shortly after India became independent, most of the leading multi-national drug companies established themselves as trading concerns. Their initial investments were insignificant compared to their turnover. They started by importing the finished drug formulations and marketing them. Subsequently, they imported the formulations in bulk and got them repacked in this country. Under pressure from Government, as a next stage, they imported the formulations in bulk drugs and got them processed into formulations on a "job-work" basis by Indian companies. All these activities were carried on without investing in factories or employing technical personnel. Thus, foreign companies could remit substantial profits and build up large reserves and assets within the country for subsequent use or investment. Annexure I indicates the initial investment of foreign companies in this country and how these investments, within a comparatively short period, multiplied several fold.

4. Between 1952 and 1965 and even up to 1968, well-known multinational units and a few Indian units operating in this country received a big impetus to boost their turnover in the shape of "Permission Letters" 364 items were permitted to be manufactured by 15 leading foreign units. Four of these items were bulk drugs and the remaining 360 items were formulations, many of which could have been easily manufactured by the Indian sector. These formulations included house-hold remedies such as formulations containing vitamins and minerals, many of which did not require a doctor's prescription, cough mixtures, ring worm ointments, 'health salts', 'gripe mixtures', laxative tablets, eye drops, malted tonics, digestive tablets, ointments for burns and piles, tonics containing calcium, alcohol based tonics, etc. Annexure II makes interesting reading in this connection.

5. In 1965, the Government of India announced certain liberalisation of its licensing policies in respect of all industries, including drugs and pharmaceuticals, in order to overcome the shortages which were developing. Subsequently, after devaluation of the rupee and the liberlisation of import policy, two further notifications were issued—one in 1966 and the other in 1967—Permitting manufacturers to diversify production into the manufacture of 'new articles', and to expand production of licensed or registered capacities up to 25% without any amendment to the licences under the Industries (Development and Regulation) Act. This was, however, subject to the condition that no additional plant and machinery, other than balancing equipment procured indigenously, was installed. The application of this policy in respect of all the industries including the drugs and pharmaceuticals, was, however, reviewed in 1970, because it was felt that under the policy permitting diversification, foreign units and these belonging to large houses were likely to expand their activities in contravention of Government's policies. The concession of permitting diversification had, therefore, to be withdrawn, and such diversification as had taken place prior to that date, was required to be regularised by specific applications for "Carrying-on-business" licences (COB Licences). in the context of this new procedure, 12 foreign companies and 5 Indian companies obtained COB licences which cover 215 formulations and 20 bulk drugs. Some of the tonics and house-hold remedies which command a wide sale and which were marketed as a result of C.O.B. licences are : Santevini, Vidayalin, Surbex Becade Trox, etc. 'Valium' and 'Librium', the two largest-selling tranquillizers in the world, marketed by Roche were also included in the C.O.B. licences. The details are given in Annexure III.

6. The advent of the public sector undertakings marked an important milestone in the development of the drug-industry. Hindustan Antibiotics Limited and the Indian Drugs and Pharmaceuticals Limited together had an investment outlay of about Rs. 56 crores. The fields they ventured into were antibiotics and bulk synthetic drugs which are essential and required in large quantities. Yet, the growth of the influence of the foreign sector on drugs and pharmaceuticals market could not be deterred.

7. Thus, within a period of twenty years, multi-national Companies attained a position of dominance in the drug industry. Their success could be partly attributed to the antibiotics and synthetic drugs which they introduced in the market. The Patent law concerning drugs prevented Indian Companies from entering into the field of synthetic drugs. Multi-national companies had an extremely favourable climate in this country when they commenced operations. They managed for a good length of time with a meagre capital investment, pushed up the sales of their products remitted profits to their principals abroad and built up substantial reserves. Governments' policy permitted payment of royalty even on drug formulations. Whatever basic drugs they manufactured were mostly utilised for captive consumption. High prices were maintained for their drugs for several years. Added to this, money-spinning tonics and household remedies which they could market on the basis of "Permission Letters" and "COB Licences" swelled their profits. By the time, Indian companies, particularly those in the western region, braced themselves up to the situation and introduced competitive products, the sales promotion machinery of foreign companies was streamlined and perfected. High pressure sales techniques coupled with distribution of medical samples on a liberal scale to the medical profession was their forte. Attractively get-up medical literature and international brand names of drugs appearing in advertisements in foreign medical journals with which top consultants in the medical profession were acquainted, played their part in popularising the drugs of foreign companies Large sums of money were spent by foreign companies in systematically training their "medical detailers" and the general tone of detailing resorted to by them was that their products contained "something plus" over products with identical composition marketed by Indian units and that the edge in their quality was the outcome of their superior expertise and international standing.

8. In contrast, Indian companies were swept off their feet by the new range of drugs introduced by foreign companies. When the medical profession fell in for such drugs and discarded the coventional drugs which were in use till then, the Indian sector of the industry took time to gear itself to the changed pattern. M/s. Standard Pharmaceuticals in Calcutta and M/s. Alembic Chemical Works Ltd. were the only two Indian companies, outside the public-sector units which evinced interest in production of penicilline and other antibiotics. A few units in West Bengal embarked on manufacture of synthetic drugs for treatment of tuberculosis, leprosy, malaria, diabeties etc. These products which were manufactured from basic or near-basic stage, did not make much headway in the market compared to the same products marketed by foreign companies, partly because the latter were produced from late-stage intermediates but mainly because the rapport between the Indian companies and the medical profession was tenuous and ineffective. Besides, the medical services were not geared to serve the sections affected by these diseases and suitable distribution mechanics were not evolved.

9. In so far as technology was concerned, it was only available with the multi-national companies operating in India and it was difficult for Indian companies to obtain the technology. Also, in general, multi-national companies operating in different countries tended to make it difficult for Indian manufacturers to obtain the technology of the products developed by them. The resource position of Indian companies in terms of finance and other facilities was no match for that of foreign units. But more than resources and products, it was the management policy, the high streamlined recruitment and training procedures for medical detailers, the aura of super-expertise that was created, the techniques employed by foreign companies to persuade doctors to prescribe their drugs and the meticulous cost and economic studies of all operations carried out by them that beat the Indian companies completely and left them far behind in the race. While a limited number of Indian companies in some parts of the country succeeded in copyiny the methods of foreign companies and establishing themsleves fairly successfully, by and large, Indian manufacturers still lag behind considerably in the fields of professional management systems and methods marketing and finance. On an all-India basis, Indian companies have not been able to make an organised effort to win the sustained support of the medical profession for their products.

10. Government's Industrial Policy Resoultion which was announced on April 30, 1956 includes "Antibiotics and other essential drugs" in Schedule B attached to it. In regard to the Industries covered by this Schedule, the policy made it clear that with a view to accelerating their future development, the State will increasingly establish new undertakings in these industries and that at the same time private enterprise will also have the opportunity to develop in this field, either on its own or with State participation. Subsequent policy changes announced in July, 1965 and 27th October, 1966 permitted drug units to diversify up to 25% of their licensed/registered capacity (by value) subject to certain conditions. In February 1970 Government made certain changes in the licensing Policy on the basis of the recommendations made by the Industrial licensing Policy Inquiry Committee, the Administrative Reforms Commission and the Planning Commission. Measures to regulate the licensing of foreign firms and larger Industrial Houses were taken. A Press Note issued on 18th February, 1970 states :—

"In the middle sector, involving investments ranging from Rs. 1 crore to Rs. 5 crores, licence applications of parties other than undertakings belonging to the larger Industrial Houses shall be given special consideration and shall be issued liberally, except where foreign exchange implications necessitate careful scrutiny. Licence

applications from undertakings belonging to or controlled by the Larger Industrial Groups and foreign branch subsidiaries, shall be considered for normal expansion, where such expansion is necessary to develop to minimum economic level which would ensure greater cost efficiency. The provisions of the Monopolies a Restrictive Trade Practices Act will be taken into account".

11. The Government also revised the diversification policy of 1966 in July, 1970. This ploicy prohibi foreign firms from effecting diversification without an Industrial Licence and also stipulated that C.O.B. licen should be obtained in cases where diversification was effected earlier on the basis of 1956 policy.

12. A Press Note issued by Government on July, 21, 1971 explained that the "Liberalised Industrial Licen Policy" announced by Government sought to strike a balance between the requirement of accelarated indust growth and encouragement of small and medium entrepreneurs on the one hand and the need to prevent conc tration of economic power in the hands of few large business groups on the other. In January, 1972, Indian fi were permitted by Government to increase their licensed capacities on the basis of maximum utilisation of plant a machinery and diversify up to 100%. The Press Note issued on February 2, 1973 sums up Central Governme basic philosphy on the development of the drugs industry (and other industries), taking into account the gro priorities envisaged under the Fifth Five Year Plan. We reproduce below the relevant portions from the Press N which need to be highlighted for the purpose of our discussions in this Chapter :—

"Government have carefully reviewed their policies relating to industrial development in the light of experience gained in the implementation of the Industrial Licensing Policy of 18 February 1970 and in context of the approach to the Fifth Five Year Plan. The Industrial Policy Resolution of 1956 has laid dc the basic principles that govern Government's approach towards industrial development. These princ have been derived from the Directive Principles of State Policy contained in the Constitution and from adoption by Parliament in December 1954 of the socialist pattern of society as the objective of social and ec mic policy. The Industrial Policy Resolution of 1956 will continue to govern Goverrment's policies for ac ving the objectives of growth, social justice and self-reliance in the industrial sphere.

Role of Public Sector

2. As pointed out in the Industrial Policy Resolution the adoption of the socialist pattern of society as national objective, as well as the need for planned and rapid development, requires that all industries of basic strategic importance, or in the nature of public utility services, should be in the public sector. Other industries wh are essential and require investment on a scale which only the State, in the present circumstances could provide, h also to be in the public sector. In the context of the approach to the Fifth Five Year Plan, the State will have take direct responsibility for the future development of industries over a wide field in order to promote the cardi objectives of growth, social justice, self-reliance and satisfaction of basic minimum needs.

Licensing Policy

3. ** ** **

4. ** ** **

5. Government consider it desirable to consolidate the list of industries which are opened, along with oth applicants, for the participation of larger industrial houses (as defined in the MRTP Act). In the context of approach to the Fifth Plan, the core industries of importance to the national economy in the future, industries hav direct linkages with such core industries, and industries with long term export potential are all of basic, critical a strategic importance for the growth of the conomy. A consolidated list of such industries is attached in Appendi Such of the industries included in Scheduled A of the Industrial Policy Resolution 1956 will be reserved for the pu sector. Larger houses will be eligible to participate in and contribute to the establishment of industries in the included in Appendix I along with other applicants, provided that the item of manufacture is not one that is res for production in the public sector or in the small-scale sector. They will ordinarily be excluded from the indust not included in this list except where, as is permitted under existing arrangements, production is predominantly exports.

6. Foreign concerns and subsidiaries and branches of foreign companies will be eligible to participate ir industries specified in Appendix I along with other applicants but will ordinarily be excluded from the industries included in this list. They will also be entitled as at present to invest in industries where production is predomina for exports. Their investments will be subject as higtherto to the "guidelines on the dilution of foreign equity". will be examined with special reference to technological aspects, export possibilities and the over-all effect on balance of payments.

Small-scale and Cooperative Sectors

7. In the implementation of the licensing policy, Government will ensure that licensing decisions conform to growth profile of the Plan and that techno-economic and social considerations such as economics of scale appropr technology, balanced regional development and development of backward areas are fully reflected. Governme

policy will continue to be to encourage competent small and medium entrepreneurs in all industries including those listed in Appendix I. Such entrepreneurs will be preferred *vis-a-vis* the larger industrial houses and foreign companies, in the setting up of new capacity. Licensing policy will seek to promote production of ancilaries, wherever feasible and appropriate, in the medium or small-scale sector, cooperatives and small and medium entrepreneurs will be encouraged to participate in the production of mass consumption goods with the pubik sector also taking an increasing role. Other investors will be allowed to participate in the production of mass consumption goods only if there are special factors such as sizable economies of scale resulting in reduced prices, technological improvements, large investment requirements, substaintial export possibilities or as part of modernisation. Government also intend to enalarge and intensify a vareity of positive measures deisgned to promote the growth of small and medium entrepreneurs.

8. ** ** **

9. The existing policy of reservation for the small-scale sector involving investment in machinery and equipment up to Rs. 7.5 lakhs, and in the case of anacillary industries up to Rs. 10 lakhs will be continued. The area of such reservation will be extended consistent with potentialities and performance of the small-scale sector. The policy of encouragement to the cooperative sector will receive special emphasis in industries which process agricultural raw materials such as sugarcane, jute cotton or produce agricultural inputs such as fertilisers. The cooperative sector is also ideally suited for the manufacture and distribution of mass consumption goods.

Joint Sector

10. Government's policy regarding the joint sector is derived from the Industrial Policy Resolution 1956 and the objective of reducing the concentration of economic power. In appropriate cases, the Central and State Governments have taken equity participation either directly or through their Corporations with private parties. Some joint sector units have come up in any way. This type of joint sector unit is a device which may be resorted to in specific cases having regard to the production targets of the Plan. Each proposal for establishing a joint sector unit of this nature will have to be judged and decided on its merits in the light of Government's social and economic objectives. The Joint sector will also be a promotional instrument, as for instance, in cases where State Governments go into partnership with new and medium entrepreneurs in order to guide them in developing a priority industry."

13. It is now worth considering whether the drug industry, as it has now emerged, is in conformity with the requirements of the country. The fact that the drug industry has made phenomenal progress within the last two decades cannot be gainsaid. In 1947, drug production was of the value of Rs. 10 crores. In 1973, the gross output is estimated to be of the order of Rs. 370 crores. The indigenous output ofbulk drugs is estimated at Rs. 75 crores. The publication of the Development Council for Drugs and Pharmaceuticals entitled "Indian Pharmaceuticals Industry 1973" sets out the range of bulk drugs a that is produced in the country together with their production capacity. The list of drugs set out in the publication is sufficiently imposing in the context of the development taking place in other countries. However, a critical appraisal of our achievements reveals many interesting facts. These facts, together with our observations, are set out below :—

(a) About 70% of the total sales turnover of drugs in the country, namely, Rs. 370 crores belongs to foreign sector. (Annexure-IV)

(b) Out of the total turnover of Rs. 370 crores, the value of tonics, house-hold remedies, vitamins and minerals etc. comes to about Rs. 70 crores.

(c) 27 years after independence, 10 firms with 100% foreign equity are operating in the country. Six of these are engaged solely in the manufacture of drug formulations. There are six branches of foreign companies operating in India and are engaged in the manufacture of bulk drugs and/or formulations. Their total turnover in 1973 was about Rs. 22 crores and their indivdual turnover ranged from Rs. 0.13 crores to Rs. 9.7 crores. According to a reply given in the Parliament, another firm M/s. C.E.Fulford has been operating without securing an industrial or C.O.B. licence and importing raw materials worth Rs. 42 lakhs for processing a single item, namely, gentamycein injection. An analysis of the drug companies holding foreign equity in issued capital is given below :—

Category	
100%	10
50–99%	24
40–50%	15
26–40%	11
Below 26%	6
TOTAL :	66

(d) The value of imports of bulk drugs, penultimates, intermediates and chemicals was about Rs. 35 cr during 1973-74.

(e) The total outflow of foreign exchange towards payment of royalty, technical fees and dividends du 1969 to 1973 is about Rs. 26 crores (Annexure V). This figure does not reflect the additional for exchange remittance that is implicit in purchases of bulk drugs, intermediates etc. by foreign compa in India at prices dictated by their foreign principals. These prices bear no relation to either the cos manufacture of the final products or international prices. In order to check these malpractices, Gov ment are now progressively canalizing the items wherever such cases are brought to light. Likewise, orts, a substantial portion of which is made by foreign companies in India to their principals abroad, often made at prices which are not quite favourable to the country. An interesting feature about rei ances made by foreign companies to their principals is that even today remittances towards 'Head Of expenses have to be permitted because of the operation of trading companies with 100% foreign intere

(f) Only 19 foreign Companies manufacture bulk drugs,. The rest have built up their turn-o on formulations, many of which are common-house-hold preparations which are advertised in lay press. Annexure VI shows the stages from which manufacture of bulk synthetic drugs is c ried out by foregin companies. A reply (Annexure VII) recently given by the Minister of Pet leum and Chemicals to a question raised in the Lok Sabha of the Parliament (Question N 2919 answered on 3-12-1974) indicated that few companies have made available any portion of th bulk drug production to others.

(g) Foreign companies manufactured in 1973 bulk drugs worth about Rs. 19 crores. The two pu sector units together produced bulk drugs of value of about Rs. 24 crores, while the Ind Sector of the industry including the small-scale sector was responsible for about Rs. 32 cro Manufacture of bulk synthetic drugs from late-stage intermediates imported by foreign compar from their principals at prices dictated by the latter would put the country to double loss on when the country imports late intermediates and secondly, when the profits accruing from t sale of the finished formulations are remitted abroad. Every rupee worth of bulk drugs would prode about Rs. 3 worth of formulations.

(h) Some multi-national units hold an almost mono-polistic position in this country in regard to the supply o life-saving drug formulations such as Methyldopa, Indomethacin, Furosemide, Prenylamine lactat gentamycin sulphate, diphenylhydantoin sodium etc. The Committee understands that the Ministry o Petroleum and Chemicals, perhaps with the intention of increaing production of bulk drugs in the count have laid down a working principle that no company (including its sister concerns) with a turnover i excess of Rupees two crores would be allowed to manufacture drug formulations unless it manufactur the related bulk drugs. Such a restriction, in the view of this Committee, has not only worked to the de triment of the Indian sector of the drug industry but also created shortages. Even today many foreig companies are importing mostly bulk drugs and processing them into formulations, though firms applyin today for formulation activity only are denied this facility. Manufacture of bulk drugs requires subs tantial financial outlay and takes time. If this condition continues to be imposed, the Indian companie which have the technological base and the know-how for the manufacture of formulations will suffer se rious set backs. The Committee recommends that this restriction should be removed and forign companie which process formulations from imported bulk drugs should be made to manufacture the bulk drug within a specified period. As regards the Indian sector of the industry, the Committee has recommended later on in this Chapter that a more liberal policy is necessary in order to encourgage the Indian compa nies to make their contribution to the production of bulk drugs and formulations.

(i) The initial investment made by foreign companies is insignificant compared to the volume of the turn-ove built up by them. The early part of this Chapter recounts how most of the foregin companies started a trading concerns, later imported drugs in bulk and processed them into formulations through other firm on a 'job work' basis, remitted profits to their principals and concomitantly built up reserved from which they subsequently established processing facilities of their own. Annexure I reveals that the capital issued on account of considerations other than cash and bonus shares consititutes a substanital proportion o the toal capital

(j) We had mentioned earlier that foreign companies built up their financial sinews and achieved the presen dominant position mainly through sale of formulations which were allowed to be manufactured by the through the issue of "Permission Letters" which continued up to 1968 and COB licences. The leg backing for "Permission Letters" under the Industries (Development & Regulations) Act, and the manne in which COB licences were secured by foreign companies were examined by this Committee through specially constituted Sub-Committee. The latter discussed with the officials in the Ministries connecte with the processing and issue of "Permission Letters" and "COB Licences" and also obtained clarification from the Secretaries of the Ministry of Petroleum and Chemicals, the Directorate General of Technic

Development and the Ministry of Industrial Development. The Committee's view is that "Permission Letters" do *not* have any legal backing in terms of the provisions of the Industries (Development and Regulations) Act *vide* Annexure VIII. Likewise, most of the companies which were granted C.O.B. licences did not inform the Directorate General of Technical Development of the particulars of their diversification activities, "including their revised manufacturing programmes and the new articles proposed to be manufactured and the value of the minor balancing plant, if any added by them" as required by governments' Press Note of October 27, 1966. The authorities concerned did not verify whether effective steps had been taken by the companies for the items covered by their C.O.B. applications. Permission Letters and C.O.B. licences have given undue advantage to foreign companies to the detriment of the Indian sector.

Shri S. S. Marathe, Dr. B. Shah, Dr. S. S. Gothoskar and Dr. P. R. Gupta have expressed their reservations on the interpretation and conclusions regarding COB Licences/Permission Letters. (Para j)

(k) On February 19, 1970 the policy permitting diversification and the exemptions granted under the Industries (Development & Regulations) Act were revoked by govenment. Foreign companies were specifically prevented from augmenting their production capacities. Annexure IX shows the extent to which these firms have contravened government notification. This fact is known to the Directorate General of Technical Development who receive production statistics from the companies and the Ministry of Petroleum and Chemicals. On directions from the Economic Sub-Committee of the Cabinet, it is understood that the contravening firms were disallowed raw materials needed for normal annual expansion. Foreign interests are compaigning for regularization of the excess capacities of production. Their views are that shortages of drugs would result otherwise and that the country's requirements are so enormous as to accommodate any production that Indian companies may achieve. The Indian sector of the industry has represented to this Committee that the public sector unit and the Indian firms which are in a position to take up the manufacture of most of the bulk drugs involved have not been approached by Government and that drugs such as Metronidazole have all along been manufactured from the penultimate stage intermediates. What the foregin firms are keen about is the processing of all the bulk drugs produced by them into formulations which they feel they are entitled to in terms of Ministry of Petroleum and Chemicals Notification No. 3(3)/65-Ch. III of 27th May, 1969. Lastly, the Indian sector argues that regularization of excess capacities will induce foreign undertakings to produce more in contravention of Government's policies in the hope that exess production will continue to be regularized so long as the country's reqirements of drugs remain unfulfilled. The Committee's view is that the long term objective of buliding up a self-reliant Indian sector of the drug industry should not be lost sight of, while at the same time any solution which is arrived at should be such as not to result in shortages of drugs. With this object in mind, the Committee has spelt out its views on how best the excess production capacities of foreign companies should be regularized later on in this chapter.

(l) Indian drugs manufacturers could be broadly classified into four categories; namely :—

(i) Those who have a small turn-over and are engaged only in the manufacture of simple house-hold remedies, such as, cough-syrups, fever tablets, "gripe-mixtures" for infants, ointments for colds or wounds etc. The number of manufactures under this class might exceed a thousand and their activities are confined to the district round about their locations or the States in which they operate.

(ii) Companies which concentrate exclusively on catering to government hospitals and other medical institutions against rate contracts.

(iii) A more progressively inclined category of manufacturers—about a couple of hundred in number—run by technically—competent enterepreneurs who manufacture a good range of pharmacopecial preparations used by hospitals and other medical institutions, supplemented by a range of good quality proprietary medicines. They may also be interested in the manufacture of basic drugs.

(iv) Companies which market newer drugs, operate a research establishment albeit on a moderate scale, manufacture bulk drugs and are engaged in export to limited extent. Units falling in this category have been able to develop sufficient financial resources and marketing organisation to withstand competition from multi-national concerns.

It is obvious that the categories at (i) and (ii) cannot survive long in the face of the aggressive and well-organised marketing techiniques employed by units falling within categores (iii) and (iv) and by the multi-national companies which market drugs under internationally—known brand names. Units under (ii) operate on bare margins of profits and are therefore compelled to cut on product development research and even on employment of adequately qualified technical personnel to supervise manufacturing and technical operations. These self-defeating practices will not sustain these companies for long unless they diversify their product-mix, adopt "Good manufacturing Practices", complete in the open market and develop the will and strength to survive and progress.

Companies falling under (iii) and (iv) consititute the backnone of the future drug industry in the country. government takes special interest in these Units and helps them they can play a useful role in the devel ment of the drug industry.

Quite a number of small-scale drug units have been receiving raw material licences for values which have relation to their turnover or status and are reported to have sold off the raw materials. Such malpractic have tarnished the image of the Indian sector of the industry.

(m) In a separate chapter in our Report, the Committee has pointed out how remiss most of the State Gover ments, barring a few States such as Maharashtra, Gujarat, Karnataka, Kerala and to a lesser extent We Bengal and Tamil Nadu, have been in enforcing stringently the quality control measures over drug manu facturers. In particular, pre-licensing inspections and ispection of manufacturing process have not be rigid in some States. This will have the effect of increasing the incidence of sub-standard drugs., Likewi in the absence of concertaed efforts between the police and the Drug Control Departments and witho the co-operation of the general public, the menace of adulterated drugs cannot be effectively tackele General laxity in enforcement of qulity control measure have adversely affected the interests of the India sector of the drug industry. The Committee also understands that the leaders of the foreign sector of th drug industry have been making statements that quality control over drugs can be maintained only b those firms which have organised research in a big way, thereby hinting obliquely that Indian firm which lag behind in financial resources may not be able to market quality drugs.

(n) In the field of drugs, it may not be so difficult to make a good formulation as it is to sell it. Neithe the dealer nor the patient has any choice of his own while supplying or purchasing drugs. There may b several good products of the same drug available in the market but the patient will perforce have to bu the drug prescribed by the doctor. In the course of our visit, members have had occasion to see severa well-organised Indian units, including some in the small-scale sector which have technical competenc to produce high quality drugs. The representation of these firms was that adequate Government suppor would enable them to fulfil the needs of the country. While Government's support for such undertaking is important, more vital is the need for the units themselves to maintain an effective "dialogue" with th medical profession regarding their products, which is absent today.

(o) A feature which the Committee specially noted was that Indian units, particularly the small and medium scale sectors have yet to appreciate more and more the importance of professional management, system and procedures, cost accounts and carefully worked out pricing policies. Many of them are ownd by persons who have had no bakground of drug manufacture and drug testing and who have not been con versant with the ethics of the profession. The prices of drugs produced are adjusted well below those of similar products produced by well-organised firms, without any consideration for the economics of operations. Ill-paid staff and ill-organised manufacturing facilities result in the lowering of quality control measures. The stolest for improvement and progress is totally absent.

(p) In regard to Patent provisions relating to drugs, the Committee was keen on ascertaining the impact of the Patent Act on the drug industry. Quite a number of the principals of multi-national units operating in this country, we were informed, asserted their patent rights over life-saving or essential drugs such as Chlo ramphenicol, Tolbutamide, Oxytetracycline, Metronidazole, etc., and proceeded legally against Indian and other concerns which tried to import the bulk drugs and process them into formulations. The Patent Act was amended in 1970 with the specific object of helping the Indian sector of the drug industry. The Committee was glad to know that young scientists in the country have now bestirred themselves and started producing bulk drugs. However, all applications for drug patents remain "frozen" in this country from 1963. This has created certain anomalies in the implementation of the 1970 Act according to which a "Licence of right" can be given only after three years of the sealing of patents. This means that unless a patent is sealed, no "Licence of right" can be given. The task of examining the "frozen" patent applications and sealing the patents covered by them it is understood, would take a long time. In the matter of imports of drugs, indigenous manufacturers had represented to us that bulk drugs which are available from overseas countries at competitive prices cannot in many cases, be imported because of the anomaly that obtain in this country in regard to drug patents.

(q) While Government has been pressing drug manufacturers, with a trun-over of Rs. 2 crores to take-up the manufacture of bulk drugs, Indian manufacturers had a different story to tell the Committee. There have been instances where Indian companies have accomplished the manufacture of bulk drugs before the foreign companies who were the researchers of such drugs could do so in this country. Glybenclamid, an anti-diabatic drug, has been reported to be manufactured by an Indian Company, whereas two com panies with foregin equity participation have still to commence production of the drug. Similarly, another Indian unit is manufacturing bulk Propranolol and Practolol and making their formulations. The plea of the Indian units that the multi-national units in India should be compelled to buy the bulk drugs from the Indian manufacturers, so long as their quality is accepted by the Drugs Controller (India) is still under

Government's consideration. In the past, Indian units were compelled to buy bulk Tolbutamide, Vitamin B12 etc. from units with foregin interests even when there was only one source of supply. A small-scale unit Kerala which reportedly is manufacturing a number of anti-cancer drugs has approached Government suggesting that formulators of the anti-cancer drugs should be compelled to buy the drugs from them. Expeditious decisions in all such cases to ban the import of the bulk drugs concerned should be taken and implemented quickly. Unless this encouragement is given, there would be no incentive for Indian companies to take up the manufacture of bulk drugs.

(r) Till about 10 years ago, foreign companies were averse to reduce their foreign equity participation. Government's attitude in this regard stiffened progressively. In consequence, foreign units were compelled to reduce their foreign equity. West Bengal drug firms, possibly because of the strong nationalistic background prevalent in that region, have been generally stronly opposed to the idea of collaboration with foreign undertakings. The rapid progress made by several Indian firms which enjoyed the benefit of foreign participation and know-how had little effect on the drug industry in West Bengal.

(s) The drug industry is concentrated in three States, namely, Maharashtra; Gujarat and West Bengal. Quite a few drug units and the synthetic drug unit of I.D.P.L. are operating in Andhra Pradesh. Karnataka has also, of late, been attracting a few drug manufacturing units.

(t) In regard to Research, barring a few, other multi-national companies have been taking the line that basic innovational research for "new drugs" involving co-ordination between multi-disciplinary teams of scientific workers requires giant outlays and top-grade research scientists. According to them, research should be concentrated in the parent organisation functioning abroad rather than be dissipated in many countries Eight Indian insitutions, including the public-sector companies and the National Laboratories maintain fairly well-organised research facilities and specialize in different classes of durgs. Six Indian firms can also be considered to have made reasonable efforts towards developing basic research activities.

On an overall basis, however, Indian comapnies, by and large, have yet to initiate research efforts. From the therapeutic angle, the diseases that are endemic in Indian and which need to be controlled or eradicated are malaria, tuberculosis, filaria, leprosy, amoebiasis, helminthiasis, malnutrition, iron-deficiency anaemin, trachoma, scabies and various types of infections. The current rage of drugs available for he treatment of these diseases cannot be said to be entirely satisfactory. The highest priority has therefore to be accorded for centrally-directed research aimed at discovering newer drugs in these fields. Besides, the discovery of new and more efficacious contraceptives also need to be given on equally high degree of priority. Foreigns firms are not interested in research on drugs for tropical diseases as the global demand for such drugs, in their view, will not be sufficiently economic. Side by side, research for new drugs for the treatment of diseases of the cardio-vascular system, metabolic disorders, diseases or disorders of the digestive and endocrine systems, venerel diseases, allergic diseases, diserders of the skin etc. cannot be ignored if the pace of growth of the drug industry is to be accelerated and the country is to be in the manstream of scientific progress.

(u) The Drugs Prices Control Order, also had its impact on the growth of the industry within the last few years. In general, while foregin drug companies managed to diversify into areas where price control is not operative e.g. laboratory chemicals, foods and nutritional products, insecticides, etc. Indian units had to face its full blast. There profitability progressively declined and thir capacity to market new formulations of drugs, particularly in competition with foreign undertakings, has been seriously impaired. The Committee has dealt with this aspect in chatper VIII.

14. Having studed the evolution of the drug industry in this country and identified the imbalances that have developed in it, the Committee would like to set forth the challanges that face the industry. The report of the Task Force on Drugs and Pharmaceuticals set up by the Planning Commission (Annexure I of Chapter II) indicates the drugs that would be needed by the country over the next ten years and the quantities in which they would be required. The Task Force also provided information as to whether indigenous technology is avialable for their production or the technology will have to be imported. The Task Force has also listed the raw materials and the intermediates which would be required for the manufacture of important durgs and the areas of research which could usefully be pursued by different sectors of the drug industry. Besides making the country self-sufficient in regard to drugs, this Committee feels that another eqully important objective, should be introduction of medical service of a rudimentary nature in the remote villages where at least common house-hold remedies for cough, cold, fever, antacid preparations for the elderly sections of the population, drugs for skin infections, preparations for treatment of acidity in children etc. should be made avialable in pilfer-proof packings and in quantities which would be sufficient for 3 to 4 days' treatment.

15. The question that poses itself before the Committee— and indeed before the country— is : What changes in the drug policies are necessary to fulfil the task that lie ahead of us? A multipronged effort is called for to achieve a number of targets sumultaneoulsy. We should reduce the import bill of the country in respect of the drugs required over the next ten years, develop as far as possible the technologies required for bulk drugs and intermediates through co-ordinated research carried out at the National Laboratories and the academic institution, try to achieve a balance between foreign exchagne inflow and outflow by boosting exports in a judicious manner without affecting the domestic demand adversely and lastly foster the development of sound and ethical small-scale sector which would not only serve as feeder units for the large-scale sector but also produce all drug formulation which are essential or which have remained the monopoly of foreign companies so far. All these exercises should be done keeping in mind the twin objectives of rdeucing the dominant position now enjoyed by the foreign sector of the industry and rapidly buildng up the Indian sector.

16. Before answering the question whether any change is required in the current drug policies of Government to help achieve the challenges ahead, a more relevant point to be considered is : Is the drug industry that has developed in conformity with the national requirements ? The profile of the drug industry, as has been elaborated by us in para 13 of this chapter, would indicate that the basic objective have been far from achieved. A beginning has no doubt been made with production of drugs in the public sector but if the public sector units are to continue the manufacture of bulk drugs after investing heavily and distributing the raw materials to other manufacturers for being processed into finished formulations, the maximum benefit out of this policy will accrue to the subsidiaries of multi-national companies in this country who have the capcity to out-do the public sector units in sales even after maintaining higher prices. Government's policy is against concentration of the industry in the hands of foreign branches/subsidiaries and larger Industrial group but the result achieved is just the contrary.

17. Government's policy assures all support for the medium and small-scale sector of the industry but our discussions with the Indian Drug Manufacturers' Association and other associations representing the interests of small and medium scale drug manufacturers give us the impression that there is little rapport between Government and these sectors of the industry. The latter feel that if they ask for protection for the bulk drugs manufactured by them, Government does not appear to be confident about their ability and technical competence. The Indian manufacturers, including the small-scale units managed on ethical lines by technically competent entrepreneurs, desire that they should be given encouragement. They sugeest stringent punishment for these companies which indulge in malpractices such as sale of raw materials etc., or which are deficient in quality control measures. To judge all the medium and small-scale units by the same yardstick, the Indian manufacturers represent, would be less than fair to the Indian sector of the industry. The Committee feels that in our anxiety to produce more drugs, we should not adopt a policy which places Indian manufacturers at a disadvantage. On the contrary if the choice were between a foreign company and an Indian company, encouragement should be given to Indian companies which are technically competent. Somehow or the other, there seem to be exaggerated notions about the capabilities of foreign companies *vis-a-vis* Indian units.

18. It was represented to us by the Indian sector of the drug industry that the general preference showed by the medical profession to the products of foreign manufacturers, the real or exaggerated shortages of drugs marketed by such manufacturers and the subtle propaganda that any shortage would lead to prevalence of spurious drugs would weigh heavily with the authorities in their actions. The Joint Secretary of the Ministry of Petroleum and Chemicals assured the Committee that such propaganda had not influenced Government. The Committee is fully aware of the fact that foreign companies in India with the commanding position they have attained in the drug industry today and with the technological and other resources which they can command from their principals abroad, may produce all the bulk drugs that are needed by the country well within the time schedule envisaged by the Task Force. But the big question that we should ask is : What would it cost the country if the future development of the drug industry is entrusted primarily to the foreign sector of the industry? In response to a querry raised by the Committee as to why the member firms of the Organisation of Pharmaceutical producers of India (an organisation which is dominated by foreign companies and firms with foreign interests), have not shown adequate interest in the manufacture of bulk drugs, the reply received from the Organisation stated that its members "are in a position to further expand their production of bulk drugs provided such expansion is immediately sanctioned by governmen without attaching any condition". This proviso pithily sums up the attitude of multifnational companies. It implies that Government should not ask them to bring down progressively their foreign equity, that no condition should be imposed to the effect that a portion of the bulk drugs manufactured by them should be distributed to other manufacturers for being processed into formulations, that no export obligations should be stipulated and, lastly that the cost of the bulk drugs and the prices of the formulations produced by them should not be investigated by government agencies and fixed. It must not be forgotten that the multi-national undertakings which are operating in India are the very firms which also control the industry in whatever countries they operate. The techniques employed by these firms all over the world are the same and are lucidly dealt with in the report of the United Nations

publications entitled "Multi-national Corporations in World Development". In the field of drugs, such corporations invest large outlays in research, develop new drugs, block others from producing such drugs for a period of 16—20 years by invoking patent protection, din the brand names into the minds of the medical profession by employing a large field force of medical detailers, resort to high pressure sales techniques, distribute drug samples on a lavish scale and rig up prices to levels which have no relation to the cost of manufacture of products or international prices. They are interested in carrying out research only on products which will have a global demand such as tranquillisers, anti-histaminics, anti-hypertensives etc. and not on drugs for treatment of tropical diseases or even cancer. If in the course of their scheduled research the drugs synthetised by them show activity against tuberculosis, helminths etc. they are marketed as such. In short, the already dominant foreign sector would become a mighty force to reckon with in the country's economy unless certain further steps are taken to curb the dominance of multinational companies.

19. Having regard to the socio-economic objectives embodied in Government's policies and the specific direction contained in the terms of reference of the Committee under this Chapter, this Committee has no hesitation to suggest that the potentiality of foreign companies to exploit their names and smother the development of the Indian sector of the industry should be blunted. A more purposeful and positive policy of helping the Indian sector should be simultaneously implemented. The scientists and technologists in the country are bubbling with a new sense of confidence and feel that they can maximize their research effort. If purchase of technology is necessitated, it should be done as recommended by this Committee in Chapter III. The Indian sector has developed high grade drug formulating skills.

20. "Does the drug industry, as it has developed, fulfil the socio-economic needs of the country? If not, how should its development be oriented?"—These questions were debated by the Committee. Nationalisation of the drug industry was discussed at length as one of the alternate solutions. Different views were expressed. One of the views was as follows :—

"In India, inspite of the efforts to plan socio-economic growth, the drugs and phramaceuticals industry like several others, operates on the principles of free market economics. The Drugs industry is dominated by the foreign units which set the pattern in this industry. The drug needs of any country are characteristic of the climatic conditions, social behaviour and economic conditions in each society. The foreign units which evolve their policies for the rich countries in temperate climates, with redically different socio-economic conditions, operating in free market systems, promote the same systems in India, which are adversely detrimental to our national interests. Even in the Western European and North American countries it is widely realised that the drug firms exploit the socio-psychological factors to reap high profit. It is said that the firms have reduced life to a disease to be cured in those countries by their sales propagation techniques.

The experience of the last one quarter of a century in India, in the operation of the multi-national drug units reinforces these fears. This has been confirmed by the studies conducted by various international agencies also.

Throughout the world, foreign firms are given facilities to operate with the hope that capital flow and technological development are facilitated. In our country however the flow of capital through the foreign units is almost nil and the accumulation of assets, through their trade operations in this country, is very rapid, as can be seen from the data provided elsewhere in this report.

The claim that flow of technology from parent foreign firms on a continuing basis is ensured because of foreign equity holdings is not valid. Firstly, such flow is usually restricted only to the technology available with the overseas parent Co. and not from other competitive overseas venders of technology even if they may be cheaper. Other points to remember in this connection are (1) introduction of technology of basic drugs newly into the Indian subsidy does not occur free since for most such introductions additional payments have nevertheless to be made notwithstanding equity interests, and (2) the overseas firms choose to permit flow of such technology to India as will serve the interest of the parent firms. Rarely *new* and *novel* technology is permitted to flow either free or even on payment. Most technologies that flow from parent foreign firms into their Indian subsidies or partners are in fact well established all over the world for the last 15—20 years and could as well have been imported into the country without taking recourse to equity participation.

Fears that technology flow will dry up if foreign equity is discouraged or stopped is also exaggerated. Countries in which the drug industry is state-owned have not suffered on this account. They have either bought such drug technologies as they need or have been able to develop them on their own.

If indeed technology flow becomes difficult due to take-over of the drug industry, it may be a boon in disguise as it will spur greater national effort in these directions and develop self reliance—a goal to which our country is committed. Success of the development of self reliance by our scientists and technologists in the atomic energy and defence field (where possibilities of import of production technology are limited) shows that even if overseas technology flow for drugs were to dry up, the country, with its strong scientific and technological capacility, will not be stranded. Indeed such an eventuality is also remote since unlike the atomic energy and defence areas, drug technology from overseas is not as restricted or difficult.

It is contended that the anti-social role of multi-nationals can be contained by laws of the land and the powers that are available with the Government. Whereas this is so, the real point at issue before the Committee is the manner in which such governmental powers have been used in the past so as to curb the activities of these companies which are not in the national interest. The Committee's findings in this regard, discussed in the various chapters of this report indicate that progress in these directions has been very slow. If this process of change is to continue at the existing rate it is doubtful if the desired objective of a truely social benefit oriented drug industry will develop in the near future. A quantum change has therefore, to take place in the rate of change if the desired goals are to be achieved quickly enough.

The contention that technology flow through equity participation by multi-nationals in the drug field is the most effective and economical because of its higher rate of obsolescence, will have to be supported by cogent facts and will also have to be examined in the context of alternative methods of technology flow not involving equity participation. As of now, no such study is available. The assertion that equity participation in several cases would be the only way by which technology flow can be ensured may be valid only for a very few cases. In these cases we may import such drugs but we should at the same time launch a crash programme of R & D to develop self reliance for such drugs. The impediment to development of domestic technology, due to patents in the drug field, have also now been largely removed. There is little doubt that Indian scientists and technologists will develop all such technology if a concerted effort is made and if subsequent use of technology use is assured.

The drain of foreign exchange by way of remission of profits by multi-nationals has to be viewed in the context of their import bill for drugs and intermediates in relation to their own export of drugs and not in terms of their total sales inclusive of formulations. It is well known that the value added in formulations is upwards of 3 times that of bulk drugs. Any comparison of the foreign remittances with the country's total experts is not relevant to the issue of social and economic costs resulting from equity participation by multi-national drug companies.

Another social cost which cannot be quantified when foreign multi-nationals hold dominent equity (i.e. their equity holdings are more than the largest single holding by Indian individuals or institutions), is in the matter of self sustaining growth based largely on domestic R & D carried out either in the company itself or that which is available from other laboratories in India. It is well known that the management and staff of Companies with dominent multi-national foreign equity holdings tend only to look overseas for most of their technological needs and often even for resolving their day to day plant problems. Even where the R & D staff is such companies propose to develop technology on their own, such initiatives are usually discouraged by their foreign collaborators and their Indian partners usually on the ground that such efforts are futile in view of the possibilities of access of information from parent foreign companies. In such a situation their is little incentive for such companies to become self reliant for their R & D needs. These social costs which are non-quantifiable are indeed very serious since they make our industry permanently dependent on overseas expertise and technology.

It is glaringly obvious that the multi-national units are not interested in producing bulk drugs in countries like India. In Europe and U.S.A. the multi-national units produce bulk drugs in a spirit of collaborative relationship. In the developing countries, such production is avoided by them and where this is done, the host country pays dearly for such drugs.

The multi-national units operating in India produce only a small fraction of bulk durgs. The main thrust of the multi-national units continues to be towards capitalizing on drug formulations and non drug items like cosmetics and luxury goods where technology and capital in-puts are much lower and which permits promotion of aggressive salesmanship and brings in much higher returns on investments. The Permission Letters and C.O.B. licences have further helped these units to build enormous assets, which are completely out of proportion to their investments. Besides, they have repatriated over the years large sums of money in the form of profits.

The selective attitudes of multi-nationals even in the field of Research and Development are dictated almost entirely by their philosophy of global trade. Indeed, their entire philosophy of building monopolies which lead inevitably to high prices and excessive profits is completely incompatible with the socio-economic needs of this country. Their capacity to manipulate is recognised throughout the world and mere regulatory measures cannot curb these activities.

We are convinced that their continued presence in this country is a powerful damper on the challenge of our achieving the technological goals of self-sufficiency and self-reliance.

Basic drugs are produced in the Indian sector, including the public sector, to the extent of about 90% in tonnage terms, and this demonstrates effectively the competence that has already been achieved in indigenous technical skills.

Continued presence in this country of the highly profit motivated multi-national sector can but promote only the business interests of this sector. Their presence in India, as a part of their global effort to capitalize on human suffering in an organised manner, must therefore cease as early as possible.

We, therefore, strongly recommend that the multi-national units in the field of drugs and pharmaceuticals should be taken over by Government and managed by the proposed National Drug Authority. Such take-over will not create any dislocation in production or distribution of drugs. Overwhelming majority of the technological and managerial personnel in these units are Indians. We are convinced that with appropriate governmental support they will carry on their respective functions with greater enthusiasm in reaching the goals set by the nation. Should there be any technical difficulty for such take-over, suitable legislative measures may be approved by the Parliament to remove it.

Interim measures aimed at facilitating the take-over of the multi-national units are recommended hereunder."

A second view was expressed as under :—

"As against these arguments in favour of taking over of multi-national drugs firms, some of the members argued that there was no case, at this stage, to justify such drastic measures. The arguments advanced by this group of members were :

While there is no difference of opinion that the activities of the multi-national corporations have to be kept under strict surveillance, there is no evidence to suggest that their relative importance has grown or is growing or that the existing instrumentalities are inadqeuate to achieve established social objectives.

Under the existing legislative framework, and in particular the Industries (Development and Regulation) Act, the Foreign Exchange Regulation Act and the Essential Commodities Act, Govt. have adequate powers to ensure that the Drug Industry, both Indian as well as Foreign conforms to established national objectives. In fact, over the last 20 years Govt. has in fact, used these powers to encourage the flow of much needed technology and also to progressively reduce the share of the multinational companies in the production of formulations. After the recent amendments of the Foreign Exchange Regulation Act, Govt. has the necessary powers to further accelerate these processes.

It is true that in the absence of any concerted or purposive policy, there will be a tendency for the multinational corporations to operate on the basis of self interest which may, in some cases, be in conflict with national interest. But this type of situation can be dealt with through the exercise of powers already available to Govt. and does not either require or justify a measure such as taking over all multi-national corporations operating in this country. It is argued that the multi-nationals have a dominant role in the Drugs and Pharmaceuticals Industry. It has to be recognised, however, that the share of the multi-national in total production has been steadily coming down and with the growth of the public sector and encouragement as envisaged in other parts of this Report to Indian private sector, this share will continue to diminish. Incidentally, the share of multi-national corporations in the Drugs and Pharmaceutical Industry in the country roughly about 40% of total production—is significantly lower than in many other Indian industries in which foreign investment is permitted, and indeed, the relative importance of the multi-national corporations in the Drugs and Pharmaceuticals Industry in India is much lower than in other developing countries and even as compared to countries like United Kingdom where nearly 2/3rd of the total production emanates from multi-national units.

The argument that multi-national companies have not and will not make any significant contribution to the transfer of technology is not borne out by experience. From the very beginning it has been Govt.'s policy to develop this industry on the lines of self-sustaining growth. Manufacture of basic drugs was accorded high priority in the development of the industry. The success of this policy is borne out by the fact that while as in the early 1950's most of the requirements of Drugs and Pharmaceuticals were imported, th shares of imports, including imported chemicals, is hardly 10% of the total value of production of the industry. Several instances can be quoted to show that governmental pressure and pursuation has already succeeded in utilising the vast resources of the multi-national Corporation to secure for the country, the kind of production and the type of technology which otherwise would not have been available. For instance as far back as 1959-61 the manufacture of Vitamin 'A' was established within the country using indigenously available Lemongrass oil. From 1963 Vit. 'C' and B, 12 had been produced from the basic stages. The same is true to the case of many other drugs such as Chloramphenicol, Insulin, wide range of corticosteroids, Erythromycin, Penthonal, ampicillin etc. Many other products such as PAS, INH, Oral anti-diabetic, calcium Gluconate and other calcium salts, and other iron salts also come into commercial production as a result of the activities of multi-national Corporation in this country.

An important reason why the continued presence of multi-nationals Corportions under appropriate surveillance is desirable, is because it provides the most effective and economical method for the transfer of technology in a field in which technological and product obsolescence is quite significant. It is often argued

that instead of permitting foreign firms to operate in this country, technology can be purchased outright. This is claimed to be cheaper and would also assist the development of domestic Research and Development. While in appropriate cases outright purchase of technology may be the most suitable method for the transfer of technology, this mode of transfer of technology cannot be generalised.

In highly specialised fields or where the new technology is confined to one or two sources, it may not always be possible to purchase the know-how. Moreover, it is one thing to buy know-how and quite another to have continuing access to improvement in technology which are taking place all the time.

Purchase of technical know-how either by making a lump-sum payment, or by way of a royalty to be paid for a fixed period provides access to an existing technology. On the other hand, when the foreign party which has provided the technology has an equity participation, the Indian company can have access to the continuing improvements in technology. There would be instances, therefore, where continuing association in the form of equity participation is the only way of securing access of new technology. It may also be the best way of ensuring that the country derives benefit from improved technology and updates it. If the objective is to provide for the masses in this country drugs and pharmaceuticals at reasonable prices, this can only be done by constant improvement in product-technology based on researches which are continuing elsewhere.

The argument that existence of foreign firms in the field of drugs and pharmaceuticals results in a drain on foreign exchange, also needs to be viewed in proper perspective. The remittance of profits by multi-nationals has been of the order of a little over Rs. 5 crores annually in the last 5 years. This constitutes 0.16% of the country's total exports. Indeed, the total annual remittance is today less than the actual exports by firms having foreign equity of more than 50%. The foreign exchange costs of the multi-national corporations, therefore, can be easiiy exaggarated.

While, as pointed out earlier, there is a clear case for appropriate administrative action and constant surveillance of the performance of the multi-national corporation, there is no case for the take over of foreign companies in the field of drugs and formulations. The multi-national character of some of the units in this industry can be—and indeed, should be—used for subserving national interest. In particular, the internationl character of their operations can be utilised to increase the exports of formulations to a much greater extent than at present. It would be our national advantage to utilise the resources and technology of multi-national corporations, provided these fimrs are made to operate in conformity with established national objectives and priorities.

The question of takeover of multinational units clearly has political overtones. The economic case for takeover of drugs and pharmaceuticals units, however, has to be based on the advantages accruing to the community from such a step ; and in this, it is difficult to make a distinction between foreign and I ndian companies. If there is a case for nationalisation of drugs and pharmaceuticals firms, the agrument would be equally applicable to units in the Indian sector, above a certain size. There is no case for limiting the take over to a segment of the industry namely the mulu-national units and no persuasive case has been made out in favour of nationalisation of the whole industry."

A third view endorsed the second view but added that the size of the wholly Indian units to be nationalised be atleast with an annual turnover of Rs.2 crores and above and those which are determined as sick units need not be nationalised and paid unnecessary compensation.

The Committee could not come to any unanimous decision though the majority of the members were of the view that foreign firms should be taken over as set out in the first view. However, the Committee was unanimous that the measures set out in the succeeding paragraph should be taken forthwith.

21. Under the Guide Lines issued for administering Section 29 of the Foreign Exchange Regulation Act, 1973, (FERA) Indian Companies having more than 40% foreign shareholding and branches of foreign companies engaged in the production of items specified in Appendix I of the Industrial Licensing Policy of February 1973 of which 'Drugs and Pharmaceuticals' is one are required within a specified period to associate Indian participation to not less than 26% of the equity of the Company. The Committee recommends that having regard to the present stage of development of the drug industry, for the purpose of FERA Guidelines, this industry should not be eligible for the preferential treatement given to items specified in Appendix I of the Industrial Licensing Policy of 1973. In the view of the Committee, foreign undertakings operating in this country should be directed to bring down their equity to 40% forthwith and further reduce it progressively to 26%. This, however, is without prejudice to other concessions to which they are eligible as a result of the industry being in Appendix I of the Industrial Licensing Policy of 1973. The Committee would further recommend that the dilution of foreign equity as suggested above, should not take the form of dispersed holding of the shares by large number of Indian nationals. This is because such widely dispersed holdings will not, in any way, reduce the effective control of the foreign equity holders. In order to serve national objectives, it would be desirable for Government to purchase these shares either by public sector undertakings which are directly or indirectly connected with the manufacture of drugs/chemicals or by public financial institutions or by Government itself.

22. Bulk drugs manufactured by companies fall under 3 categories, namely (i) against Permission Letters and COB Licences, (ii) in excess of the licensed capacities, and (iii) in accordance with the capacities specified in the IDR Act.

Regarding (i), the manner in which the production should be regularised, has been spelt out by us in Annexure VIII of the Chapter. As regards (ii), the companies concerned should be made part with 50% of the excess licensed capacities in addition to the quota of 50% of their authorised production. As regards (iii), the companies should be made part with 50% of their production to non-associated formulators.

Wherever manufacture of bulk drugs is carried on from penultimate stage, the companies concerned should be directed to manufacture the drug from basic stages within a period of two years. In regard to "new drugs" which are developed as a result of research carried out in this country, there is no need for such a condition to be imposed.

23. In respect of bulk drugs for which production capacities have not been fixed (e.g. Diazepam in the case of M/s. Roche against C.O.B. licence) the capacities should be pegged at the level of production achieved in 1973 so as *not* to affect adversely the interests of Indian units which are already engaged in the manufacture of such drugs. Likewise the capacities of all formulations should be fixed. The Committee understands that in many licences serveral formulations have been clubbed together and "combined capacities" fixed. This anomaly should be set right and the capacity of each formulation specified separately. The Committee realises that demands for certain formulations may sometime spurt up considerably and that rigid adherence to capacities mentioned in licences may occasionally lead to shortages. We would therefore suggest that units may be permitted to exceed their capacities by 15% if need in national interest.

24. Where foreign undertakings are producing in Indian drug formulations using imported bulk drugs, they should be warned that unless they start and complete the manufacture from the basic stage the bulk drugs in question within a period of three years they will not be permitted to continue marketing the formulation at the end of the three years' time limit. If however the bulk drugs are such as have been assigned to Public-Sector units, as recommended by the Committee in chapter III of this Report their manufacture should be taken up by the Public Sector units. The manufacture of essential and life saving drugs such as cardiacdrugs anti-diabetic drugs, anti-epileptic/convulsant drugs, diuertics, anti-arthritic drugs, etc., must be assigned to the Public Sector units. Government should mobilize all research telents available in academic institutions and the National Laboratories and start working on the production of the bulk drugs on a time-bound programme. If for some reasons, the public sector undertakings are not in a position to take up the manufacture of the bulk drugs, the Indian sector of the industry should be offered the second choice. The need for working on a time-bound basis should be emphasised on Indian companies also.

25. Indian drug manufacturers who are already engaged in the manufacture of those bulk drugs identified as essential by the Task Force up to 10% of their total turn-over should be freely allowed to make all drug formulations subject to their therapeutic rationale being accepted by the Drug Control authorities.

26. In no case foreign companies be allowed hereafter to manufacture house hold remedies such as alcohol-based tonics, other types of tonics, vitamin preparations, ointments for cold, burns, sprains, etc., cough mixtures, gripe mixtures, aspirin tablets, pain releiving tablets etc. beyond the capacity mentioned in the Industrial Licence or application for registration. Foreign units which are already engaged in the manufacture of these household remedies, etc. should not be granted any expansion of capacity. The manner in which drug formulations already permitted to be manufactured against Permission Letters/C.O.B. Licences issued to units are to be regularised has been set forth in Annexure VIII.

27. The Committee is informed that branches of foreign companies or foriegn companies with 100% foreign equity have been engaged in unauthorized production of drugs. We are of the view that wherever a company is found manufacturing drugs without Government's authority (valid licence), penal action should be taken against them.

28. Annexure V indicates that there is scope for tightening repatriation of money by foreign companies under various heads. The norms for payment of "Research contribution", "Technical know-how fees", "Trade Mark fees", etc. in the opinion of this Committee, need to be reviewed. We would suggest that the NDA should be entrusted with this task.

29. Remittances of money outside this country by foreign companies are permitted subject to certain conditions being fulfilled by them. Certain companies may be required to start manufacture from the basic stage in a phased manner. Export commitments are imposed in licences. Again, the principals abroad of foreign subsidiaries operating in this country may be required, by a condition in the licence, to invest money in this country. The Committee recommends that a suitale machinery should be evolved to check that the conditions imposed in industrial and other licences are fulfilled before remittances abroad are permitted.

30. The Committee understands that foreign companies which are unable to secure a foothold in the industry in the country in terms of the Industrial Policy sometimes by pass the regulations by purchasing a com operating in this country and work through it. Many foreign companies have also grown up in size by operati the small-scale sector. As already mentioned by us, the small-scale sector should be a prohibited area for fo companies.

31. Distribution of samples of drugs by drug manufacturers to the medical profession, in our opinion, is n sary, particularly to enable physicians to use them and form their opinion on the basis of the therapeutic ef achieved. Unfortunately, this practice of distributing samples has degenerated into a rat race among manufactu each one trying to excel the other in the quantity of drug samples distributed to doctors. The scale of distribu of samples resorted to is unusually heavy in many cases and leads to malpractices. Reports have been receive physicians' samples being found on the premises of drug dealers. In order to curb these malpractices, the Comm would recommend that excise duty should be levied on drug samples distributed by manufacturers. Besides, expenditure incurred on samples by drug manufacturers should not be deemed to be business expenditure for purpo of corporate taxation.

Supply of free samples may however be permitted, as at present, for the first three years from the date of introd tion of a product for the first time by an Indian company.

32. Drug manufacturers have cashed in heavily on the sale of their household remedies including vitam preparations. Most of these products are advertised in the lay press and through the medium of the radio. Su indiscriminate advertisements, in our opinion, would lead to self-medication of drugs which is not desirable. T Committee appreciates the importance of educating the people residing in rural areas about the use of househo remedies, and advertisements of drugs may have to be permitted to serve this limited need.

33. The Committee wishes to point out that drug companies have been processing life-saving and essenti drug formulations from raw materials imported from their principals at very high prices. Examples of such formul tions are gentamycin injection, corticosteroid preparations, etc. The import of some bulk drugs has been canali through the State Trading Corporation. The companies concerned are reported to have been engaged in the impor of such bulk drugs for many years. The prices of bulk drugs, intermediates and raw materials should be screened b the National Drug Authority and wherever there are reasons to doubt that they are excessive, the prices should b brought down. Such a check is necessary in the country's interests. Indeed, we would go to the extent of suggesting that if the directions issued by Government in this connection are not complied with by companies the latter should b taken over by Government under the powers vested in the Industries (Development and Regulations) Act.

34. We understand that several drug companies, both Indian and foreign, have secured industrial licences but have not implemented them. The NDA should be asked to go into those cases and suggest necessary action. NDA should also look into those units which had committed themselves to go basic in the manufacture of bulk drugs in a phased manner but have not acted in accordance with the terms of the commitment.

35. Trade Marks registered in India by foreign firms for formulations should not be permitted to be renewed if similar formulations are processed in India by Indian firms. The provisions of the Trade and Merchandise Mark Act should be examined in this connection.

36. Turning to the measures of assistance for the Indian sector of the drug industry, the discussions that the Committee had with the organisations representing the interests of this sector, including the small scale sector, and with individual manufacturers, emphasised the need for protecting the interests for those Indian manufacturers who produce basic drugs and for a more liberal allotment of canalised raw materials for essential drug formulations. Other aspects represented by the Indian sector of the drug industry were :—

—Distribution of canalised raw materials should be done on the basis of production capacity. Facilities for obtaining solvents like alcohol and acetone, ammonium sulphate, acids, etc., should be provided.

—Extending preference and help to Indian companies for manufacture of bulk drugs. For this purpose, the Patents Act should be amended.

—Encouragement to units which set up manufacturing facilities in the "backward" regions in States.

—Indian firms should be given special consideration in matters relating to exports.

—The working of the Drugs (Price Control) Order should be so rationalised as to ensure that prices of drugs are fixed without delay and that the Indian Sector gets sufficient incentive to develop.

37. As for allotment of raw materials, the Committee considers that there is force in the representation of manufacturers regarding inadequate releases of raw materials for essential new formulations or for new units. The Committee, therefore, recommends that liberal allocations of raw material for essential new formulations and to new units should be made.

38. As regards exports, the Committee recommends that (a) wholly Indian companies should be exempted from the export obligation as applicable presently; and (b) additional incentives like extra foreign exchange for import of raw materials and components should be provided in case they export their products.

39. The manner in which the Drugs Price Control Order should be rationalised so as to facilitate the working of the drug industry and the incentives that should be extended to the industry in the matter of drug prices so as to foster the production of bulk drugs have been dealt with separately in Chapter VIII.

40. Considering the general increase in the cost of machinery, equipment etc. that the small-scale sector of the drug industry should maintain for ensuring "Good Manufacturing Practices" and for effective quality control measures, the Committee recommends that the monetary limit for investment in plant and machinery for a small scale unit in the drug industry should be raised to Rs. 20 lakhs. The general representation from the small units is that it is very difficult for them to obtain import licences for machinery and equipment. The Screening Committee that functions under the Chairmanship of the Chief Controller of Imports and Exports for considering applications for import licence for machinery etc. by small-scale units, it was reported to us, adopts a very rigid attitude in this respect. This aspect, we would recommend, should be taken up by the National Drug Authority and a satisfactory solution found. We also with to point out that the recommendations made by a Committee of the Ministry of Petroleum and Chemicals immediately after the price control measure over drugs was introduced, to help the small scale sector of the industry should be implemented expeditiously.

41. Small-scale manufacturers producing bulk drugs should be advised by the State Drug Control authorities to register their production capacities with the D.G.T.D., the Drug Controller India and the Ministry of Petroleum and Chemicals. Registration of capacities should be done on the basis of the information supplied by manufacturers through the State Drug Control authorities regarding their potential capacity of production, the level of production achieved, the raw materials required for manufacture, the specifications of the drugs and their sale prices. The capacities for production, as registered, should be taken into account by Government while granting Industrial Licences under the I(DR) Act.

42. The Indian sector of the drug industry, in general, needs considerable information to enable it to plan its expansion programmes. In Chapter III, we have recommended the constitution of N.D.A. This Authority should, in our opinion, maintain a "Drug Information Service" and make available to drug manufacturers information regarding the items that can be manufactured, the Patent position regarding drugs, the processes and know-how that are available from indigenous sources, the overseas countries and companies which are in a position to provide know-how, the supply position of raw materials in world markets and the prospects for export.

43. During the course of the visits undertaken by this Committee to the Different regions of this country, some members of the industry mentioned about the apprehensions and difficulties faced by them in taking up the manufacture of new bulk drugs with the meagre resources at their disposal. It was mentioned that in 1963, applications for patents in respect of drugs and medicines were frozen and even with the enactment of the new Patents Act, 1970, which came into force in April, 1972, this freeze continues till today. It was mentioned that about 7,000 applications were still pending with the Patent Authorities and though the inventions claimed in these applications did not enjoy any protection until these are accepted or sealed, entrepreneurs, not being aware of the inventions claimed in the frozen applications, find it very difficult to adopt any process/technology and set up any manufacturing facilities for their production. They also apprehend that if any of the units starts manufacturing and marketing the drugs, which might have been covered by such frozen applications, with the sealing of such applications and consequently the patents, the patentees would have secured rights in respect of the inventions claimed whereby they would be entitled to take legal action for infringement against the entrepreneurs who would have gone ahead in the manufacture of such drugs and thereby would face the prospect of closing down their activities, which would adversely affect the industry and the public besides the members of the public would also be deprived of the drugs so produced indigenously, It is under these circumstances that the local entrepreneurs found it very difficult to decide whether or not to embark on such activities. On the other hand, it was also gathered from the Controller of Patents that no party has so far approached him for any compulsory licence, a provision under which an intending entrepreneur could take up such manufacturing activities. It was also pointed out by some that even today it is not possible for anyone who intends to manufacture and market a new drug, to ascertain whether the item is covered by any of the pending/frozen applications. It was suggested that to remove all such difficulties, the Patents Office should maintain an Information Centre to guide the entrepreneurs as to whether there are any applications pending covering the drugs sought to be produced, and that this could be done even without divulging the specifications contained in the applications.

44. The Committee recommends that a subject index should be prepared immediately and maintained by the Patent Controller's Office regarding the pending applications to guide the intending entrepreneurs, who after inspecting the same could decide the course of action themselves. It would also be helpful if the Patents Office brings out a list of patents applications which are rejected after examination by that office. The Committee agrees that so long as anxiety persists in the minds of the industry who have introduced or are in the process of introducing new drugs about the outcome of the pending applications, many of the units would shy and shun any fresh venture on production of new bulk drugs. The Committee would also recommend that wherever an Indian entrepreneur has set up any basic production within a certain specified period which might infringe on the coverage claimed in the pending applications, a suitable solution should be found out whereby the concerned entrepreneurs could continue with their manufacturing operations.

45. Whenever foreign companies apply for manufacture of bulk drugs, Government should issue a notice about the application and its terms and ask, within a period of two months, whether Indian companies and the public sector units can take up the manufacture of such drugs. The applications should be considered in the light of the replies received from Indian Companies and the public sector units. This however will not apply to applications received for bulk drugs manufactured in accordance with the recommendations made in para 24 of this Chapter.

46. Drug companies all over the country had represented to us about the difficulties experienced by them in obtaining supplies of solvents and other items such as alcohol, acetone, nitric acid, ammonium sulphate, glass vials, rubber closures, aluminium strips, etc. Most of the items are controlled by public sector agencies or Government. We are of the view that a special cell should be established in the National Drug Authority to process representations received from the drug industry in this connection and take them up expeditiously with the various agencies. Some State Governments, who have supplies of alcohol, we regret to say, have not been able to assist drug manufacturers with their requirements. In particular, units in Andhra Paradesh manufacturing life-saving drugs such as P.A.S. heparin, anaesthetic ether etc. were unable to produce to their full capacity because of shortage of alcohol.

47. Our discussions with the Indian Medical Association and other members of the medical profession lead us to believe that in matters relating to drugs, which are mainly prescribed by physicians, Government should keep the medical profession in touch with its policies and concepts on the development of the drug industry. The proposed objective of Government for giving special attention to the growth of the Indian sector of the industry should surely find support from the members of the medical profession if proper rapport is maintained by Government with them. We would suggest that for this purpose the NDA should have a top-level committee and that representatives from the medical profession, the Ministry of Health, the various sectors of the drug industry and State Drug Controllers should find a place in the top level committee.

48. For promoting the rapid growth of the drug industry, this Committee is in general, agreement with the measures suggested by the Task Force of the Planning Commission *subject to the specific orientation in policies relating to foreign and Indian companies advocated by us in this chapter as a result of the term of reference assigned to us.*

49. On the subject of exports, this Committee, while fully agreeing with the view that unless the country steps up exports, the availability of foreign exchange for import of chemicals, drugs and intermediates may not be adequate, feels that export of basic chemicals, solvents and bulk drugs that we import or are deficient in, should not be allowed.

50. On the subject of drug research, we agree with the recommendations of the Task Force that a centralized committee should be set up to supervise the overall planning and work in this field. The NDA may be assigned the supervisory task. In our view, the Indian Council of Medical Research should concentrate its attention particularly on the discovery of newer drugs for tropical diseases. The Recommendations of the Task Force on the subject of drug research, is also supported by this Committee.

51. The Committee feels that the necessity for import of technology by the drug industry, wherever it is needed, should be screened by the "NDA". The terms of payment for imported technology have been set out in para. 105 of chapter III. In the case of drugs with low volume turn-over such as anti-cancer drugs etc., which are imported today, if any Indian unit wishes to study the possibility of their manufacture in this country by assessing their demand the import of such drugs should be permitted for a period of two years. At the end of two years, if the sales volume of the drugs exceeds Rs10 lakhs in value, the company which imports the drugs should be permitted to undertake the bulk manufacture of the drug on payment of a scale of royalty up to 5% on the net sales realisation of the finished product (*i.e.* sales value minus excise duty and trade commission). Export obligations need not be insisted upon in such cases.

52. We have been asked to make recommendations for a balanced dispersal of the drug industry in the country Considering the vastness of the country and the strategic importance of this industry in the maintenance of health care, the Committee is convinced that dispersal of the industry is essential. Even within States, the industry should not be allowed to concentrate in or around leading towns and cities. States should provide sufficient incentives to the industry and help them to develop in the 'backward' regions, where basic facilities such as good water supply and electricity are available and where transport and disposal of effluents will not present problems. At present, the drug industry is concentrated in Maharashtra, Gujarat and West Bengal. Even in these States the industry is concentrated in one or two large metropoliton cities. Also other States, excepting Andhra Pradesh have practically no industry worth the name. Andhra Pradesh is developing on right lines and Karnataka has been offering sufficient incentives to attract pharmaceutical units. Unless the Central and State Governments work in unison, it will be difficult to achieve any measure of success towards the goal of rational dispersal of the industry in different regions.

53. Unfortunately the industry has very little idea of the raw material and other resources that are available in various States. Barring a few States, most of the States have not made any survey of the raw material resources available in their area. We would recommend, as a first step, that States should enlist the support of drug manufactures, leading organic chemists, botanists etc. and make a survey of the raw materials, plant products, animal

products, solvents etc. that are avilabl in their regions. Taking the drugs and intermediates identified by the Task Force as essential for the country, the States should publish brochures setting forth the raw material position and the facilities and concessions that prospective manufacturers can hope to receive. We would specifically recommend to the State Governments that manufacture of bulk drug being capital intensive, they should form joint sector ventures in collaboration with well-established companies or technical entrepreneurs. At present only Tamil Nadu Government is participating in a joint-sector venture which manufactures both drug formulations as well as basic drugs. Our discussions with the scientists in West Bengal indicate that there is good scope for development of phytochemical industry in that state, in the Joint Sector. More joint-sector ventures are in our opinion necessary for manufacture of glass containers, tubings for ampoules and glass ampoules. Similarly, the aluminium foil industry for manufacture of strip-packing of tablets is also a suitable field for such joint-sector ventures. In chapter III, this Committee has elaborated the plant products that can be cultivated in India. The importance of phytogenetic studies and agricultural botany in the cultivation of medicinal plants needs no emphasis. The scope for manufacture of drugs from animal glands and tissues is considerable. For this purpose, well-organised slaughter-houses operating under ideal conditions and fitted with arrangements for referigeration of animal glands etc. are necessary. This Committee has no doubt that on the drug industry has before it the picture of the raw materials and facilities available in the States, new units can be expeoted to be started in various parts of the country.

54. We wish to make a special mention of the discussions we had with the scientists from West Bengal. The Committee was also specially invited by West Bengal Government to see the chemical and other plants functioning in Durgapur. The Committee feels that the growth of the drugs industry is largely dependent upon that of the chemical industry, particularly the organic chemical industry, which in turn, is based on coal-carbonisation complexes and petroleum-based complexes. Prices of petroeum products have today shot up in the world markets. Consequently, this country may have to manage with inadequate supplies of petroleum products. India, with its abundant supplies of coal, should therefore develop coal-carbonisation plants which could provide many basic raw-materials for the drug industry. The Committee notes that the coal-carbonisation complex situated in Durgapur, has already been developed to a certain stage and would therefore, recommend that its potentialities should be explored fully by the Central Government.

55. Similarly, there is scope for developing coal-carbonisation complexes in the Western and Southern regions. We understand that the coal-reserves in Chandrapur District in Maharashtra and Kothagudam in Andhra Pradesh can constitute the nucleus round which coal carbonisation complexes can be developed. The Committee would urge on the State Governments and Central Government to give serious consideration to the development and utilisation of these coal resources.

56. The concept of "industrial estates" is yet to be developed in very many States. The need for ensuring continuous electric power to drug units should not be lost sight of. Similarly water supply in abundance are needed by many units. These aspects are not taken care of even now by many States. Unless these aspects are streamlined, drug manufacturers may not be attracted.

57. Our recommendations for regularising production by foreign units in excess of their licensed capacity is subject to the overall condition that this should only be allowed if Indian Sector or the public sector is not manufacturing this or there is no scope of it being manufactured in the near future.

SUMMARY OF RECOMMENDATIONS

(1) The Committee recommends that the restrictions stated to have been imposed on the Industry requiring the units having a turnover of Rs. 2 crores and more to produce the bulk drugs required for new formulations, should be removed for the Indian Sector, and the foreign companies which have been producing formulations based on imported bulk drugs, should be made to manufacture the bulk drugs within a specified period.

[Chapter—V, para 13(h]

(2) As regards the Indian sector of the Industry, more liberal policy is necessary to encourage the Indian companies to make their contribution to the production of bulk drugs and formulations.

[Chapter—V, para 13(h)]

(3) The Indian sector should maintain an effective dialogue with the medical profession regarding their products.

[Chapter—V, para—13(n]

(4) To encourage the Indian sector to take up the manufacture of bulk drugs, Government should impose ban on the import of such items, as and when it comes to the notice of Government. Expeditious decision should be taken by Government in this regard.

[Chapter—V, para 13]

(5) Highest priority has to be accorded to centrally-directed research aimed at discovering newer drugs for the treatment of tropical diseases like malaria, filaria, etc., Side by side, research for new drugs in the treatment of diseases of cardio-vascular system, metabolic disorders etc., as well as for anti-conceptive purposes, need to be accelerated.

[Chapter—V, para 13(t)]

(6) Besides making the country self-sufficient in regard to drugs, medical service of a rudimentary nature in the remote villages should be introduced, where common house-hold remedies for cough, cold, fever, antacid preparations etc., should be made available in pilfer-proof packings sufficient to meet 3-4 days treatment.

[Chapter—V, para 14].

(7) The Committee feels that in our anxiety to produce more drugs, we should not adopt a policy which places the Indian manufacturers at a disadvantage. On the contrary, if the choice were between the foreign companies and the Indian companies, encouragement should be given to the Indian companies which are technically competent.

[Chapter—V,—para 17].

(8) The Committee suggests that the potentiality of foreign companies to exploit their names and smother the development of Indian sector of the Industry should be blunted and a more purposeful and positive policy to help the Indian sector should be simultaneously implemented.

[Chapter—V, para 19].

(8A) The Committee recommended by a majority view that the multinational firms should be taken over forthwith.

[Chapter—V, para 20].

(9) The Committee recommends that having regard to the present stage of development of the drug industry for the purpose of FERA guidelines, this industry should not be eligible for the preferential treatment given to items specified in Appendix—I of the Industrial Licensing Policy of 1973. Foreign undertakings operating in this Country should be directed to bring down their equity to 40% forthwith and further reduce it progressively to 26%. This however, is without prejudice to other concessions to which they are eligible as a result of the Iudustry being in appendix—I of the Industrial Licensing Policy of 1973. The Committee would further recommend that dilution of foreign equity should not take the form of dispersed holdings of the shares by large number of Indian nationals. It would be desirable for Government to purchase these shares either by public sector undertakings which are directly or indirectly onnected with the manufacture of drugs/chemicals, or by public financial institutions or by Government itself.

[Chapter—V, para 21]

(10) The companies who are producing bulk drugs in excess of their licensed capacities, should be made to part with 50% of their production beyond their licensed capacity, in addition to 50% of their authorised production.

[Chapter—V, para 22]

(11) Those who are producing in accordance with the specified capacities should be made to part with 50% of their production to non-associated formulators. In regard to new drugs which are developed as a result of research carried out in this country, there is no need to impose such a condition. This will automatically; negate the Government Notification No. 3(3)/65-Ch. III dated the 27th May, 1969.

[Chapter—V, para 22].

(12) Wherever manufacture of bulk drugs is carried on from penultimate stage. the companies concerned should be directed to manufacture the drug from basic stage within a period of two years.

[Chapter—V, para 22].

(13) In regard to the capacities approved for the manufacture of bulk drugs against permission letters and c.o.b. licences, the Committee recommends that having regard to the national need for bulk drugs, the permission letters and c.o.b. licences issued to such firms, may be regularised on the condition that

(a) all bulk drugs are manufactured from the basic stages; and
(b) 50% of the production of basic drugs should be made available to non- ossociated Indian formulators.

[Chapter—V, para 22 Annexure VIII].

(14) So far as formulations covered by Permission letters/C.O.B. Licences are concerned, in order that there may not be a gap between production and market demand thereby creating a shortage in the market, the Indian firms applying for the manufacture of such formulations should be given licences liberally forthwith and the foreign firms should be asked to switch over within one year to the manufacture of bulk drugs and formulations to the extent of 50% of the production of basic drugs by them, and the balance 50% to be supplied to non-associated formulators.

[Chapter—V, para 22, AnnexureVIII]

(15) In regard to bulk drugs for which no capacities have been fixed in the c.o.b. licences, capacities should be pegged at the level of production achieved in 1973. Likewise, the capacities of all formulations should be fixed.

In regard to formulations for which combined capacities have been fixed, the capacity for each formulation should be specified separately. Wherever demand warrants, the firms may be permitted to exceed their capacity by 15%, if needed in national interest.

[Chapter—V, para 23].

(16) Where foreign undertakings are producing in Indian drug formulations using imported bulk drugs, they should start and complete manufacture from the basic stage within a period of three years, failing which they should not be allowed to continue marketing the formulations after the said period. If, however, the manufacture of such bulk drugs have been assigned to the public sector units, their manufacture should be taken up by the public sector. All research talents available in the academic institutions and the national laboratories should be mobilized and work on the production of bulk drugs on a time-bound programme should be undertaken. If for some reason, the public sector undertakings are not in a position to take up the manufacture of the bulk drugs, the Indian sector of the Industry should be offered the second choice, who, in turn, should take up this work on a time-bound programme.

[Chapter—V, para 24].

(17) Indian drugs manufacturers who are already engaged in the manufacture of the bulk drugs, identified by the Task Force, up to 10% of their local turnover should be freely allowed to make all drug formulations, subject to their therapeutic rationale being accepted by the Drug Control authorities.

[Chapter—V, para 25].

(18) Foreign companies which are already engaged in the manufacture of house-hold remedies such as alcohol-based tonics, vitamin, preparations etc. should not be granted any expension in capacity, nor should they be allowed to take up such activity as additional items hereafter, nor be allowed to manufacture such items beyond the capacity mentioned in the Industrial Licence or application for registration.

[Chapter—V, para 26].

(19) The Committee suggests that penal action should be taken against branches of foreign companies or 100% foreign equity holding units, manufacturing drugs without Government authority (Valid licence).

[Chapter—V, para 27].

(20) The Committee suggests that the NDA should review the norms for payment of research contribution, technical know-how fees etc., by foreign companies.

(Chapter—V, para 28].

(21) The Committee recommends that a suitable machinery should be evolved to check that the conditions imposed in industrial and other licences are fulfilled by foreign firms before remittances broad are permitted.

[Chapter—V, para 29].

(22) The small scale sector should be a prohibited area for foreign companies.

[Chapter—V, para 30].

(23) The Committee recommends that excise duty should be levied on drugs sample distributed by manufactures. All expenditure incurred on samples by drug manufacturers should not be deemed to be business expenditure for purposes of corporate taxation. Supply of samples may however be permitted, as at present, for the first three years from the date of introduction of a product for the first time by an Indian Company.

[Chapter—V, para 31].

(24) The Committee appreciates the importance of educating the people residing in rural areas about the use of house-hold remedies, and advertisments of drugs may have to be permitted to serve this limited need.

[Chapter—V, para 32].

(25) The prices of imported bulk drugs, intermediates and raw materials should be screened by the NDA and wherever there are reasons to doubt that they are excessive, the prices should be brought down. If the directions, issued by Government in this connection are not complied with by the companies, the letter should be taken over by Government.

[Chapter—V, para 33].

(26) The NDA should look into the cases of all unimplemented licences, including those involving basic manufacture of bulk drugs in a phased manner, and should suggest necessary action.

[Chapter—V, para 34].

(27) Trade Marks registered in India by foreign firms for formulations should not be permitted to be renewed if similar formulations are processed in India by Indian firms. The provisions of the Trade and Merchandise Marks Act should be examined in this connection.

[Chapter—V, para 35].

(28) In regard to allotment of raw materials to Indian sector, the Committee recommends that liberal allocations of raw materials for essential new formulations and to new units should be made.

[Chapter—V, para 37]

(29) Indian firms should be given special consideration. in matters relating to exports, as follows:—

(a) wholly Indian companies should be exempted from the export obligation as applicable presently; and
(b) additional incentives like extra foreign exchange for import of raw materials and conponents should be provided in case they export their products.

[Chapter—V, para 38].

(30) The monetary limit for investment in plant and machinery for a small scale unit in the drug industry should be raised to Rs. 20 lakhs.

[Chapter—V, para 40].

(31) The NDA should look into the difficulties experienced by the small scale sector in obtaining import licences for machinery and equipment and a satisfactory solution be found. The Committee also wishes to point out that the recommendations made by a Committee appointed by the Ministry of Petroleum & Chemicals, soon after the Price control measure cover drugs were introduced to help the small scale sector of the industry, should be implemented expeditiously.

[Chapter—V, para 40]

(32) Small scale manufacturers producing bulk drugs should be advised by the State Drug Control Authority to register their production capacities with the DGTD, Drug Controller (India), and the Ministry of Petroleum & Chemicals. Registration of capacities should be done on the basis of the information supplied by manufacturers through the State Drug Control authorities regarding their potential capacity of production, the level of production achieved, the raw materials required for manufacture, the specifications of the drug and their sale prices. The capacities for production as registered should be taken into account by Government while granting Industrial Licences.

[Chapter—V, para 41]

(33) The NDA should maintain a comprehensive Drug Information Service in respect of the items mentioned in para 42.

[Chapter—V, para 42].

(34) The Committee recommends that a subject index should be prepared immediately and maintained by the Patent Controller's Office, regarding the pending applications to guide the intending entrepreneurs who after inspecting the same could decide the course of action themselves. It should also be helpful if the Patents Office brings out a list of patents applications which are rejected after examination by that office. The Committee would also recommends that wherever an Indian entrepreneur has set up any basic production within a certain specified period which might infringe on the coverage claimed in the pending applications, a suitable solution should be found out whereby the concerned entrepreneurs could continue with their manufacturing operations.

[Chapter —V, para 44].

(35) Whenever foreign companies apply for manufacture of bulk drugs, Government should issue a notice about the application and its terms and ask the Indian companies and the public sector units to inform with a period of two months, whether they can take up the manufacture of such drugs. The applications should be considered in the light of the replies received from Indian companies and the public sector units. This, however, will not apply to applications received for bulk drugs manufactured in accordance with the recommendations made in para 24.

(Chapter—V, para 45)

(36) A special cell should be established in the NDA to process the representations received from the drug industry in connection with the availability of raw materials, solvents etc. from indigenous sources. NDA should look into this problem expeditiously in consultation with the various agencies involved.

(Chapter—V, para 46)

(37) The Government should keep medical profession in touch with the policies and concepts on the development of drug industry. For this purpose, NDA should have a top-level Committee consisiting of the representatives of the medical profession, Ministry of Health, various sectors of the drug industry and State Drug Controller.

(Chapter—V, para 47)

(38) Export of basic chemicals, solvents and bulk drugs which we import or are deficient in, should not be allowed.

(Chapter—V, para 49)

(39) Indian Council of Medical Research should concentrate its attention particularly on the discovery of the newer drugs for tropical diseases. NDA should be assigned the supervisory task in this regard. The Committee endorses the recommendations of the Task Force on the subject.

(Chapter—V, para 50)

(40) NDA should screen the import of technology required by the drugs industry. The import of drugs having low-volume turnover, like anti-cancer drugs, should be allowed for a period of 2 years. At the end of two years, if the sales value exceeds Rs. 10 lakhs, the concerned unit should be permitted to undertake the bulk manufacture of the drug, on payment of royalty upto 5% of net sales realisation of the finished products i.e. sale value minus excise duty and trade commission. Export obligations need not be imposed in such cases.

(Chapter—V, para 51)

(41) Considering the vastness of the country, dispersal of the industry is essential. Within states, the industry should not be allowed to concentrate in or around towns and cities. States should provide sufficient incentives to the industry and help them to develop in the backward regions where the basic facilities are available.

(Chapter—V, para 52)

(42) State Governments should enlist the support of drug manufacturers, leading organic chemists, botanists etc. and make a survey of the raw materials, plant products, animal products, solvents etc. that are available in their regions. States should also publish brochures setting forth the raw material position and the facilities and concessions that prospective manufacturers can hope to receive. They should also form Joint Sector Ventures in collaboration with well established companies or technical entrepreneurs. West Bengal offers good scope for development of phyto-chemical industry in that State in the Joint Sector. Joint Sector Ventures should also be set up for the manufacture of glass containers, tubings for ampoules and other packing materials like aluminium foils etc.

(Chapter—V, para 53)

(43) In view of the soaring prices and inadequate availability position of petroleum-based chemicals, greater attention should be paid on coal-carbonisation, as abundant supplies of coal are available in the country. The coal carbonisation complex situated in Durgapur has already been developed to a cetrair stage and its potentiality should be explored fully by the Central Government. Similarly the coal reserves in Maharashtra and Andhra Pradesh should be utilised and coal carbonisation complexes be developed in those regions. The Committee would urge on the State Governments and Central Government to give serious consideration to the development and utilisation of these coal resources.

(Chapter—V, paras 54 & 55)

(44) Uninterrupted supplies of electric power and abandant supply of water should be ensured to the drug industry.

(Chapter—V, para 56)

(45) Our recommendations for regularising production by foreign units in excess of their licensed capacity is subject to the overall condition that this should only be allowed if Indian Sector or the public sector is not manufacturing this or there is no scope of it being manufactured in the near future.

(Chapter—V, para 57)

ANNEXURE—I

Growth of Assets of Important Units Having Foreign Equity

(Chapter—V, para 3)

S. No.	Name of the Firms	Original Equity	Present total paid-up capital of the Indian firm.			Paid up capital held by the foreign share-holders			Total of4-5&6	Total 7,8&9	Turn-over		
			Issued for Cash	Issued for consideration other than Cash	Issued by bonus Shares	Issued for Cash	Issued for consideration other than Cash	Issued by bonus Shares	Rs./ Lakhs	Rs./ Lakhs	Year		Reserves
		Rs.	Rs.	Rs.	Rs.	Rs.	Rs.	Rs.				Rs. Lakhs	Rs. Lakhs
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)
1.	A.C.C.I.	35,34,000	310,00,000	..	124,00,000	235,00,000	..	93,00,000	534.00	328.00	1972-73	3316	298
2.	Anglo-French Drug Co.	10,000	10,000	..	..	8,000	..	..	0.10	0.08	1973	227.69	49
3.	Bayer (I) Ltd.	4,00,000	300,00,000	..	..	172,34,500	..	..	300.00	172.345	1973	1578	368
4.	Beechem .(I) Ltd.	1,00,000	1,00,000	5,00,000	..	1,00,000	5,00.000	..	6.0	6.0	1973-74	127	1
5.	Boehringer—Knoll	15,00,000	35,00,000	..	25,00,000	16,80,000	..	12,00,000	60.00	28.80	1972-73	346.86	54
6.	Boots Co. Ltd.	10,00,000	42,50,050	9,99,950	25,00,000	20,00,050	9,99,950	15,00,000	77.50	45.00	1973	778.43	126
7.	Burroughs Wellcome & Co.	5,00,000	45,00,070	4,99,930	..	45,00,070	4,99,930	..	50.00	50.00	1973	419.10	103
8.	Ciba of India Ltd.	3,00,000	61,00,000	14,00,000	412,50,000	34,75,000	14,09,300	268,12,500	487.50	316.87	1973	3122.00	403
9.	Cyanamid (I) Ltd.	1,50,200	26,05,300	44,09.300*	..	1,50,200	44,09,300	..	70.146	45.595	1973	1201.00	485
10.	Glaxo Labs.	1,50,000	210,00,000	150,00,000	360,00,000	30,00,000	150,00,000	360,00,000	720.00	540.00	1973-74	3639.00	758
11.	Johnson & Johnson	20,00,000	24,00,000	..	12,00,000	18,00,000	..	9,00,000	36.00	27.00	1973	489.36	92
12.	Merck Sharp & Dohme	180,00,000	180,00,000	..	..	108,00,000	..	..	180.00	108.00	1973	1051	93
13.	Parke Davis Ltd.	87,50,000	105,00,000	..	..	87,50,000	..	..	105.00	87.50	1973	1062	291
14.	Pfizer Ltd.	2,00,000	265,91,550	..	292,36,680	200,00,000	..	220,00,000	558.28	420.00	1973	2570	823
15.	Reckitt & Colman.	30,00,000	190.00,000	60,00,000	..	115,00,000	60,00,000	..	250.00	175.00	1972-73	802.74	144
16.	Richardson Hindustan Ltd.	2,000	50,00,000	..	20,00,000	27,50,000	..	11,00,000	70.00	38.50	1972-73	546	93
17.	Roche Product Ltd.	100,00,00	100,00,000	..	..	89,00,000	..	..	100.00	89.00	1973	926	330
18.	Sandoz (I) Ltd.	10,00,000	140,00,000	10,00,000	..	80.00,000	10,00,000	..	150.00	90.00	1973	1556.42	489
19.	Searle (I) Ltd.	60,00,000	60,00,000	..		27,00,000	..	..	60.00	27.00	1973	185.33	36
20.	Wyeth Labs. Ltd.	33,30,000	75,00,0000	..	..	55,50,000	..	..	75.00	55.50	1973	393	63
21.	Abbott Labs. Ltd.	1,00,000	1,00,000	..	..	1,00,000	..	..	1.00	1.00	1973	824.07	159
22.	C.E. Fulford Ltd.	4,00,000	4,00,000	..		4,00,000	..	..	4.00	4.00	1973	159.48	11
23.	Dental Products of India	2,00,000	3,40,000	..		1,66,600	..	..	3.40	1.666	1973	19.00	8

24. E. Merck Ltd.	20,00,000	62,21,800	12,78,200	..	32,21,800	12,78,200	..	75.00	45.00	1973	477.28	34
25. Criffon Labs.	2,00,000	1,81,740	18,260	..	1,40,20	18,260	..	2.00	1.588	1973	243.00	30
26. Indian Schering Ltd.	83,500	1,00,000	..	5,00,000	88,700	...	4,43,500	6.00	5.32	1973-74	414	81
27. Roussel Pharm	1,96,000	6,37,000	17,000	..	2,18,000	..	..	6.54	1.18	1973	233.66	49
28. Dupher Interfran	8,00,000	27,00,000	..	9.00,000	13,50,000	..	4,50,000	36.00	18.00	1973	324.86	64
29. Goeffrey Manners & Co.	1,000	5,01,000	..	90,99,000	3,60,000	..	39,60,000	96.00	43.20	1973	1536.69	218
30. Hoechst Pharm	20,00,000	80,00,000	..	95,52,200	40,00,000	..	47,76,100	175.52	87.76	1973	2172.48	619
31. Martin & Harris	N.A.	16,77,090	1,50,000	19,00,000	1,000	1,50.000	17,01,090	37.27	18.52	1973	122	N.A.
32. Organon (India) Ltd.	97,54,900	97,54,900	..	..	47,79,900	..	..	97.54	47.79	1973	316	25
33. Suhrid Geigy Ltd.	7,20,000	27.00,000	..	233,00,000	12,82,000	..	110,68,000	260.00	123.50	1972-73	1500.51	262
34. Synbiotics Ltd.	60.00,000	75,00,000			36.00,000	..	..	75.00	36.00	1972-73	313.80	99
35. Uni-Sankyo Ltd.	1,00,000	11,90,000			5.81,100	..	..	11.90	5.83			N.A.
36. Wander Ltd.	9,70,000	4,67,500	5,22,500*	5,10,000	22.000	3,74,000	2,04,000	15.00	6.00	1973	127.77	17
37. Warner Hindustan Ltd.	70,00,000	70,00,000	..	28.00,000	35,00,000	..	14.00,000	70.00	35.00	1973	639.00	154

*Towards Import of Equipment.

ANNEXURE

List of Permission/No Objection Letters issued
(Chapter V—Para 4)

S. No.	Permission/No objection letter No. & date	Item of manufacture	Capacity, if any	Remarks
1	2	3	4	5
1. *Hoechst Pharmaceuticals Ltd. Bombay*				
1.	3/15/62-Ch.III dt. 15-10-62	(i) Hostacycline Drope (ii) Hostacycline Syrup	25,000 bottles of 10 ml each per annum 10,000 bottles of 80 ml each per annum	*Within overa capacity of Fost
2.	3/15/62-Ch. III dt. 24-9-62	(i) Hostacortin (ii) Hostacortin H (iii) Pyracortin (iv) Pyracortin Forte (v) Novalgin Quinine *(vi) Fostavital	6 lakh tablets p.a. 35 lakh tablet p.a. 10 lakh tablet p.a. 10 lakh tablets p.a. 5 lakh Dragees p.a. 20 lakh dragees p.a.	approved in Li No. L/22/No.-164 60 dt. 2-7-60
3.	3/15/62-Ch. III dt. 11-6-1962	Afran	6 lakh tablets p.a.	
4.	3/14/61-Ch. III dt. 19-8-61	(i) Aspasan (ii) Efosin (iii) Polyfen (iv) Tumoson (v) Reverin (vi) Baralgan Tabs. (vii) Baralgan Amps.	12 lakh tablet p.a. 240 litres p.a. 120 lakh tablets p.a. 8000 Kgs. p.a. 10 lakhs vials (350 mg/vial) 2 lakhs vials (275 mg/vial). 30 lakh tablets p.a. 7.5 lakh amp. p.a.	
2. *Geoffrey Manners*				
1.	1/56/62-Ch. III dt. 1-11-62	Benzathino Penicillin	G 360 Kgs. p.a.	
2.	1/56/62-Ch. III dt. 20-8-1962	Meprobamate	3000 Kgs. p.a.	
3.	1/56/62-Ch. III dt. 9-4-1963	Antibiotics Vials	34,000 p.m.	
4.	3/69/62-Ch. III dt. 22-3-1963	Multivitamin Tabs.	60 lakhs p.a.	
5.	3/20/61-Ch. III dt. 27-5-1961	Premarin Tabs.	2.5 lakhs, p.m.	
6.	22/475/A(II)/60 dt. 19-1-1961	Dristan Tabs.	5 lakhs p.m.	
7.	22/438/IA(II)/60 dt. 19-1-1961	Zactrin Tabs.	1 million p.m.	
8.	22/465/IA(II)/60 dt.17-9-1960	Equaprin Tabs	12.5 lakhs p.m.	
9.	22/370/IA(II)/ dt. 26-10-1960	Trisulfose Tabs.	1 million p.m.	
10.	22/240/IA)II)/59 dt. 29-7-1959	Prozine	1 million p.m.	
11.	22/146/IA(II/58 dt. 6-10-1958	Equanitrate Brand Maprobamate and pentnacrythritol Tetran Nitrate T Tablets.	2.5 lakhs p.a.	
12.	HC-1/71/57 dt. 31-7-1957 & dt. 31-3-1958	(i) Penicillin V. Tablets 1 lakh IU per tab. 2 lakh IU per tab. (ii) Penicillin V with Triple sulpha Tabs	1 lakh p.m. 2 lakh p.m. 2 lakhs p.m.	
13.	22/100-IA(LB)/56 dt. 22-1-1958	Quanil Brand Moprobamate Tabs. (400 mg & 200 mg).		
14.	22/172-IA/LB/56 dt. 1-2-1957	(i) Clutamic Acid B Complex Tabs. (ii)) Vit. B-12-B.I. Rosperin Tabs. (iii) Malt Tonic (iv) Gripe Mixture (v) Laxative Tabs.		
15.	22/172/IA/II/56 dt. 4-9-1958	Manners Health Salt.		
16.	22/313/IA/II/59 dt. 16-6-1961	Manners Health Compound		

1	2	3	4	5
17.	22/172/IA/II/57 dt. 22-4-1957	(i) Lopvit (ii) Manovit (iii) Vitamycetni (iv) Protisole (v) Homules		
18.	22/125/IA/II/58 dt. 31-8-1959	Preparation 'H' Ointment		
19.	22/172/IA(I.A)/56 dt. 3-12-1956	(i) Ointment for ringworm (ii) Pain balm for head-aches (iii) Cold Tabs. (iv) Cough Syrup		
3.	*UNI-Laboratories Ltd.*			
1.	22/487/IA/II/60 dt. 22-1-1960	Aceto Phona Lisatin	20 Kgs. p.m.	
2.	22/309/IA/II/59 dt. 23-12-1959	(i) Chlorpromazine Hcl. (ii) Injections (25 mg. /cc).	5 lakh p.m. 100 litres p.m.	
4.	*Boots Co. India Ltd.*			
1.	22/433/IA/II/60 dt. 31-10-1960	Junivite (Kentitone)	20 gallons p.m.	
2.	22/430/IA/II/60 dt. 31-10-1960	Strong cremaffin with Phenolphthaloin	300 gallons p.m.	
3.	22/431/IA/II/60 dt. 31-10-1960	Otoxpear Drops	30 gallons p.m.	
4.	22/429/IA/II/60 dt. 24-1-1961	(i) Milk of Magnesia (ii) Chirana Cherry Cough Syrup (iii) Screen Travel Sickness Tab.	 600 gallons p.m. 8000 p.m.	
5.	22/449/IA/II/60 dt. 31-1-1961	Supersan	200 gallons p.m.	
6.	22/491/IA/II/60 dt. 1-2-1961	Opsan Eye Drops	90 litres p.m.	
7.	22/432/IA/II/60 dt. 5-11-1960	Cobe-tone Elixir	400 gallons p.m.	
8.	3/34/62-Ch. III dt. 27-7-62	Furamide Compound Tabs.	12 lakhs/year.	
9.	3/34/62-Ch. III dt. 28-1-1963	(i) Magmist Tabs. (ii) Safersol	120 lakhs. p.a. 200 litres p.a.	
10.	3/38/62-Ch. III dt. 9-3-1964	(i) Sweetex Liquid (ii) Penicillin V. with Triple Sulphanomide Tabs.	6000 litres p.a. 12 lakhs p.a.	Within over a Tableting capacity
11.	22/127/IA/LA/55 dt. 31-1-1956	(i) Jackosin Emulsion (ii) Triple Sulphanamide Tabs.	— —	
12.	40/70/58-M.C. dt. 18-6-1958	Elixir of Figs. (Figine)		
13.	22/196/IA/II/59 dt. 9-4-1959	(i) Sulphacitamide Eye Oint. 10% (ii) Fydal ex Tabs. (iii) Fydal Tabs. (iv) Didandin Tabs. (v) Penicillin V. Tabs. (vi) Thyroid Tabs. (vii) Chirana Cough Lozenges (viii) Calcium Gluconate Tabs. (ix) Sulpha Citramide Sodium Solution 10%		
14.	22/181/IA/II/59 dt. 11-4-1959	Piperli (Piperazine Citrate Syrup).		
15.	22/179/IA/II/59 dt. 18-4-1959	(i) Hydrocorterone Acetate Eye Drops (ii) Cortesone Acetate Eye Drops. (iii) Cortesone Acetate Eye Ointment (iv) Tablets of Cortesone Acetate B.P. (v) Hydromycin Ointment (iv) Hydromyoin Eye/Ear Ointment		
16.	22/212/IA/II/59 dt. 5-1959.	Delta-Stab Nesal Spray.		
17.	22/435/IA/II/60 dt. 31-10-1960	Tablets Cobeton	2 lakhs p.m.	
18.	22/230/IA/II/59 dt. 31-10-1960	Entamide Feeroate Tabs.	6 tabls. p.m.	
19.	22/483/IA/II/60 dt. 27-1-1961	Pipre lix Tabs.	1.05 lakhs p.m.	
20.	22/492/IA/II/60 dt. 1-2-1961	(i) Aprenox Tabs (5mg) (ii) Aprenox Tabs (2.5 mg),	2 lakhs p.m. 3 lakhs p.m.	

1	2	3	4	5
17.	22/172/IA/II/57 dt. 22-4-1957	(i) Lopvit (ii) Manevit (iii) Vitamycetni (iv) Protisole (v) Homules		
18.	22/125/IA/II/58 dt. 31-8-1959	Preparation 'H' Ointment		
19.	22/172/IA(LA)/56 dt. 3-12-1956	(i) Ointment for ringworm (ii) Pain balm for head-aches (iii) Cold Tabs. (iv) Cough Syrup		
3.	*UNI-Laboratories Ltd.*			
1.	22/487/IA/II/60 dt. 22-1-1960	Aceto Phona Lisatin	20 Kgs. p.m.	
2.	22/309/IA/II/59 dt. 23-12-1959	(i) Chlorpromazine Hcl. (ii) Injections (25 mg. /cc).	5 lakh p.m. 100 litres p.m.	
4.	*Boots Co. India Ltd.*			
1.	22/433/IA/II/60 dt. 31-10-1960	Junivite (Kentitone)	20 gallons p.m.	
2.	22/430/IA/II/60 dt. 31-10-1960	Strong cremaffin with Phenolphthaloin	300 gallons p.m.	
3.	22/431/IA/II/60 dt. 31-10-1960	Otoxpear Drops	30 gallons p.m.	
4.	22/429/IA/II/60 dt. 24-1-1961	(i) Milk of Magnesia (ii) Chirana Cherry Cough Syrup (iii) Screen Travel Sickness Tab.	 600 gallons p.m. 8000 p.m.	
5.	22/449/IA/II/60 dt. 31-1-1961	Supersan	200 gallons p.m.	
6.	22/491/IA/II/60 dt. 1-2-1961	Opsan Eye Drops	90 litres p.m.	
7.	22/432/IA/II/60 dt. 5-11-1960	Cobe-tone Elixir	400 gallons p.m.	
8.	3/34/62-Ch. III dt. 27-7-62	Furamide Compound Tabs.	12 lakhs/year.	
9.	3/34/62-Ch. III dt. 28-1-1963	(i) Magmist Tabs. (ii) Safersol	120 lakhs. p.a. 200 litres p.a.	
10.	3/38/62-Ch. III dt. 9-3-1964	(i) Sweetex Liquid (ii) Penicillin V. with Triple Sulphanomide Tabs.	6000 litres p.a. 12 lakhs p.a.	Within over a Tableting capacity
11.	22/127/IA/LA/55 dt. 31-1-1956	(i) Jackosin Emulsion (ii) Triple Sulphanamide Tabs.	— —	
12.	40/70/58-M.C. dt. 18-6-1958	Elixir of Figs. (Figine)		
13.	22/196/IA/II/59 dt. 9-4-1959	(i) Sulphacitamide Eye Oint. 10% (ii) Fydal ex Tabs. (iii) Fydal Tabs. (iv) Didandin Tabs. (v) Penicillin V. Tabs. (vi) Thyroid Tabs. (vii) Chirana Cough Lozenges (viii) Calcium Gluconate Tabs. (ix) Sulpha Citramide Sodium Solution 10%		
14.	22/181/IA/II/59 dt. 11-4-1959	Piperli (Piperaz ine Citrate Syrup).		
15.	22/179/IA/II/59 dt. 18-4-1959	(i) Hydrocorterone Acetate Eye Drops (ii) Cortesone Acetate Eye Drops. (iii) Cortesone Acetate Eye Ointment (iv) Tablets of Cortesone Acetate B.P. (v) Hydromycin Ointment (iv) Hydromyoin Eye/Ear Ointment		
16.	22/212/IA/II/59 dt. 5-1959.	Delta-Stab Nesal Spray.		
17.	22/435/IA/II/60 dt. 31-10-1960	Tablets Cobeton	2 lakhs p.m.	
18.	22/230/IA/II/59 dt. 31-10-1960	Entamide Feeroate Tabs.	6 tabls. p.m.	
19.	22/483/IA/II/60 dt. 27-1-1961	Pipre lix Tabs.	1.05 lakhs p.m.	
20.	22/492/IA/II/60 dt. 1-2-1961	(i) Aprenox Tabs (5mg) (ii) Aprenox Tabs (2.5 mg),	2 lakhs p.m. 3 lakhs p.m.	

1	2	3	4	5
21.	3/11/61-Ch. III dt. 15-4-1961	Strepsils Lozenges	8 lakhs p.m.	
22.	3/38/62-Ch. III dt. 4-2-1963	(i) Motha Quanlone (ii) Dexamethasone Tabs.	42 lakhs p.m. 16.80 lakhs p.m.	
23.	3/2/63-Ch. III 9-3-1964	(i) Ivax	12.000 Kgs p.m.	Within licensed over all capacity.
		(ii) Ascorbic Acid Tabs (50mg & 100 mg).	1.50 million p.a.	
24.	22/102/IA/LA/55 dt. 24-4-1956	Penicillin Lozenges		
25.	535/IA/II/57, dt. 1-4-1957	Sugar Coated Tabs.		
26.	22/120/IA/II/53 dt. 23-9-1958	Dolfa Stab Tabs.		
27.	22/230/IA/II/59 dt. 27-4-1959	Entamide Tabs.		
28.	22/211/IA/II/59 dt. 7-5-1959	Halazone Tabs.		
29.	22/102/IA/II/55 dt. 22-10-1959	Enzolets		
30.	23/311/IA/-1/59 dt. 19-11-1959	Hydranox 50 mg. Tabs.		
31.	8191-IA/II/57 dt. 18-12-1957	Mylol		
32.	40/67/58-HC dt. 31-5-58	Librox		
33.	49/(11)/52-IA(4)/60 dt. 25-11-60	Chloriside Dust		
5.	*M/s. May and Baker Ltd.*			
1.	22/259/IA/11/59 dt. 30-3-60	Chlorpromazine Hcl. B.P.	2508 Kgs.p.a.	
2.	22/434/1A/11/60 dt. 16-8-60	'Anthical' Cream	1200 Kgs. p.a.	
3.	22/168/1A/CA/56 dt. 11-10 -56	Anthisan Injection (includes Veterinary)		
4.	22/168/1A/CA/46 dt. 11-10-56	Avomine Tabs	—	
5.	22/244/1A/11/59 dt. 16-1-60	Avoprin Tabs	50.40 lakh Tab. p.a.	
6.	22/137/1A/CA/56 dt. 19-6-56	Acriflavine Powder 5 mg.	—	
7.	22/168/1A/CA/56 dt. 11-10-76	Gardenal Sodium Inj.	—	
8.	22/168/1A/CA/56 dt. 11-10-56	Largactil injection (including veterinary)	—	
9.	22/46/IA/L/54 dt. 16-9-55	Nivaquine injection	—	
10.	22/158/1A/CA/56 dt. 3-9-56	Plasmosan brand sol	—	
11.	22/244/IA/11/59 dt. 16-1-60 and dt. 19-10-60	Rovamycin Capsules	6 lakh p.a.	
12.	22/93/1A/L/55 dt. 17-5-55	(i) Sulphamerazine tablets (ii) Sulphadimidene tabs.	Within the overall capacity	

1	2	3	4	5
13.	22/168/IA/CA/56 dt. 11-10-1956	Anthionaline Sol.	—	
14.	3/8/60-Ch. III dt. 24-2-61	Carbachol injection	300 litres p.a.	
15.	22/378/IA/11/60 dt. 15-5-60	Digestol Tabs.	2.40 lakhs p.a	
16.	22/422/IA/11/60 dt. 20-7-60	Embazin Sol.	1800 litres p.a.	
17.	3/75/62-Ch III dt. 19-1-63.	Embazin Promix Powder	108 tonnes p.a.	
18.	22/409/IA/11/60 dt. 18-1-61	Strinacin tabs	30.000 p.a.	
19.	22/137/IA/LA/55 dt. 14-5-56	Sulphanilamide Powder 1 lb.		
20.	22/377/IA/11/60 dt. 15-6-60	Trinamide Powder	—	
21.	3/75/52-Ch. III dt. 27-7-63	Peroxyl Sol.	55,000 litres p.a.	
22.	22/19/IA/L/55 dt. 28-6-55	Anthicol brand lotion	—	
23.	22/244/IA/II/59 dt. 16-1-60	Rovamycin brand Spyramaycin Capsules	6 lakhs	
		Avoprin brand promethazine chloro-theopylline with acetyl salicylic acid	30.4 lakhs	
24.	22/158/IA/LA/56 dt. 3-9-56	Plasmosan brand solution	--	
25.	22(L-22)IA-II/60 dt. 26-7-60	Embazin Brand Sulpha-Quinozaline Solution		
6.	*M/s Roche Products Ltd.*			
1.	22/399/IA/11/60 dt. 13-10-60	Rovimix	Consuming Vitamin A 2.4 tonnes	
2.	3/53/61-Ch. III dt. 28-2-62	(i) Taractan 15 mg. tabs.	4 million p.a.	
		(ii) Taractan vials 50 mg.	150 litres p.a.	
		(iii) Prostigmin tabs.	1 million p.a.	
		(iv) Prostigmin ampoules & vials	280 litrds p.a.	
3.	3/39/62-Ch. III dt. 1.8.62.	Librax tabs	6 million p.a.	
4.	3/39/62-Ch. III dt. 25-9-62	Librium Ampoules	150 litres p.a.	
5.	3/39/62-Ch. III dt. 6-11-62	Marplan tabs.	4 million p.a.	
7.	*Sandoz (India) Limited*			
1.	22/481/IA/II dt. 18-1-62	Bephan Retard Tabs	60 lakhs p.a.	
2.	3/6/61-Ch. III dt. 8-1-61	Mellaeric Tabs	100 lakhs p.a.	
3.	3/6/61-Ch. III dt. 5-4-61	(i) Vitamin C + Ferronicum Tabs	50 lakhs p.a.	
		(ii) C.C.F. Sandoz	75 lakhs 0.a.	
		(iii) Ferintrin Caps.	100 lakhs p.a.	
		(iv) Ferintrin Syrup	30,000 litres p.a.	
		(v) Calcibronate+Bl	10,000 -do-	
		(vi) Ferintrin Sol.	1,000 -do-	
		(vii) Calcibronate+Bl.	10,000 -do-	
		(viii) Calcibronate+Bl Granules	10,000 -do-	

1	2	3	4	5
4.	3/43/62-Ch. III dt. 6-11-62	Nutrolac Tabs Caps.	200 lakhs p.a.	
5.	3/43/62-Ch. III dt. 20-12-62	(i) Cal. Sandoz Tabs fortified with Vit. D.	200 lakhs p.a.	
		(ii) Calglufor	300 lakhs p.a.	
6.	HC/1/23/58 dt. 4-3-58	(i) Cal. Sandoz Chock Tab	—	
		(ii) Belladenal Retd.	—	
		(iii) Bellargal Rtd.	—	
		(iv) Sandosten + G.S. Spray	—	
		(v) Sandortin + G.S. Syrup	—	
7.	22/125/IA/11/55 dt. 14-5-57	Ferronicum	18,000 litres p.a.	
8.	3/43/62-Ch. III dt. 4-9-62	(i) Cal. Sandoz C Vit. B 12	80,000 litres p.a.	
		Calcium Sandoz Multi dose with Vit. D2 and B 12	14,250 litres p.a.	
9.	22/296/IA/11/60 dt. 11-7-60	(i) Acylanid 2 ml ampl.		
		(ii) Ballafine 1 ml.		
		(iii) Godilanid		
		(iv) Digilanid 2 ml.		
		(v) Digoxin 1 ml.		
		(vi) Dihydorgot 1 ml.		
		(vii) Gynirgon II 1 ml.		
		(viii) Hydergone 1 ml.		
		(ix) Laboline 1 ml.	—	
		(x) Mothergin 1 ml.		
		(xi) Noogynergan 1 ml.		
		(xii) Scillaron 1 ml.		
		(xiii) Strophosid 1 ml.		
		(xiv) Syntocinon 1-1/2 ml.		
8.	*Anglo French Drug Co. (Eastern) Ltd.*			
1.	22/100/IA/L/55 dt. 4-7-55	(i) Maxamottes		—
		(ii) Lypofax Tablets		—
2.	2008/IA/II/57 dt. 15-4-1957	Sulpha Tablets		—
3.	22/214/IA/II/59 dt. 14-5-59	Malfax		—
4.	5/213/IA/II/59 dt. 1-6-59	Afder		—
9.	*Parke Davis (India) Ltd.*			
1.	22/239/IA/II/59 dt. 21-8-59	Prednisolone tabs. (5 mg.)	60,000 p.a.	
2.	3/22/61-Ch. III dt. 26-7-61	Chemoprim Tabs.	5 lakhs per month	
3.	3/61/62-Ch. III dt. 10-12-62	Benadriyl Lozenges	25,000 × 100 p.m.	
10.	*Indo Pharma Pharmaceutical Works (P) Ltd.*			
1.	3/6/62-Ch. III dt. 6-11-62	(i) Spasmindon Pediatric drops	600 litres p.a.	
		(ii) Scabin ointment	3000 kg. p.a.	
2.	3/6/61-Ch. III dt. 16-8-62	Ferrous Gluconate, B.P. Sugar coated tabs.	12 million p.a.	
3.	3/55/61-Ch. III dt. 28-7-62	Asmacort T. Indon Tabs.	36 lakhs p.a.	
4.	3/35/61-Ch. III dt. 24-7-62	Piperazine Indon Tabs.	72 lakhs p.a.	
5.	3/6/62-Ch. III dt. 2-3-62	Diuret Indon Tabs.	1 lakhs p.a.	

1	2	3	4	5
6.	22/450/IA/II/60 dt. 13-9-60	Neospasmindon Tabs.	—	
7.	22/410/IA/II/60 dt. 13-6-60	Vitamin don 'C' 500 mg. tab.	—	
8.	22/279/IA/II/60 dt. 27-5-60	(i) Asmacortindon tabs. (ii) Gravidindon tabs. (iii) Lysindon B (iv) Maprotonecindon Tabs (v) Salexindon Tabs	50 lakhs p.a. 12 lakhs p.a. 600 litres p.a. 12 lakhs p.a. 12 lakhs p.a.	
9.	22/282/IA/II/59 dt. 13-1-60	(i) Predinsolen Indon Tabs (ii) Meprindon	1 lakh p.m. 2 laks p.m.	
10.	22/268/IA/II/59 dt. 13-1-60	(i) Dexamethafon tabs (ii) Hydrochloro Thiazide tabs	1 lakh p.m. 1 lakh p.a.	
11.	22/85/IA/II/58 dt. 3-11-59	(i) Butazolone Indon (ii) Gariatindon (iii) Maprocolone Indon (iv) Talbutamide Indon (v) Asmatriad Indon	— — — — —	
11.	*M/s. Glaxo Laboratories India Ltd. Bombay*			
1.	3/24/62-Ch. III dt. 26-7-62	(i) Hydroxocobalamin (vial of 5 ml.) (ii) Anacobin B (Vial of 5 ml.)	30,000 p.a. 30,000 p.a.	The party obtained COB Licence No. L/22/454 72 Ch. III dt. 7-11-72
2.	22/468/IA/II/60 dt. 17-1-61	Aluminium Hydroxide Magnesium Carbonate Gel. Tabs. (Almacarb)	5 (five) lakhs tablets p.m.	
3.	22/349/IA/II/60 dt. 16-1-60	Volpar Foaming tabls.	1 (one) million tabs p.m.	
4.	22/9/IA/II/57 dt. 25-7-58	Prodasin tablets	—	
5.	HC-1/64/57 dt. 11-9-57	Capsulating Vitamins and other products	—	
6.	22/203/IA/II/59 dt. 20-4-59	Distivit Vitamin B12 Tabs.	—	
7.	3/1/63-Ch. III dt. 5-8-63	Radio-Malt	500 Kgs. p.m.	
8.	22/22/L/R/52 dt. 22-5-54	Complex B tabs Folic Acid Vitamin B Complex B2 Macrafolin-Iron Tabs. Complex B liquid Complex B Forte Tabs Complex B Forte Vials Comycin S Vials Comycin S Stabs. Solution Comycin S Syrup Comycin S Tabs. Crystamycin Vials Seolomycin Vials		
9.	22/104/IA/L/55 dt. 15-7-55 & 4-8-55	Helmacid Tabs. Helmacid Liquid Helmacid with Sonna		
12.	*Merck Sharp & Dohme of India Ltd.*			
1.	22/346/IA/II/60 dt. 29-1-60	'Vitmol' Compound		
2.	1/24/60-Ch. III dt. 7-12-62	(i) Tri-redisol H (ii) Periactin Elixir (iii) Periactin Tabs	Within the overall licensed capacity 12 lakhs	

1	2	3	4	5
13. *Johnson & Johnson of India Ltd.*				
1.	3/73-62-Ch. III dt. 16-1-1963	(i) Plaster of Paris B.P.C. (ii) K.Y. Jelly (iii) Calamine B.P. (iv) Calamine I.P.	500 tons 2500 lbs. 50 tons 50 tons	
14. *Cyanamid (India) Ltd.*				
1.	A & I-31(1)/65 dt. 4-5-1965	Ledermycin Dimethyl Chlortotracycline 300 mg.	—	
2.	3(28)/62-Ch. III dt. 8-1-1963	Diethyl Carbamazine tablets	10 lakhs	
3.	3(15)/63-Ch. III dt. 22-6-1963	Vi Magna Multivitamin Drops	2400 litres	
4.	3(28)/62-Ch. III dt. 22-10-1962	Stresscap Capsules	18 lakhs	
5.	3(28)/62-Ch. III dt. 4-8-1962	Aureomycin Chlortetracycline Soluble oblets	1.50 lakhs	
6.	3(39)/61-Ch. III dt. 27-7-1962	Pethibamate tablets	9 lakhs	
7.	3(39)/61-Ch. III dt. 4-7-1961	Ledercort Cream with Neomycin	48000 tubes of 5 gm.	
8.	3(39)/61-Ch. III dt. 28-9-1971	(i) Incremin with iron Syrup (ii) Lederkyn Acetyl Pedictric suspension	3500 litres 36000 litres	
9.	A& I-10(2)/61 dt. 24-1-1961	(i) Aurofac (ii) Aurofac 2 A	— —	
10.	22(362) IA (II)/60 dt. 19-5-1960	Filibon Capsules	—	
11.	22(367)/IA(II)/60 dt. 30-3-1960	Ledermycin Capsuls	14 lakhs	
12.	22(366)/IA(II)/60 dt. 14-3-1960	Austrin Capsules	—	
13.	22(222) IA(II)/(II)/59 dt. 30-5-1959	Vi Magna Granules	—	
14.	22(232)IA(II)/59 dt. 12-5-1959	Varidase Baclal Tablets	—	
15.	22(151)/IA(II)/58 dt. 1-10-1958	(i) Liver injection (ii) Achromycin Soluble tablets	—	
16.	22(180)IA(II)/58 dt. 6-1-1959	Aureomycin Ointment	—	
17.	22(105)IA(II)/58 dt. 16-8-1958	Ledercort tablets	—	
18.	22(348) IA(II)/60 dt. 13-3-60	Ledercort Acetonide Cream Ointment Ledercort Diacetate Parenteral	48000 tabs of 5 gms, each 48000 tabs. of 5 gms. each 25,000 amp. of 5 ml. each.	
19.	22(105)IA(II)/58 dt. 5-6-1958	Incremin Lysine Vitamin Drops	—.	
20.	22(72)-IA(II)/58 dt. 24-4-1958	(i) Achromycin V. Liquid Pediatric Drops. (ii) Achromycin V Syrup	— —	
21.	22(72)IA(II)/58 dt. 30-1-1958	Achromycin Hcl Ophthalmic oil suspension	—	
22.	22(53)IA(II)/57 dt. 17-10-1957	Lederplex Parenteral	—	
23.	22(18) IA(II)/57 dt. 27-5-1959	(i) Lederkyn tablets & Syrups (ii) Achromycin V Caps.	— —	
24.	22(20)IA/(II)57 dt. 28-5-1957	Protein preparations	—	

1	2	3	4	5
25.	22(58)IA(L)/54 dt. 1-11-1966	Miltown tablets	—	
26.	22(58)IA(L)/54 dt. 12-7-1956	Achromycin Intramuscular	—	
27.	22(58)IA(LA)/55 dt. 1-3-1956	Delphical Sol.	—	
28.	9422-IA(A)/55 dt. 19-12-1955	(i) Pacitane tablets (ii) Diamox tabs.	— —	
29.	22(52)IA/52 dt. 22-9-1955	Aureomycin Stress Formula Caps.	—	
30.	22(52)IA(R)/54 dt. 1-8-1955	Simple Liver Inj.	—	
31.	22/52/IA(R)/52 dt. 12-7-54	Liver Inj. with Folvite	—	
32.	22/52/IA(R)/52 dt. 30-12-1953	Folvite Solution Folvite Tablets Folvron Capsules Folvron Elixir Gevral Capsules Gevrabouse Elixir Hetraxan tablets Hetrazan Syrup Ledercillin Torches, Lederplex Liquid Lederplex Capsules Normecytin tablets Normecytin-Fovite tablets Perfolin capsules Perihemiz capsules Ferihemin Liquid Prenetal Capsules Sulfaguanidine tablets Sulfamerazince tablets Triple Sulfas Vi-Delta capsules Vi-Delta Emulsion Vi-Magna Capsules Vi-Magna Syrup		

15. *Alembic Chemicals Works Co. Ltd.*

1.	22(262)IA(II)/59 dt. 19-2-1960	(i) Multivitamin Preparations	1080 litres
		(ii) Ante Ananomia Preparations	
		Injections	600 litres
		Tablets	600,000
		Oral	2400 litres
		(iii) Antinauseant Preparation	1,44 lakh tabs.
		(iv) Anti Hasmerrhagic Preparation	2.40 lakh tabs
		(v) Anthe Imintic Preparation	0.60 lakh tabs.
		(vi) Enzyme Preparations	
		(i) Trypsin Injection	6000 ml.
		(ii) Chyrmotrypsin Injection	6000 ml.
		(iii) Ointment	75.6 kgs.
		(vi) Bioflavinoid preparation	2.40 lakhs tabs.
2.	22(110)IA(L)/75 dt. 21-9-1955	(i) Sylomin tablets (ii) Silomag tablets (iii) Alzide PAS tabs. (iv) Zeet tabs. (v) Chlorpromazine Hcl tabs. (vi) Alzide Streptomycin Inj.		

16. *Deys Medical Stores (Manufacturing) Pvt. Ltd.*

1.	40(124)/58-MC dt. 15-7-1958	(i) Aralon tablets (ii) Aralin tablets (iii) Franol tablets (iv) Milibis tablets (v) Monodral tablets (vi) Philips Milk of Magnesia tablets & Syrup (vii) Tolopapue tablets	

1	2	3	4
2.	22(423)-IA(II)/60 dt. 14-7-1960	(i) Dexamethasone tablets (ii) Dexamethasone Eye Drops	72 lakhs tablets 2.40 lakhs vials
3.	22(424)IA(II)/60 dt. 14-7-1960	Carbutamide tablets	—
4.	3(44)/61-Ch. III dt. 25-5-1962	(i) Papsamer tablets (ii) Synephrical tablets	67 lakhs 30.6 lakks
5.	3(44)/61-Ch. III dt. 1-11-1962	Fenarol tablet	29.20 lakhs
17.	*Standard Pharmaceuticals Ltd.*		
1.	3422/IA(LA)56 dt. 14-5-1956	Anthelmintic and Vermifuge	—
2.	22(172)IA(II)/58 dt. 1-12-1958	(i) Alliquin Tablets (ii) Lucitone (iii) Dectomet	— — —
3.	3(21)63-/Ch. III dt. 10-10-1963	Phthalyl Sulphathiazole Diodo Oxyquinoline Ante Tussive Cought Syrup Contraceptive Tablets	24 lakhs Tablets 24 lakhs Tablets 30000 kgs. 24 lakhs Tablets
4.	1(33)/62-Ch. III dt. 9-1-1963	Tensolysin Hystalizine Hypnodyne	—
18.	*German Remedies Ltd.*		
1.	22(98)IA/II/58 dt. 21-1-1961	Sulfone tablets	5 lakhs
2.	3(1)/61-Ch. III dt. 20-1-1962	Selvigon dragees/drops	36 lakhs 600 litres
3.	3(20)/62-Ch. III dt. 5-11-62	Itridal tablets (20 mg. Protheiphendyl and Cyclobarbitone sodium 100 mg) Sulfone tablets Thrombophob ointment Heemocuro ointment Heparin vials Itridal ampolles Sulfono suspension	7.2 lakhs 30 lakhs 1800 kgs. 36000 vials 1.2 lakhs 6000 litres
19.	*Reckitt & Colman of India Ltd.*		
1.	3(19)/61-Ch. III dt. 27-9-61	Loxene	50,000 lbs.
2.	3(46)/60-Ch. III dt. 24-1-61	All purpose ointment	30,000 kgs.
20.	*M/s. Martin and Harris Ltd.*		
1.	HC-1(20)/58 dt. 19-2-58	Agarol Anusol ointment Anucol supponsitories Cal Bis-ma Gelusil tablets Sloans liniment Sloans Balm Tedral tablets plain Proloid tablets Angiers emulsion	
2.	3691-IA(II)/58 dt. 24-7-58	Magnesia Magma USP	
3.	22(283) IA (II)/59 dt. 5-1-60	Strik	384,000 litres
4.	HC-1(25)/57 dt. 7-3-57	Formulations of Aspirin, Sulpha drugs, PAS, INH, Diodohydroxyquinoline Hormones, and gladular products, Vitamin preparations Malt extract and fish liver oil Anti malarial drugs, Anti histamine drugs Antileprosy drugs, Barbiturates, Ephedrine Hcl.	

1	2	3	4	5
M/s. Ciba of India Ltd.				
1	22(90)-IA (ii)/55 dt. 13-6-1957	(i) Nimecol (ii) Bradex-violoform		
2	HC-1(24) 56 dt. 30-9-1957	(i) Serpasil tablets, drops and ampoules from locally manufactured serpasil (Reserpin). (ii) Adelphane tablets from locally manufactured serpasil (Reserpine) and imported 1-4 dihydrazinophthazine. (iii) Elkosin syrup from locally manufactured Elkosin (Sulphasomidine). (iv) Triolandren ampoules from locally manufactured perandren (Testosterone propionate) and imported Testosterone valerianate and undecylenate. (v) Remandren from locally manufactured perandren (Methyl Testosterone) and imported Thiayoestradiol.		
	HC-1(149)'57 dt. 24-1-1958	(i) Antrenyl tablets—from oxyphenonium bromide. (ii) Neuro-Transentin tablets from Adiphenine Hcl and Phenobarbitone BP (iii) Spasmo labalgin tablets—from Amidopyrine B.Pc. Allobarbitone BPC and Adiphanine Hcl. (iv) Priscophen tabs—from phenobarbitone BP tolazoline Hcl. B.P.C. and Aidphenine Hcl. (v) Etieyclin li ng—from Ethinyl oestradiol B.P.C. (vi) Pyribenzamine tabs—from Tripelemanamine Hcl. U.S.P. (vii) Triscol tabs—from tolazoline Hcl B.P.C.		
	Ampoules	(i) Cibalgin amps—from Amidopyrine B.P.C. and Allobarbitone B.P.C. (ii) Dial amps—from Allobarbitone B.P.C. (iii) Percorton amps.—from Deoxycortone acetate B.P.C. (iv) Priscol amps—from Tolazoline Hcl. B.P.C. (v) Perandren Micro-crystules—from testosterone isobutyrate.		
	Ointments:	(i) Antistine cream—from Antazoline Hcl. B.P.C. (ii) Pyribenzamine Elixir—from Tripelennamine Hcl USP. (iii) Privine Sol. and Emulsion—from Naphasoline Nitrate and Sulphathiazole ex-atul.		
4.	22(107)IA(11)58 dt. 10/11-4-1958	(i) Antistine Previne Nebulisers (ii) Retal in tablets.		
5.	22(20)IA(II)/59 dt. 28-4-1959	(i) Entobex tablets.		
6.	22(229) IA(II)/59 dt. 13-5-1959	(i) Cortisone Eye ointment (ii) Cortisone Eye Drops. (iii) Ultra cortenol Eye Ointment (iv) Ultra cortenol Eye Drops.		
7.	22(228) IA(11)/59 dt. 11-9-1959	(i) Esidrex tablets (ii) Millicorten preparation (iii) Mexaform tablets (iv) Doriden tablets (v) Apreso line and ecolid tablets.		

1	2	3	4	5
8.	22(228) IA(11)/59 dt. 2-1-1960	(i) Adelphrine Psidrex tablets.		
9.	22(331) IA (11)/59 dt. 9-1-1960	(i) Antrenyl Drops		
10.	22(374) IA(ii)/60 dt. 5-11-1960	(i) Orisul tablets 4 million p.a. (ii) Orisul syrup 150 kg		
11.	22(460) IA(11)/60 dt. 14-11-1960.	(i) Millicorten voform Cream	1 lakh tubes	
12.	3(13)/61-Ch. III dt. 11-9-1961	Ortrivin drops Orisul Eye ointment	1 lakh containers (10 each) 1 lakh tubes (5 gm each)	
13.	2(13)/61-Ch. III dt. 14-5-1962	(i) Testosterone Undecyclineate (ii) Testosterone valerinate	15 kgs. 15 kgs.	
14.	3(36)/62-Ch. III dt. 6-8-1962	(i) Ismelin tablets (10 mg) (ii) Ismelin tablets (25 mg)	7.5 million. one million.	

LIST OF COB LICENCES

S.No.	Name of the Company	Licence No. and Date	Items of manufacture p.a. and capacity.	
1	2	3	4	
1.	M/s Merck Sharp & Dohme of India Ltd.	L/22/422 71-Ch. III dt. 9-9-1971	1. Mintezol Tablets 2. Tri-redisol Tabs 3. Tri-relisol Drops 4. Perideca Elixir 5. Hydro met tabs 6. Thibendole	2.5 million Nos 10 million 1500 litres 2500 litres 2 million 500 bgs
2.	M/s Abbott Labs (India) Ltd.	L/22/423 71-Ch. III dt. 20-9-71	1. *Injectables* (a) Bejectal (b) Bejectal C Liner (c) Bejectal T (d) Revodox	Rs. 79 lakhs
			2. *Liquids* (a) Calcidrine (b) Cecon drops (c) Iberol liquid (d) Kalteri-C-Neomycin (e) Selsun Suspension (f) Surbex Syrup (g) Torfin (h) Vidaylin (i) Vidaylin M (j) Vidaylin M Drops (k) Vidaylin Drops (l) Iberet C	2,36,000 Lts.
			3. *Tablets* (a) Bevidox (b) Cecon '500' (c) Erythrocin 100 mg (d) Erythrocin 250 mg (e) Iberol (f) Optilets (g) Optilets M (h) Pramilets (i) Sucaryl (j) Surbex Sugar coated (k) Surbex T.	100 million
			4. *Capsules* (a) Nembutal (b) Tridine	3 lakh Nos.
			5. *Granules* (a) Erythrocin (b) Pentothal	5737 Kg
3.	M/s Glaxo Labs. (India) Ltd.	L. 22/430 71-Ch. III dt. 2-12-1971	Betneton Tabs.	2.4 million
4.	M/s Wyeth Labs. Ltd.	L/22/428/71-Ch. III dt. 26-10-1971	(i) Testosterone Pure (ii) Testoserene Enanthate (iii) 17-Alpha Hydro Progesterone caproate (iv) Testosterone Hexa Hydro-Benzoate	25 Kgs 45 Kgs 270 Kgs. 5 Kgs

1	2	3	4	
5.	M/s Roche Products Ltd.	L/22/438/72-Ch. III dt. 11-4-1972	(i) Supradyn Tabs (ii) Dehydroemetine tabs (iii) Valium Tabs and ampoules (iv) Cidro cal Effervescent tablets (v) Gantrisin eye ointment (vi) Injectable Veterinery preparations (vii) Vitamin Premix (viii) Rovisol	Within the overall licensed capacity.
			Bulk Drugs	
			1. Dehydroementine Hcl	95 Kgs
			2. Chlordiazepoxide	624 Kgs
			3. Vitamin E	Capacity to be fixe after one year operation.
			4. Diazepam	
6.	Burroughs Wellcome & Co. (India) Ltd	L/22/440/72-Ch. III dt. 1-5-1972	*Tablets* 1. T. Banocide 100 ml 2. T. Dapsones 5 ml 3. T. Tanoxin Pediatric 4. T. Nori—A 5. T. Komadrin 6. T. Oxoxine 6a. T. Actefed *Injections* 7. Inj. Actidil 8. Inj. Banocide Plus 9. Inj. Lanoxin 10. Inj. Suphentrene 11. Antepar Liquid Wormer 12. Antepar Worm Powder 13. Antepar Tabs. 14. Banocide 400 mg 15. Burmidin 5g tabs 16. Burmidin 30% Inj. 17. Franocide Inj. 18. Burmidin Oral 19. Fasool Drench. 20. Carbachol Inj. *Other Pharmaceutical Products* 21. Baxocid Brand Syrup 22. Alcopar flavoured Grannules 23. T. Migril 24. T. Wellcome Seltzer 25. Neosporin Powder 10 mg 26. Neosporin grannules	Within the overall licensed capacity.
7.	M/s Searle (India) Ltd.	L/22/443/72-Ch. III dt. 26-6-1972	(i) Lamotil Tablets (ii) Lamotil liquid	84 lakhs tabs 900 litres (within the overall capacity)
8.	M/s Glaxo Labs. (India) Ltd.	L/22/454/72-Ch. III dt. 7-11-72	1. Tablets* 2. Liquids 3. Ointments 4. Sterile Inj 5. Antibiotics Vials 6. Solids & Powders (Details as in Appendix)	395.524 million 10,11,033 litres 24,774 Kgs 34.120 litres 109.75 lakhs 32.555 Kgs
9.	M/s Boehringer Knoll Ltd.	L/22/463/73-Ch. III dt. 12-2-1973	(i) Calciluvin Syrup (ii) Mittavin Capsules (iii) Soventol Expectorant (iv) Chloramphycin ear drops (v) Chloramphycin eye ointment (vi) Strepto Paraxin Padeatric For the following items the firm already hold a licence, but higher capacities were regularised under COB Licence. 1. Ampoules Nos 2. Grannules 3. Capsules 4. Liquid (Oral) 5. Liquids for external use 6. Ointments & Jelly 7. Powder	20 lakhs 25,000 Kgs 534 lakh litres 1.5 lakh litres 2600 Kgs 6200 Kgs 1700 Kgs

1	2	3	4	
10.	M/s Smith Kline & French (India) Ltd.	L/22/484/73-Ch. III dt. 29-9-1973	1. Tablets 2. Liquids 3. Ointments 4. Capsules 5. Powders 6. Inhalers 7. Injectables	918 lakhs 34,000 litres 1,55,300 Kgs 145 lakhs 43,310 Kgs 21,600 Nos 3 lakh Nos.
11.	M/s Laboratories Grimault Ltd.	L/24/71 dt. 24-1-1974	1. Tablets & Caps 2. Liquids 3. Ointments 4. Solutions 5. Granules 6. Injectables (amp) 7. Injections (Lit) (Details as in Annexure 'A')	361.03 lakhs 3.72 lakh litres 2900 Kgs 1900 litres 16500 litres 4.80 lakhs 36 litres
12.	M/s Uni-Sankyo Ltd.	L/22/407/71-Ch. III dt. 15-3-1971	1. Fungal Diastase 2. Chloroheniramine Maleate 3. Pyrizanamide 4. Specialities incorporating the above products)	18 tonnes 2 tonnes 3 tonnes Capacity to be fixed.
13.	M/s Ciba of India Ltd	L/22/413/71-Ch. III dt. 16-6-1971	1. Dexamethasone Trimethyl Acetate 2. Calcium Coramine	3 Kgs p.a. 1.5 tonnes p.a.
14.	M/s Sandoz India Ltd. Bombay	L/22/416/71-Ch. III dt. 16-7-1971	1. Intestopan Vaginal Tablets 2. Intestopan suspension 3. Intestopan Forte Capsules 4. Hematrine Liquid 5. Intestopan Q Capsules 6. Sandocycline Capsules 7. Phenipan Sandoz (Dry Syrup) 8. Folestine tablets 9. Torecan ampules 10. Torecan tablets 11. Santevini (These items will be manufactured within the overall capacities of the various types of formulations already approved in their favour plus 25% to cover the additional capacity for the aforesaid items.)	
15.	M/s May & Baker Ltd	L/22/417/71-Ch. III dt. 6-7-1971	1.(a) Conray 280 b. Conray 420 2. Embacetin 3. Osbil 4. Surmontil 5. Tegeron Cream (Veterniary) 6. Vallergan BASIC MANUFACTURE 1. Chloramphenicol Ointment 2. Metronidazole	These items will be manufactured within the overall capacity of formulations already licensed in their favour. 65 Kgs 602 Kgs
16.	M/s. Pfizer Ltd. Bombay	L/22/418/71-Ch. III dt. 6-7-1971	1. Prenex Capsules Vistaril Syrup, Marax Capsules Heptuna Capsules, Diadin Liquid, Anorexon tablets Distodin (Hexachlorophene) (To be manufactured within the overall capacity).	
17.	M/s Tata Fision Industries Ltd. Bombay	L/22/421/71-Ch. III dated 30-7-71	Infivit Injection etc. Infivit Inj. 95,000 × 5ml. vial Emetine Inj. 360,000 Ampoules	
18.	M/s Gluconate Ltd.	L/22/402/70-Ch. III dt. 16-12-1970	Pethidine Hydrochloride	250 Kgs.
19.	—do—	L/22/403/70,-Ch. III dt. 16-12-1970	1. Acriflavine 2. Proflavine	1000 Kgs 3000 Kgs
20	M/s Atul Products Ltd.	L/22/430/71-Ch. III dt. 10-12-1974	Para Chlono Benzone Sulphanomide	20 tonnes

1	2	3	4	
21.	M/s Repatakos Brett & Co. Ltd.	L/22-485 73-Ch. III dt.	Aminculv Elixin (300 ml Bottle)	56,770
			Eupepline Elixir	85,290
			Hovita Syrup	87,461
			Kantamesim Tablets	4,18,360
			Dizitonin R.B. Tabs.	5,00,000
			Katemesim Injs. (1ml amp.)	15,528
22.	M/s Orient Pharma (P) Ltd.	CIL. 273(74) dt. 21-6-74	A. R. *Tablets*	
			1. Ossopan	53.38 lakhs
			2. Binisec	
			3. Pankreo	
			4. Aminoplylline	
			5. Sulphadimidine	
			6. Ephedrine Hcl.	
			7. Vitamin B Complex	
			8. Sulphaguanidine	
			9. A.P.C.	
			10. Robdden	
			11. Epedosin	
			12. Ripason	
			13. Premenolysin	
			14. Recosen	
			B. *Capsules*	
			1. Oricetin	5.9 lakhs
			2. Yellamycin	
			C. *Injections*	
			1. Epidosin	6.7 lakhs
			2. Robudon UD	
			3. Robudon UV	
			4. Ravexen	
			5. Recosen	
			6. Ripason	
			7. Dextrose	
23.	M/s Alembic Chemical Works Co., Baroda	LLS No. 586/74 dt. 30-11-74	1. Supramide V Tablets	180 lakhs Nos.
			2. Tricobal H	1850 litres
			3. Alvite Injections	

Appendix

M/s Glaxo Laboratories (India) Ltd., Bombay

I. *Tablets*

1. Trox
2. Volpar Foaming tablets
3. Dilosyn Tablets
4. Aluminium Hydroxide Magnesium
5. Carbonate Gel. Tabs (Alnocarb)
6. Secrodyl Tablets
7. Secrosterone tablets
8. Natalines
9. Vitebin 6 mg cap. 30 mg., 100 mg
10. Becadex Forte Caps
11. Celin 500 mg
12. Complex B
13. Complex B Forte
14. Folic Acid 5 mg
15. Vitamin B Complex B2
16. Peeazid tablets 100 mg.
17. Maccrafolin Iron tablets
18. Helmacid tablets
19. Predasin tablets
20. Comycin-S tablets
21. Eltroxin Tabs 0.01 mg+0.05 mg.
22. Adexolin capsules
24. Kapilin Tablets
25. Prepalin Capsules
26. Vitamin A & D Capsules
27. Radiostolume Caps.
28. Laxene
29. Myanesin 0.5 mg.
30. Testaform 5 mg
31. Dyloform 0.01 mg.
32. Serial 28
33. Volidan V
34. Lutoferin 5 mg+10mg.

II. *Liquids:*

1. Multivite Deca Drops
2. Dilopact Syrup
3. Entacyl Elixir
4. Dilosyn Syrup
5. Complex B Liquid
6. Macrafolin Iron Syrup
7. Complin S. Syrup
8. Becadex Syrup
9. Becadex Drops
10. Helmacid Syrup
11. Maerabin Liquid
12. Ostocalcium B12 Syrup
13. Guanimycin Sus. Forte
14. Adexolin Liquid
15. Prepalin Liquid
16. Efcorlin NE/E Drops
17. Diapec
18. Elixir Myanesin
19. Kapilin Liquid
20. Radiostolume Liquid

III. *Ointments*

1. Crystapen H.P.
2. Mystrepton
3. Mystrepton H.B.
4. Mycil.
5. Efcorlin Eye Oint.
6. Betnovate-C Skin Oint.
7. Betnovate Skin (Greasy) Oint.
8. Betnovate-N Skin (Greasy) Oint.
9. Betnovate-C Skin (Greasy) Ointment
10. Derobin-C
11. Efcorlin-N Skin Oint.
12. Efcorlin-N Eye Oint.
13. Parvel Jelly

MALTS.

Radio Malt.

IV. *Sterile Injections*

1. Dextrose 5% BP
2. Dextrose 5% with Sodium
3. Chloride 0.9%

   Dextrose 10% —do—
4. Sodium Chloride BP
5. Sodium Chloride and Gum Acacia BP
6. Anacobin 500 mg. + 1000 mg.
7. Jectof or Injection
8. Complex B 139 ml.
9. Complex B Forte 5 ml.
10. Bacdex 10 ml.
11. Macrabin-H 500 mg 5 ml.
12. Macrabin-E 1000 mg 5 ml
13. Qaleiosterlin B12
14. Fantorin
15. Kapilin
16. Prepalin 1 ml.
17. Prepalin Forte 1 ml.
18. Progestin 10 mg. 1 ml.
19. Progestin 25 mg. 1 ml.
20. Testaform 10 mg.
21. —do— 25 mg.
22. Efcorlin soluble
23. Mersalyl 1 cc
24. Mersalyl 2 cc
25. Myanesin

V. *Antibiotic vials*

1. Comycin—S 1 g.
2. Comycin S 2 g.
3. Comycin S Stab. Solution
4. Seclomycin 5 dose.
5. Crystamycin 1 dose
6. PAM
7. Benapen Forte
8. *Solids & Powders*
   1. Holmacid with Senna
   2. Anathanine
   3. Crystapen V Granules

M/s Laboratories Grimault (India) Limited

Tablets & Capsules	Liquids	Ointments
1. Amicline	1. Grimault's Linctus	1. Meladinine
2. Digitaline	2. Grimault's Syrup	2. Paraminel
3. Meladinine	3. Hemopatol	3. Psorline
4. Natisedine	4. Sorbiline	4. Relaxyl
5. Retanitrine Plain	5. Omilcal +F	
6. Phenobarbitone	*Solutions*	*Granules*
7. Psorline P	1. Meladinine	1. Evacuol
8. Tuxyne	2. Psorline	2. Glutaneurol
9. Alucinol		
10. Beneuron	*Injectables*	*Injections*
11. Beneuron Forte	(*ampoules*)	(*Litres*)
12. Glyciphage	Lactisyn	1. Be-Douze 500 Mog
13. Hepasulfol		2. Be-Douze 1000 Mog
14. Hepasulfol AA		3. Hydroxycobalomino
15. Meprophen		
16. Plurizyme		
17. Suxifer		

Chapter-V. Para. 13(a)

ANNEXURE–IV

Turnover of drug Manufacturing firms with foreign Equity Exceeding 50%

Chapter–V. Para 13(a)

(Rs./Lakhs)

S. No.	Name of the firms	1971/1971-72			1972/1972-73			1973/1973-74		
		Drugs	Non Drugs	Total	Drugs	Non Drugs	Total	Drugs	Non Drugs	Total
1	2	3	4	5	6	7	8	9	10	11
1.	M/s. Alkali & Chemical Corp. of India Ltd.	99	2378	2477	119	2578	2697	116	3000	3110
2.	M/s. Anglo-French Drug Co. (Eastern) Limited	193	..	193	223	..	223	228	..	228
3.	M/s. Abbott Laboratories (I) (P) Limited	614	..	614	752	..	752	824	..	824
4.	M/s. Bayor (India) Limited	230	821	1051	289	1031	1320	311	1267	1578
5.	M/s. Beecham (India) (P) Limited	30	96	126	35	73	108	26	101	127
6.	M/s. Boehringer-Knoll Limited	410	..	410	365	..	365	406	..	400
7.	Boots Co. (India) Limited	521	25	546	631	29	660	748	30	778
8.	M/s. Barroughs Wellcome & Co. (I) (P) Limited	279	43	322	322	45	367	391	29	420
9.	Ciba of India Limited	1263	1003	2266	1331	1289	2620	1454	1668	3122
10.	Cyanamid India Limited	788	154	942	892	168	1050	999	202	1201
11.	M/s. B. Merck (I) Private Limited	302	..	302	380	..	380	469	8	477
12.	M/s. Glaxo Laboratories (I) Limited	1995	1250	3245	1901	1195	3096	2331	1207	3538
13.	M/s. Johnson & Johnson of India Limited	232	174	406	210	147	357	295	194	489
14.	M/s May & Baker Limited	808	33	841	664	34	698	907	65	972
15.	M/s. Merck Sharp & Dohme of India Limited	856	..	856	868	..	868	1051	..	1051
16.	M/s. Parke Davis (India) Limited	883	..	883	1024	..	1024	1062	..	1062
17.	M/s. Pfizer Limited (Bombay I)	1766	318	2084	2062	376	2438	2177	393	2750
18.	M/s. Reckitt & Colman of India Limited	144	573	717	135	668	803	N.A.	..	N.A.
19.	M/s. Richardson Hindustan Limited	439	85	524	508	38	546	643	95	738
20.	M/s. Roche Products Limited	892		892	920	..	920	928	..	928
21.	M/s. Sandoz (India) Limited	623	389	1012	713	513	1226	963	594	1557
22.	M/s. Searle (India) Limited	77	31	108	105	41	146	146	39	185
23.	M/s. Smith Kline & French (I) Limited	359	..	359	525	..	525	636	..	636
24.	M/s. Wyeth Laboratories Limited	316	..	316	339	..	339	393	..	393
25.	M/s. Griffon Laboratories	173	..	173	221	..	221	243	..	243
26.	M/s. C.W. Cairnick Co. (Asia) Branch	7	..	7	9	..	9	13	..	13
27.	M/s. C.E. Fulford Limited	65	..	65	120	..	120	160	..	160
28.	M/s. Cooper Laboratories	25	..	25	22	..	22	26	..	26
29.	Ethnor Limited	173	..	173	211	..	211	258	..	258
30.	M/s. Nicholas of India Limited	128	..	128	124	..	124	152	..	152
31.	Indian Schering Limited	272	..	272	321	..	321	414	..	414
32.	M/s. Roussel Pharmaceuticals Limited	148	..	148	186	..	186	234	..	234

1	2	3	4	5	6	7	8	9	10	11
33.	M/s. Dental Products of India Limited	15	..	15	21	..	21	19	..	19
34.	M/s. John Wyeth (Bros).	388	..	388	432	..	432			
	Firms with Foreign Equity Between 40 & 50%									
1.	M/s. Associated Capsules (P) Limited	51	..	51	77	..	77	..	..	..
2.	M/s. Cure-Well (I) Limited	..	..	..	22	..	22			
3.	M/s. Dupher Interfran Limited	184	68	252	210	76	286	232	93	325
4.	M/s. Geoffrey Manners & Co. Limited	837	349	1186	988	391	1399	1071	465	1536
5.	M/s. Hoechst Pharmaceuticals Limited	1375	104	1479	1650	183	1833	1988	184	2172
6.	M/s. Martin & Harris (P) Limited	356	40	396	373	47	420	117	5	122
7.	M/s. Organon (India) Limited	211	..	211	245	..	245	284	32	316
8.	M/s. Suhrid Geigy Limited	707	609	1316	808	703	1511	944	1067	2011
9.	M/s. Synbiotics Limited	304	..	304	314	..	314	363	..	363
10.	M/s. Uni-Sankyo Limited	12	..	12	7	..	7	..	..	..
11.	M/s. Wander Limited	94	..	94	96	..	96	128	..	128
12.	M/s. Warder Hindustan Limited				585	103	688	557	82	639
13.	M/s. Whiffens (India) Limited	7	..	7	6	..	6	6	..	6
14.	M/s. Carter Wallace & Co. Limited	40	..	40	65	..	65	92	..	92
15.	M/s. U.S. Vitamins & Pharmaceuticals Limited	132	..	132	171	..	171		...	
	Firms with Foreign Equity Between 26 & 40%									
1.	M/s. Biological Evans Limited	306	..	306	290	..	290	270	..	270
2.	M/s. Cibatul Limited	158	285	443	181	322	503	152	338	490
3.	M/s. German Remedies Limited	368	..	368	425	..	425	524	..	524
4.	M/s. Me-Gaw-Revindra Laboratories (I) Limited	64	16	80	82	22	104	103	27	130
5.	M/s. Mysore Industrial & Testing Laboratory Ltd.	50	..	50	53	..	53	42	..	42
6.	M/s. Rallis India Limited	431	4879	5310	477	5519	5996	633	5698	6331
7.	M/s. Smith & Nephew (India) Limited	43	92	135	37	90	127	41	113	154
8.	M/s. Uni-UCB (India) (P) Limited	48	..	48	48	..	48	61	..	61
9.	M/s. J.L. Morison, Son & Jones Limited	18	326	344	26	168	194	27	91	118
10.	M/s. Christian Hoden Limited	12	..	12	14	..	14	32	..	23
11.	M/s. Ward Blenkinsop Limited	10	11	21	12	4	16	17	13	30

ANNEXURE I

Chapter-V. Para. 13 (c)

Remittances of Drug Firms

(Firms with Foreign Equity exceeding 50%)

Sl. No.	Name of the firms	Year	Dividends	Research	Royalty	Tech. Fees	Head Office Expanses	Profits	Total
1	2	3	4	5	6	7	8	9	10
1.	Abbott Laboratories	1969	Nol	..	..	..	..	..	Nil
		1970	22.65	..	..	..	..	..	22.65
		1971	22.65	..	..	..	..	..	22.65
		1972	14.86	..	..	..	..	..	14.86
		1973	14.86	..	..	..	..	..	14.86
2.	Alkali & Chemical Corpn. of India	1969-70	30.76			2.98			33.74
		1970-71	34.54			0.09			34.63
		1971-72	32.20			0.09			32.29
		1972-73	32.24	..	..	0.08	..	..	32 32
		1973-74	..	..	..	..	..	..	..
3.	Anglo French Drug Co	1969	2.57	..	..	..	..	..	2.57
		1970	0.60	..	..	..	..	..	0.60
		1971	0.60	..	..	..	..	..	0.60
		1972	0.60	..	..	..	..	..	0.60
		1973	0.59	..	..	..	..	..	0.59
4.	Bayer India Ltd.	1969	..	..	..	..	..	..	Nil
		1970	..	..	..	2.07	..	..	2.07
		1971	Nil	..	.	..	..	..	..
		1972	22.53	..	..	..	..	..	22.53
		1973	41.37	..	..	..	..	..	41.37
5.	Beechem Ltd.	1969-70	6.07	..	..	..	..	..	6.07
		1970-71	5.89	..	..	..	..	..	5.89
		1971-72	6.57	..	..	..	..	..	6.57
		1972-73	5.48	..	..	..	..	..	5.48
		1973-74	2.67	..	..	..	..	..	2.67
6.	Boehringer Knoll Ltd.	1969	2.66	..	..	..	..	..	2.66
		1970	..	..	..	..	..	..	..
		1971	1.37	..	..	..	..	..	1.37
		1972	1.71	..	..	..	..	..	1.71
		1973	2.30	..	..	..	..	..	2.30
7.	Boots Company Ltd.	1969	5.72	..	0.22	..	..	..	5.94
		1970	6.12	..	0.30	..	..	..	6.42
		1971	6.12	0.22	..	..	..	..	6.34
		1972	6.35	..	.	..	..	..	6.35
		1973	Nil	1.44	..	..	..	..	1.44
8.	Burroughs Wellcome & Co. Ltd.	1969	7.55	..	..	..	..	..	7.55
		1970	7.55	..	..	..	..	..	7.55
		1971	7.55	..	..	..	..	..	7.55
		1972	9.44	..	..	..	..	..	9.44
		1973	11.14	..	..	..	..	..	11.14
9.	Ciba of India Ltd.	1969	19.94	..	..	..	..	..	19.94
		1970	19.94	..	..	..	..	..	19.94
		1971	35.89	..	..	..	..	..	35.89
		1972	23.54	..	..	..	..	..	23.54
		1973	23.54	..	2.12	22.55	..	..	48.21
10.	Cyanamid Ltd.	1969	24.10	..	..	..	..	..	24.10
		1970	24.10	..	..	..	..	..	24.10
		1971	24.10	..	..	..	..	..	24.10
		1972	24.10	..	..		..	..	24.10
		1973	35.65	..	..	..	..	..	35.65

1	2	3	4	5	6	7	8	9	10
11.	E. Merck Ltd.	1969	0.97	..	..		.		0.9
		1970	1.19	.	..		..	..	1.1
		1971	0.97	..	..	..	..	.	0.9
		1972	1.73	..		..	..		1
		1973	2.19	..	..	..	..	.	2
12.	Glaxo Laboratories Ltd.	1969-70	62.51	..	..	42.24	..	..	104
		1970-71	62.51	..	..	36.57	..	.	99.0
		1971-72	62.1	..	..	35.6	..	.	9
		1972-73	77.0	..	..	29.0	..	..	106.
		1973-74	66.6	..	..	32.1	..	..	98.
13.	Johnson & Johnson Ltd.	1969	5.10	..	..	.	..	..	5.1
		1970	5.10	..	..	..	..	..	5.1
		1971	5.10	..	..	..	..	..	5.1
		1972	10.38	..	..	..	..	.	10.3
		1973	7.02	..	..	..	..	..	7.0
14.	May & Baker Ltd.	1969-70	..	..	..	..	..	50.00	50.00
		1970-71	..	..	..	..	..	44.90	44.9
		1971-72	..	..	..	..	..	30.00	30.0
		1972 (8 months)	..	..	..	..	..	52.96	52.9
		1973	Nil	..	..	..	.	..	N
15.	Merck Sharp & Dohme of India Ltd.	1969	28.54	.	.	..	..		28.
		1970	21.20	..	..	..	..		21.2
		1971	21.20	..	..	..	..	..	21.20
		1972	16.85	..	..	..	..	..	16.8
		1973 (13 months)	10.85	..		.	..	.	10.8
16.	Parke Davis & Co.	1969	67.31	..		..	.		67.3
		1970	67.31	..	.	.	..	..	67.3
		1971	16.51	.	.	.	..	..	16.51
		1972	26.25	..	..	.	..	.	26.2
		1973	22.75	..	..	..	..	.	22.75
17.	Pfizer Ltd.	1969	60.40	..	..	..	..	..	60.40
		1970	63.13	..	.	..	..		63.13
		1971	68.28	..	..	..	..	..	68.28
		1972	68.21	..	..	..	..	..	68.21
		1973	68.63	..	..	..	..	..	68.63
18.	Beekitt & Colman of India Ltd.	1969-70	15.63	..	.	..	..	..	15.63
		1970-71	9.25	..	..	..	..		9.25
		1971-72	14.30	..	..	..	..	.	14.30
		1972-73	14.30	..	..	..	..	..	14.30
		1973-74							
19.	Richardson Hindustan Ltd.	1969-70	2.75	..	..	..	..	..	2.75
		1970-71	3.85	..	.	..	.	..	3.85
		1971-72	3.85	..	.	..	.	..	3.85
		1972-73	3.85	..	..	..	..	..	3.85
		1973-74	4.29	..	..	..	..	..	4.29
20.	Roche Products Ltd.	1969	16.80	..	.	16.70	..	..	33.5
		1970	16.80	..	..	9.47	..	..	26.27
		1971	16.80	..	..	..	..	..	16.87
		1972	16.53	..	..	12.61	..	.	29.10
		1973	16.53	..	..	..	..	..	16.534
21.	Sandoz India Ltd.	1969	6.79	1.68	.		.	.	8.47
		1970	8.54	2.42	.	0.12	..	..	11.08
		1971	9.27	..	.	.	..	.	9.27
		1972	7.35	1.55	.	.	..	..	8.90
		1973	8.87	1.03		..	..	.	9.90
22.	Searle India Ltd	1969	..	..	..	..	..	..	..
		1970	..	..	..	..	..	..	..
		1971	..	..	..	..	..	..	..
		1972	..	..	..	..	..	..	..
		1973	..	..	..	..	..	..	..
23.	Smith Kline & French Ltd.	1969	..	..	..	..	..	27.46	27.46
		1970	..	..	..	..	..	22.23	22.23
		1971	..	..	..	..	..	27.26	27.26
		1972	..	..	..	..	13.57	..	13.57
		1973	..	..	..	..	18.01	.	18.01

1	2	3	4	5	6	7	8	9	10
24.	Wyeth Laboratories Ltd.	1969-70	6.28	..	..		..	.	6.28
		1970-71	4.19	.		..	.		4.19
		1971-72	4.19		..		.	.	4.19
		1972-73	8.24	.	..	.			8.24
		1973-74							
25.	Griffen Laboratories Ltd.	1969	1.68	..	..		.	.	1.68
		1970	2.28	..	..	..	..	.	2.28
		1971	2.85	.	..	..	..	.	2.85
		1972	0.02			..	.		0.02
		1973							
26.	C.W. Carnick Lsia	1969	..	..	..	..	0.40	0.08	0.48
		1970	Nil	..	..	..	Nil	..	.
		1971	..	..	..	..	0.80	0.12	0.92
		1972	..	..	..	..	0.46	..	0.46
		1973	Nil	..	..	..	Nil	..	..
27.	Cooper Laboratories	1969							
		1970	Nil	..	..	..	..	..	..
		1971	Nil	..	..	..	..	..	..
		1972	Nil	..	..	..	..	..	..
		1973	Nil	..	..	..	..	..	..
28.	Dental Products of India	1969	0.11	..	..	.	..	..	0.11
		1970	0.15	..	..	..	.	..	0.15
		1971	0.44						0.44
		1972	0.29						0.29
		1973							
29.	Ethnor Ltd.	1969							
		1970	Nil						
		1971	Nil						
		1972	Nil						
		1973	Nil						
30.	Roussell Pharmaceuticals Ltd.	1969	Nil						
		1970	Nil						
		1971	Nil						
		1972	Nil						
		1973	Nil						
31.	CE Fulford Ltd.	1969	Nil						Nil
		1970	Nil						
		1971	Nil						
		1972	1.52	..					1.52
		1973	0.75	..	..	..			0.75
32.	Indian Schering Ltd.	1969-70	1.33	..	..	..	.	.	1.33
		1970-71	3.33	..	..	..	..	..	3.33
		1971-72	8.00	..	..	..	..	..	8.00
		1972-73	3.90	..	..	..	.	..	3.90
		1973-74	3.93	..	..	..	.	.	3.93
33.	Nicholas of India	1969-70	..	..	..	..		4.70	4.70
		1970-71	..	..	..	..	..	4.27	4.27
		1971-72	..	.	..	..	.	7.48	7.48
		1972-73	..	.	..	..		7.09	7.09
		1973-74	..	..	..	..		7.26	26
34.	John Wyeth Bros.	1969-70	..	..	..	..	..	.	Nil
		1970-71	.	..	..	..	..	21.95	21.95
		1971-72	..	..	..	..	..	40.74	40.74
		1972-73	..	..	..	..	..	34.19	34.19
		1973-74	..	..	..	..	..	..	

Firms with Foreign Equity between 40% and 50%

(Rs. lakh

Sl. No.	Name of the firms	Year	Dividends	Research	Royalty	Tech. Fees	Head Office Expenses	Profits	Tot
1	2	3	4	5	6	7	8	9	10
1.	Associated Capsules Ltd.	1969	..	..	..	..	..	..	Ni
		1970	..	..	..	..	..	..	Ni
		1971	..	..	..	..	..	..	Ni
		1972	..	..	..	..	..	..	Ni
		1973	..	..	..	..	..	..	Nil
2.	Curewell India Ltd.	1969-70	..	..	..	..	..	..	Ni
		1970-71	..	..	..	..	..	..	Ni
		1971-72	..	..	..	..	..	..	Ni
		1972-73	..	..	..	..	..	..	Nil
		1973-74	..	..	..	..	..	..	Ni
3.	Duphar Interfran Ltd.	1969	1.34	..	0.05	..	..	..	1.39
		1970	1.34	..	1.16	0.16	..	..	1 66
		1971	2.15	..	.25	..	..	..	2.40
		1972	1.60	..	0.33	0.35	..	..	2.28
		1973	..	..	0.39	.	..	..	0.39
4.	Geoffrey Manners & Co.	1969	6.73	..	..	..	..	..	6.73
		1970	7.34	..	..	..	..	..	7.34
		1971	8.15	..	..	..	..	..	8.15
		1972	8.82	..	..	..	..	..	8.82
		1973	8.82	..	..	.	..	..	8.82
5.	Hoechst Pharmaceuticals	1969	Nil	..	..	..	..	..	Nil
		1970	Nil	..	..	..	..	..	Nil
		1971	8.78	..	..	..	..	..	8.78
		1972	20.75	..	..	..	..	..	20.75
		1973	21.19	..	..	..	..	..	21.19
6.	Martin & Harris (P) Ltd.	1969	Nil						
		1970	Nil						
		1971	Nil						
		1972	Nil						
		1973	Nil						
7.	Organon (India) Ltd.	1969	..	..	..	..	..	..	..
		1970	..	..	..	0.50	..	..	0.50
		1971	..	..	..	..	..	..	..
		1972	..	..	0.97	..	..	..	0.97
		1973	2.86	..	0.95	..	..	..	3.81
8.	Sahrid Geigy Ltd.	1969-70	29.08	1.30	1.52	0.76	..	..	32.66
		1970-71	14.76	0.58	0.68	..	..	..	16.02
		1971-72	14.54	..	0.59	..	..	..	15.13
		1972-73	..	..	0.67	..	..	..	0.67
		1973-74							
9.	Synbiotics Ltd.	1969-70	7.92	..	..	..	..	..	7.92
		1970-71	5.92	..	..	..	..	..	5.92
		1971-72	..	..	..	..	..	..	..
		1972-73	..	..	..	..	..	..	..
		1973-74	2.67	..	..	..	..	..	2.67
10.	Uni Sankyo Ltd.	1969-70	Nil						
		1970-71							
		1971-72							
		1972-73							
		1973-74							
11.	Wander Ltd.	1969	1.04	..	..	..	..	..	1.04
		1970	0.60	..	..	..	..	..	0.60
		1971	0.30	..	1.77	..	.	..	2.07
		1972	0.59	..	1.82	..	..	..	2.41
		1973	0.94	..	..	..	..	..	0.94

1	2	3	4	5	6	7	8	9	10
12.	Warner Hindustan Ltd.	1969	2.80						2.80
		1970	3.15						3.15
		1971	3.15						3.15
		1972	5.41			2.55			6.96
		1973	8.82			1.75			9.57
13.	Carter Wallace & Co. Ltd.	1969-70	Nil						
		1970-71	Nil						
		1971-72	Nil						
		1972-73	Nil						
		1973-74	Nil						
14.	U.S. Vitamins & Pharmaceuticals Ltd.	1969-70	1.60	—	—	—	—	—	1.60
		1970-71	0.25	—	—	—	—	—	0.25
		1971-72	0.25						
		1972-73	0.25						
		1973-74							
15.	Whiffens (India) Ltd.	1969-70	0.75	—	—	—	—	—	0.75
		1970-71	0.63	—	—	—	—	—	0.63
		1971-72	0.31	—	—	—	—	—	0.31
		1972-73	0.31	—	—	—	—	—	0.31
		1973-74	—	—	—	—	—	—	—
		Firms with Foreign Equity between 26% and 40%							
1.	Biological Evans Ltd.	1969	0.38	—	—	—	—	—	0.38
		1970	0.38	—	0.09	—	—	—	0.47
		1971	0.38	—	0.28	—	—	—	0.66
		1972	0.37	—	—	—	—	—	0.37
		1973	0.37	—	—	—	—	—	0.37
2.	Cibatul Ltd.	1969	—	—	—	—	—	—	..
		1970	—	—	—	—	—	—	Nil
		1971	—	—	—	—	—	—	Nil
		1972	—						
		1973	—						
3.	German Remedies Ltd.	1969	1.30	—	—	—	—	—	1.30
		1970	1.30	—	—	—	—	—	1.30
		1971	1.41	—	—	—	—	—	1.41
		1972	2.31	—	—	—	—	—	2.31
		1973	2.45	—	—	—	—	—	2.45
4.	Me-Gaw-Ravindra Laboratories (I) Ltd.	1969-70	—	—	1.75	—	—	—	1.75
		1970-71	—	—	1.02	—	—	—	1.02
		1971-72	—	—	1.38	—	—	—	1.38
		1972-73	—	—	1.66	—	—	—	1.66
		1973-74	—	—	2.14	—	—	—	2.14
5.	M.I.T. Laboratories	1969	Nil						
		1970							Nil
		1971							
		1972							
		1973							
6.	Rallis India Ltd.	1969	6.24	—	—	—	—	—	6.24
		1970	6.22	—	—	—	—	—	6.22
		1971	6.22	—	—	—	—	—	6.22
		1972	6.21	—	—	1.87	—	—	8.08
		1973	6.10	—	0.32	1.61	—	—	8.03
7.	Smith & Nephew Ltd.	1969	0.91	—	—	—	—	—	0.91
		1970	0.91	—	—	—	—	—	0.91
		1971	0.85	—	—	—	—	—	0.85
		1972	0.84	—	—	—	—	—	0.84
		1973	—	—	—	—	—	—	..
8.	UNI-UCB Ltd.	1969	0.15	—	—	—	—	—	0.15
		1970	0.15	—	—	—	—	—	0.15
		1971	0.79	—	—	—	—	—	0.79
		1972	0.79	—	—	—	—	—	0.79
		1973	0.79	—	—	—	—	—	0.79
9.	J. L. Morrison, Son & Jones Ltd.	1969							
		1970							
		1971	Nil						Nil
		1972	Nil						Nil
		1973	Nil						Nil

1	2	3	4	5	6	7	8	9	10
10.	Wand Blenkinshop Ltd	1969	Nil						
		1970	Nil						
		1971	Nil						
		1972	Nil						
		1973	Nil						
11.	Leukoplast & Co.	1969							
		1970							
		1971	Nil.						
		1972							
		1973							
12.	Christian Hoden Ltd.	1969							
		1970	Nil						
		1971	Nil						
		1972	Nil						
		1973	Nil						
		Firms with Foreign Equity below 26%							
1.	Capsultation Service Ltd.	1969-70							
		1970-71	0.24	—	—	—	—	—	0
		1971-72	0.24	—	—	—	—	—	0.
		1972-73	0.20	—	—	—	—	—	0.
		1973-74	..						
2.	Gelikeps (P) Ltd.	1969							
		1970							
		1971	Nil						
		1972							
		1973							
3.	Raptakos Brett Co.	1969	0.45	—	—	—	—	—	0.4
		1970	0.39	—	—		—	—	0.
		1971	0.39	—	—	—	—	—	0.
		1972	0.62	—	—	—	—	—	0.6
		1973	0.25	—	—	—	—	—	0.2.
4.	Chowgule Co.	Not for drug activity.							
5.	Leukoplast & Co.	Nil							
6.	Themis Chemical Ltd.	Nil							

ANNEXURE VI

Import Content in Bulk Drug Manufacture

Chapter-V. Para. 13(f)

Sl. No.	Firm	Name of the Bulk Drug	c.i.f. Price in rupees per k.g. of the Bulk Drug	Selling Price	Imported raw-materials	Import content per k.g. (c.i.f.) Rs.	Percentage of Import content on c.i.f. Price	Percentage of Import content on selling Price
1	2	3	4	5	6	7	8	9
1.	Payer India Limited.	Chloroquin Phosphate	125.4	260	Hydroxy Chloroquinoline Novaldiamine.	97.88	78	37
2.	May & Baker	Sulphadiazine	53.6	102	2—Aminopyramidine	33.00	62	32
		Metronidazole	125	400 (Approx.)	2—Methyl-4--nitroimidazole	86.10	78	22
3.	Hoechst	Forsemide	565	1200 (STC price)	Lasamide	312	59	26
		Avil Maleate	273	NA	Berayl Pyridine Sodamide	155	56	—
		Tolbutamide	34	91.71	Maleic acid Butylamine	15.7	46	17
4.	Parke Davis	Chloramphenicol	1200	662	Banzeldehyde Methyl Bromide Lithium Hydride	54	4.5	8
		Amodiaquin	NA	232	4, 7-Dichloroquinoline	100.7	—	43
5.	Boehringer Knoll	Ephedrine Hcl.	209	NA	Ketol	192	92	—
6.	Pfizer Limited	Chlorpropamide	67	107.72	n-Propyl Isocyanate Triethylamine Hyflusupercel	33.22	49	31
		Tetracycline	136	850	Hyflusupercel Ethyl Cellulose Corn steep liquor Glass wool	44.46	32.4	5
		Oxytetracycline	187	950	Hyflusupercel Ethyl Cellulose Triethylaine Sod. Nitrate Glass wool	30.24	16	3
		PAS	NA	53	Hyflusupercel	0.15	NA	Neg.
7.	Parke Davis.	Diphenhydramine Hcl.			Benz Hydrol	40		
					Beta Dinethyl Aminoetanol	8		
						48		

ANNEXURE VII

Statement Showing the Name of Foreign Company, Bulk Drug Manufactured, Licence No./Permission/no Objection Letter No and Date etc.

(Chapter, V Para 13f)

Sl. No.	Name of the Company	Item of bulk drug Manufactured	Lic. No./Permission Letter No. & date	Licensed approved capacity P.A.	% of bulk drug made available to others.		
					1971	1972	1973
1	2	3	4	5	6	7	8
1.	M/s. Cyanamid India Limited	Tetracycline	Lic. No. L/22/N-132/60 dt. 29-1-1960 and amendment No. 22(168) IA (11)58 dt. 31-8-61.	10 tonnes	Nil	Nil	Nil
2.	M/s. Reckitt and Colman of India Limited.	Para Chlore Meta xylenol	Lic. No. L/22/404/71-Ch. III dt. 25-1-1971	50 tonnes	This material is required for their captive consumption in Dettol.		
3.	M/s. Bayer India Limited.	Chloroquin Phosphate	L/22/99/62-Ch.III	4 tonnes	Nil	Nil	Nil
		Resotren	dt. 3-1-1962	540 Kgs.	Nil	Nil	Nil
		Cresival		240 ,,	Nil	Nil	Nil
		Entodon		200 ,,	Nil	Nil	Nil
		Etaine Hcl-		400 ,,	Nil	Nil	Nil
		Piperazine Hezahydrate		1000 ,,	Nil	Nil	Nil
		Piperazine Phosphate		350 ,,	Nil	Nil	Nil
		Mesulphen B.P.	L/22/351/67-Ch. III dt. 15-12-1967	10 tonnes	Nil	Nil	Nil
		Chloroquin Phosphate (S.E.)	L/22/477 73-Ch. III dt. 3-8-1973	12 tonnes	Nil	Nil	Nil
		Badional Substance	No. 1(6)72-Ch. III	(For captive	Nil	Nil	Nil
		Detigon Substance	dt. 31-7-1972	consumption)	Nill	Nill	Nil
		Lacidal Substance			Nil	Nil	Nil
		Diphenyl hydentoin			Nil	Nil	Nil
4.	M/s. Boehringer Knoll	Chloramphenicol	L/22/N-125/60 dt. 5-1-1960	30 tonnes	Nil	Nil	Nil
		Chloramphenicol Monostearo ylglycolate	L/22/26/66-A&I dt. 7-4-1966	12 tonnes	Nil	Nil	Nil
		Ephedrine B.P.	L/22/140/62-Ch. III dt. 1-12-1962	18 tonnes	Nil	Nil	Nil
		Carbutamidl	Nil				
		Oc-inum Mucate & D Mucate.					
		Ocinum D Amidosulphonate	Nil		Nil	Nil	Nil
		l-Ephedrine Hydrohodanate.	Nil		Nil	Nil	Nil
			,,		Nil	Nil	Nil
		Chloramphinicol Palmiate	,,		Nill	Nil	Nil
		Leptazol B.P.	,,	(For captive	Nil	Nil	Nil
		Multifungin Substance	,,	consumption)	Nil	Nil	Nil
		Priatan Substance	,,		Nil	Nil	Nil
		Soventol Hcl. & Salicylate	,,		Nil	Nil	Nil
5.	M/s. Boots Company (India) Limited	Insulin	L/22/N-30/60-Ch. III dt. 8-11-1960	1500 MU	Nil	Nil	Nil
		Diloxamide Furoate	L/22/420/71-Ch. III dt. 26-7-1971	12 tonnes	Nil	Nil	Nil
6.	M/s. Merek Sharp and Dohme of India Limited	Chlorthiazide and hydrochlorthiazide	L/22/N-57/58 dt. 18-9-1958 and amendment.	3 tonnes	Nil	Nil	Nil
		Cyproheptadine	No. L/22/101(IA)(II)/58				
		Cortisone, Dexamethasone and other Hormones	dt. 25-8-1959	120 Kgs.	Nil	Nil	Nil
		Phthalyl Sulphathiazole		3.5 tonnes	Nil	Nil	Nil
		Succinylsulphathiazole		3.5 tonnes	Nil	Nil	Nil
		Vitamin B12		144 kgs.	N.A.	N.A.	91.5 kgs.
		Indomethacin blend	Nil	(for captive	Nil	Nil	Nil
		Methyl Dopa Gran	,,	consumption)	Nil	Nil	Nil
		Benztropine Meaylate	,,		Nil	Nil	Nil
		Ethacryinc Acid	,,		Nil	Nil	Nil

1	2	3	4	5	6	7	8
[illegible]		[illegible]	L 22 [illegible] dt. 19-11-[illegible]		Nil	Nil	Nil
		[illegible]			Nil	Nil	Nil
		[illegible]	L 22 32 [illegible] Ch. III	1x9 tonnes	Nil	Nil	Nil
		[illegible] Lactate	dt. 19-11-[illegible]		Nil	Nil	Nil
		Gluconate	L 22 3x3 [illegible] Ch.III		Nil	Nil	Nil
		Ferrous Gluconate	dt. [illegible]-1967		Nil	Nil	Nil
		[illegible]			Nil	Nil	Nil
		[illegible]			Nil	Nil	Nil
		Ferrous Fumerate	L 22 281/65-Ch. III dt. 28-12-1965	20 tonnes	Nil	Nil	Nil
		Magnesium Gluconate	L 22 288/65-Ch. III dt. 1-10-1965	5 tonnes	Nil	Nil	Nil
		Active Principles of Podophyllum	L/22/166/63-Ch. III dt. 21-8-1963 amended vide	54 tonnes	Nil	Nil	Nil
		Active Principles of Senna and Belladone	1/77)'62-Ch. III dt 16-5-1967	Capacity yet to be fixed	Nil	Nil	Nil
		Digoxin B.P.	L/22,240 64-Ch. III dt. 26-10-1964	Capacity yet to be fixed	Nil	Nil	Nil
		Intestopan Substance (S.C)	L 22 372 64-Ch. III dt. 24-11-1969	28,8 tonnes	Nil	Nil	Nil
8. M/s. Burroughs Wellcome & Co		Adrenaline & Adrenaline Acid & Tartarate	L 22 N-33 58 dt. 12-2-1958	48 Kgs.	Nil	Nil	Nil
		Bephenium Hydroxyaaphthoate	L 22 348 67-Ch. III dt. 1-12-1967	5 tonnes	Nil	Nil	Nil
		Chlorcyclizine Hel.	L 22 N-33 58 dt. 12-2-1958	60 kgs.	Nil	Nil	Nil
		Dapsone & Solapsone	L 22 N-33 58 dt. 12-2-1958	10.8 tonnes	Nil	Nil	Nil
		Cycline Hel. & base	L 22/348 67-Ch. III dt. 1-12-1967	250 kgs.	Nil	Nil	Nil
		DCC	L/22/224/64-Ch. III dt. 10-8-1964	2 tonnes	Nil	Nil	Nil
		Digoxin	L/22/211/64-Ch. III dt. 2-5-1964	To be fixed	Nil	Nil	Nil
		Emetine Hel.	L/22 N-33 58 dt. 12-2-1958	150 kgs.	Nil	Nil	Nil
		Ferrous Succinate	L 22 328 67-Ch. III dt. 14-3-1967	5 tonnes	Nil	Nil	Nil
		Isoprenalin Sulphate	L 22 348 67-Ch. III dt. 1-12-1967	100 kgs.	Nil	Nil	Nil
		Methlamphetamine Hel.	do.	200 kgs.	Nil	Nil	Nil
		Methyl Stearate	L 22 206 64-Ch. III dt. 4-4-1964	1.2 T	Nil	Nil	Nil
		Paracetamol	L 22 325 67-Ch. III dt. 3-3-1967	3 tonnes	Nil	Nil	Nil
		Primethamine Hel.	L 22/N-33 58 dt. 12-2-1958	240 kgs.	Nil	Nil	Nil
		Succinyl Choline	L 22 297 66-Ch. III dt. 4-3-1966	5 kgs.	Nil	Nil	Nil
		Tubocuracine Cl2	L 22 308 66-Ch. III dt. 20-7-1966	To be fixed.	Nil.	Nil	Nil
		Zinc Undecylenate	L/22/348 67-Ch. III dt. 1-12-1967	200 Kgs.	Nil	Nil	Nil
9. M/s. Ciba-Geigy Ltd.,		Antrenyl	L 22 414 71-Ch. III dt. 16-6-1971	415 Kgs.	Nil	Nil	Nil
		Crude Quinoxis	-do-	2x50 Kgs.	Nil	Nil	Nil
		Ianabol	-do-	60 Kgs.	Nil	Nil	Nil
		Entobex	-do-	2150 Kgs.	Nil	Nil	Nil
		Sulphonamides	-do-	95 tonnes	Nil	Nil	Nil
		Calcium Coramine	L 22 413 71-Ch. III dt. 16-6-1971	1.5 T	Nil	Nil	Nil
		Dexamethasone	-do-	3 kgs.	Nil	Nil	Nil
		Trimethyl Acetate			Nil	Nil	Nil
		Isidrex	L 22 322 67-Ch. III dt. 11-9-1970	2T	Nil	Nil	Nil
		Mestranol	L 22 293 66-Ch. III dt. 15-1-1966	6 kgs.	Nil	Nil	Nil
		Ismelin	L 22 163 63-Ch. III dt. 31-5-1963	252 kgs.	Nil	Nil	Nil

1	2	3	4	5	6	7	8
		Lynestrenol & derivatives	L/22/293/66-Ch. III dt. 15-1-1966	199.2 Kgs.	Nil	Nil	Nil
		Navidrex	L/22/163/63-Ch. III dt. 31-5-1963	5 Kgs.	Nil	Nil	Nil
		Napresol	L/22/324/67-Ch. III dt. 20-2-1967	500 Kgs.	Nil	Nil	Nil
		Oestradial, Oestradiol Propionate	L/22/317/66-Ch. III dt. 15-10-1966	18 Kgs.	Nil	Nil	Nil
		Ethinyl Oestradiol	L/22/468/73-Ch. III dt. 20-3-1973	50 T	Nil	Nil	Nil
		Rutin	L/22/38/55	12 Kgs.	Nil	Nil	Nil
		Serpasil	dt. 22-6-1965 &	18 Kgs.	Nil	Nil	Nil
		Perandren	22/555/IA(II)/61	60 Kgs.	Nil	Nil	Nil
		Lutocycline	dt. 16-8-1961				
		Testosterone esters & Progesterone	L/22/100/62-Ch. III dt. 8-1-1962	102 Kgs.	Nil	Nil	Nil
		Testosterone Undecylineate	2(13)/61-Ch. III dt. 14-5-1962	15 Kgs.	Nil	Nil	Nil
		Testosterone Valerinate	-do-	15 Kgs.	Nil	Nil	Nil
10.	M/s. C. Merck (India) Pvt. Ltd.	Vitamin E	L/22/424/71-Ch. III dt. 27-9-1971	4 tonnes	Nil	Nil	Nil
		Rutin	-do-	4 tonnes	Nil	Nil	Nil
11.	M/s. May & Baker Ltd.	Sulpha Drugs (Sulphadiazine Phthalyl Sulphathiazole Sulphamerazine etc.)	L/22/23/54 dt. 21-9-54 & L/22/N-146/60 dt. 21-3-60 & L/22/69 dt. 7-11-52 & 22(65) IA(II) 57 dt. 27-4-60	210 tonnes	Nil	Nil	Nil
		Mepyramine Maleate B.P.	L/22/N-13/60-Ch. III dt. 19-7-1960	2 tonnes	Nil	Nil	Nil
		Promethazine Hcl & Base	-do-	500 Kgs.	Nil	Nil	Nil
		Promethazine 8-Chloro-theophyllinate	L/22/131/62-Ch. III dt. 13-9-1962	300 Kgs.	Nil	Nil	Nil
		Prochlorperazine Maleate	L/22/N-13-/60-Ch. III dt. 19-7-1960	250 Kgs.	Nil	Nil	Nil
		Chlorpromazine Hcl. B.P.	22(260) IA (II)59 dt. 30-3-1960	2508 Kgs.	Nil	Nil	Nil
		Di-Iodochlorohydroxy Quinoline	L/22/41/55/ dt. 3-8-55 & letter 22(85)IA(II)55 dt. 20-2-1961	4.2 T	Nil	Nil	Nil
		Metronidazole	L/22/417/71-Ch. III dt. 6-7-1971	602 Kgs.	Nil	Nil	Nil
		Acetrasol	L/22/23/54 dt 21-9-54 & letter 22(61)IA(II)54 dt. 5-8-1959	1800 Kgs.	Nil	Nil	Nil
		Neptal	L/22/23/54 dt. 21-9-54	136 Kgs.	Nil	Nil	Nil
		Chloramphenicol Cinnamate	L/22/417/71-Ch. III dt. 6-7-1971	65 Kgs.	Nil	Nil	Nil
		Ephedrine Hcl.	R/22/69 dt. 7-11-52	Not specified	Nil	Nil	Nil
		Psedudo Ephedrine Hcl.	-do-	,,	Nil	Nil	Nil
12.	M/s. Parke Davis	Chloromycetin	L/22/9/62-A & I dt. 5-4-62	20 tonnes	Nil	Nil	Nil
		Benadryl Hcl.	L/22/64/56 dt. 22-9-1956	6 T	Nil	Nil	Nil
		Camoquin Hcl.	-do-	36 T	Nil	Nil	Nil
13.	M/s. Pfizer Ltd.	Tetracyclines	L/22/37/67-A & I dt. 13-7-1967	14 T	Nil	Nil	Nil
		Chlorpropamide		645 T	Nil	Nil	Nil
		PAS & its Salts	L/22/329/67-Ch. III dt. 13-7-1967	110 T	Nil	Nil	Nil
		I.N.H.	L/22/36/55 dt. 26-3-55 & letter No. 1 (39)/61-Ch. III dt. 28-4-62 & L/22/373/69-Ch. III dt. 4-10-1969	80T	Nil Nil	Nil Nil	Nil Nil
		Benminth	L/22/429/71-Ch. III dt. 23-11-1971	300 Kgs.	Nil	Nil	Nil
14.	Richardson Hindustan Ltd.	Menthol	L/29(3)(ii)/62-Ch. III dt. 17-11-1962	Not fixed.	Nil	Nil	Nil
15.	Reche Products Ltd.	Vitamin A	L/22/292/65-Ch. IIII dt. 11-11-65	20 m m u	Nil	Nil	Nil
		Dehydroemetine Hcl.	L/22/438/72-Ch. III dt. 11-4-1972	95 Kgs.	Nil	Nil	Nil

1	2	3	4	5	6	7	8
		Chlordiazepoxide Vitamin E Diazepam Sulphamethoxazole	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
16.	M/s. Searle (India) Ltd.	Spironolacetone	L/22/330/67-Ch. III dt. 30-9-1967	[illegible]	Nil	Nil	Nil
		Propantheline Bromide Dimenthydrinate Methyl Testosterone Testosterone Diphenoxy-late Hel.	L/22/378/70-Ch. III dt. 12-2-1970	[illegible] 1000 Kgs. 15 Kgs. 50 Kgs. 200 Kgs.	[illegible] Nil Nil Nil Nil	Nil Nil Nil Nil Nil	Nil Nil Nil Nil Nil
		DL-Panthenol		5 Tonnes	Nil	Nil	Nil
17.	M/s. Wyeth Laboratories Ltd.	Cortis Costeriods- (Prednisolone/Acetate Prednisone & Hydrocortisone/Acetate)	L/22/N-142/59 dt. 12-2-60 L/22/330/67-Ch. III dt. 29-3-1967	720 Kgs.	Nil	Nil	Nil
		Methyl Testosterone	L/22/N-142 dt. 12-2-1960	33.30 Kgs.	Nil	Nil	Nil
		Testosterone Testosterone Propionate Testosterone Enanathate Testosterone Hexahydro Benzoate	& L/22/329/71-III dt. 26-10-1963	25,000 Kgs. 180 Kgs. 35 Kgs. 5 Kgs.	Nil Nil Nil Nil	Nil Nil Nil Nil	Nil Nil Nil Nil
		Ethinyl Estradiol	L/22/N-142 dt. 12-2-60	7.50 Kgs.	Nil	Nil	Nil
		17-Alpha Hydroxy Progesterones Caproate	L/22/428/71-Ch. III dt. 29-10-1971	350 Kgs.	Nil	Nil	Nil
		Progesterone & intermediates	L/22/330/67-Ch. III dt. 29-3-1967	[illegible]	Nil	Nil	Nil
		Ethoheptazine Citrate	L(10)/65-Ch. III dt. 27-5-1966	As per requirements	Nil	Nil	Nil
18.	M/s. Glaxo Laboratories Ltd.	Methyl Salicylate B.P. Merselyl B.P. Vitamin K Piperazine Adipate Methyl Testosterone Ethisterone Progesterone Testosterone Propionate Contramine Mephesin & Chlorphensin Chlorphenesin	L/22/54/54 dt. 19-10-1954 & L/22/394/70-Ch. III	5005 Kgs.	Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil	Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil	Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil Nil
		Calcium Sannoside	L/22/N-154 dt. 25-5-1960	[illegible]			
		Beta Ionone	CH-0[illegible] dt. 5-3-[illegible]	[illegible]	Nil	Nil	Nil
		Ethinyl Oestradiol	L/22/177/63-Ch. III dt. 26-11-1963	3,750 Kgs.	Nil	Nil	Nil
		Vitamin B 12	L/22/210/64-Ch. III dt. 17-4-1964	61	Nil	Nil	Nil
		Cortisone Hydrocortisone Betamethasone Prednisolone Predisone	L/22/236/64-Ch. III dt. 12-10-1964	3000	Nil	Nil	Nil
		Trichloroethyl Phosphate	L/22/279/65-Ch. III dt. 14-7-1965	[illegible] Kgs.	Nil	Nil	Nil
		Vitamin A	L/22/405/71-Ch. III dt. 13-4-1971	30[illegible]	Nil	Nil	Nil
		Magestrol Acetate Dimenthisterone Methdilasine Hel.	L/22/447/72-Ch. III dt. 15-12-1972	157.5 Kgs. 10.5 Kgs. 180 Kgs.	Nil Nil Nil	Nil Nil Nil	Nil Nil Nil
19.	Alkali & Chemicals Corporation of India.	–		Nil	Nil	Nil	Nil
20.	Anglo French Drug Co.	–	–	Nil	Nil	Nil	Nil
21.	Beechem (India) Ltd.			Nil	Nil	Nil	Nil

1	2	3	4	5	6	7	8
22	Johnson & Johnson India, Ltd.	—	—	Nil	Nil	Nil	Nil
23.	Abbott Laboratories Ltd.	—	—	Nil	Nil	Nil	Nil
24.	Smith Kline & French	—	—	Nil	Nil	Nil	Nil
25.	Laboratories Grimault Ltd.		—	Nil	Nil	Nil	Nil
26.	Anglo Thai Corporation						
27.	G.W. Carnrick & Co.						
28.	Chesborough Laboratories.						
29.	Cooper Laboratories						
30.	Dental Products						
31.	Ethnor Ltd.						
32.	C.E. Fulford						
33.	Indian Schering Ltd.						
34.	John Wyeth Bros.						
35.	Nicholas of India Ltd.						
36.	Ronssel Pharmaceuticals Ltd.						

These Companies are yet to obtain Industrial Licence under the IDR Act, 1951.

ANNEXURE-VIII

Chapter V Para 13 (i)

Report of the Sub-committee on Permission Letters, Diversification and C.O.B. Licences

During the visit of the Committee to various drugs and pharmaceutical units and also by written representations it was brought to the notice of the Committee by the Indian sector that the permission letters and C.O.B. licences were issued to many foreign firms to manufacture mainly formulations with the result that the foreign firms have attained a dominant position in the Industry to the detriment of the Indian sector. The question of permission letters and C.O.B. licences was raised on the floor of the Parliament on a number of occasions and the Minister, in reply to the question, stated that the Committee on Drugs and Pharmaceuticals Industry, appointed by the Government, will go into this question in detail. The Committee appointed a Sub-committee consisting of the following :

1. Shri K. S. Chavda
2. Dr. Ranen Sen
3. Prof. B. V. Ranga Rao
4. Shri P. S. Ramachandran.....Convener

Shri Jaisukh Lal Hathi, Chairman also participated in the meetings. This Sub-Committee went into the question of permission letters and C.O.B. licences in detail. The Ministry of Petroleum & Chemicals had made available to the sub-committee some files relating to the issue of permission letters and C.O.B. licences. The Sub-Committee had also the benefit of hearing the views of the Secretary, P & C Ministry, the Secretary, I.D. Ministry and the Secretary, Techinical Development. A questionnaire was also issued to these Ministries and the Department and the replies received from them have been carefully considered by the Sub-Committee.

2. The general view expressed by the representatives of the Ministries was that the industrial licences, the permission letters and the C.O.B. licences have the same legal sanction. Having regard to the stage of development of the industry, during the first 16 years from 1952--68 permission letters were issued to the firms and C.O.B. licences were issued after 1970. According to them the permission letters were a corollary to the registration certificates and were in the nature of calrification.

3. The Committee has examined the provisions of the Industries (Development & Regulation) Act to ascertain whether the permission letters and the C.O.B. licences issued can stand the test of legal scrutiny.

4. The Industries (D&R) Act, 1951 came into force on 8th May, 1952. Under Section 10, every existing undertaking had to register the undertaking within a prescribed time. A certificate of registration as prescribed under the Rules was to be issued to such firms. There were only 10 firms which had been granted registration certificate under section 10, out of these 10 firms the following 5 firms have been given pemission letters :

1. M/s. Boots Co. India Limited.
2. M/s. May & Baker Limited.
3. M/s. Glaxo Laboratories Limited.
4. M/s. Cyanamid (India) Limited.
5. M/s. Ciba of India Limited.

All the five firms who were given permission letters are foreign firms. All other firms were given licences. In the case of the firms to whom registration certificate is granted, the item in the column Schedule Industry "22. Drugs & Pharmaceuticals" is mentioned. The view of the Ministry is that these firms can manufacture any item falling within the category of Drugs & Pharmaceuticals, and as such they need not apply for a licence so long as the firm is manufacturing any item falling within the category of Drugs & Pharmaceuticals.

5. Under Section 11A the owner of an industrial undertaking not being the Central Government which is registered under Section 10 or in respect of which a licence or permission has been issued under Section 11 shall not produce or manufacture any new article unless :—

(a) in the case of an industrial undertaking registered under section 10, he has obtained a licence for producing or manufacturing such new articles; and

(b) in the case of an industrial undertaking in respect of which a licence or permission has been issued under section 11, he has had the existing licence or permission amended in the prescribed manner.

"New article" is defined in section 3(dd) as under :—

(a) any article which falls under an item in the First Schedule other than the item under which articles ordinarily manufactured or produced in the industrial undertaking at the date of registration or issue of the licence or permission, as the case may be, fall;

(b) any article which bears a mark as defined in the Trade Marks Act, 1940, or which is the subject of a patent, if at the date of registration or issue of the licence or permission, as the case may be, the industrial undertaking was not manufacturing or producing such article bearing the mark or which is the subject of that patent.

6. The Registrar of Trade Marks, who was consulted on the interpretation of trade mark has given his opinion as under :—

"A trade mark is a mark (which includes any device, brand, heading, lable, ticket, name, signature, word, letters or numerals or any combination thereof), which is used by a trader or manufacturer to identify his goods from the goods of other traders or manufacturers in the course of trade.

The definition of a trade mark as given in Section 2(1)(v) of the Trade and Merchandise Marks Act, 1958 is as follows :—

(V) "trade mark" means—

1(i) in relation to Chapter X (other than section 81), a registered trade mark or a mark used in relation to goods for the purpose of indicating or so as to indicate a connection in the course of trade between the goods and some person having the right as proprietor to use the mark; and

(ii) in relation to the other provision of this Act, a mark used or proposed to be used in relation to goods for the purpose of indicating or so as to indicate a connection in the course of trade between the goods and some persons having the right, either as proprietor or as registered user, to use mark whether with or without any indication of the identify of that person, and includes a certification trade mark registered as such under the provisions of Chapter VII.

A trade name is the name under which a person trades or a business is carried e.g., the name of company, the name of a firm etc. (e.g. United Trading Co.).

A patent is a grant from the Government which confers on the grantee for a limited term, the exclusive privilege of marking, selling and using an invention and also authorising for the disclosure of an invention.

Brand name is another term for a trade mark. Both are the same thing. But in legal parlance the term used is 'trade mark'."

Thus even if a certificate is granted or a licence is issued, a firm cannot manufacture a new article under a new brand name without obtaining a fresh licence.

7. The 15 leading foreign firms were given permission letters to manufacture 364 items, of which 360 were formulations. It is well known that the formulations yield larger profit than bulk drugs.

8. With regard to the C.O.B. licences, 12 foreign firms and 5 Indian firms were given such C.O.B. licences which included 215 formulations and 20 bulk drugs. Of these, the share of Indian firms was insignificant. The C.O.B. licences are intended to cover the diversification of products by the firms. The Press Note dated 27th October, 1966 states that the undertakings going in for diversification has to intimate to the Directorate General of Technical Development, the particulars regarding their revised manufacturing programme and the "new articles" proposed to be manufactured and also the value and nature of the minor balancing plant, if any added by them.

9. It appears that barring M/s. Merck Sharp & Dohme, Hoechst and East India, no other firm which secured C.O.B. licence, had intimated to the D.G.T.D, the details required under the Press Note. The Sub-Committee was also told that C.O.B. licences were given to those firms which had taken "effective steps". Rule 2, (ii) of the Rules framed under the IDR Act defines "effective steps" as one or more of the following :—

(a) that 60 per cent, or more of the capital issued for an industrial undertaking which is a public company within the meaning of the Indian Companies Act, 1913 (VII of 1913) has been paid up;

(b) that a substantial part of the factory building has been constructed;

(c) that a firm order has been placed for a substantial part of the plant and mechinery required for the undertaking.

It appears from the discussions which the Sub-Committee had with the Secretaries of Ministry of Industrial Development, Ministry of Petroleum and Chemicals and D.G.T.D. on the 7th Feburary, 1975 that no verification was made whether effective steps had actually been taken by the firms applying for C.O.B. licences. But they were issued on the strength of information supplied by the applicants in their applications. The Committee feels that it

is not consistent with the provisions of the IDR Act. Section 14 provides that "before granting any licence or permission under section 11, 11A, 13 or section 29-B the Central Government may require such officer or authority as it may appoint for the purpose, to make a full and complete investigation in respect of applications received in this behalf and report to it the result of such investigation and in making any such procedure as may be prescribed". This provision has not been satisfied before or after giving C.O.B. licences.

10. The Sub-Committee has come to the conclusion that :

(1) on a proper interpretation of the IDR Act, permission letters could not be issued for new articles whether the firm has been given certificate or registration or a licence unless a new licence has been obtained by the firm for the manufacture of a new article as defined under the Act and clarified by the Controller of Trade Marks;

(2) before granting C.O.B. licences and D.G.T.D. or the authority should have verified whether effective steps have been taken by the firms in accordance with the provisions of Section 14; and

(3) the issuance of permission letters and C.O.B. licences to foreign firms have given undue advantage to these foreign firms to the detriment of the Indian sector.

The Sub-Committee, therefore recommends that so far as the bulk drugs are concerned, having regard to the national need for bulk drugs, the permission letters and C.O.B. licences issued to these companies may be regularsed on condition that—

(a) all bulk drugs are manufactured from the basic stage; and

(b) 50% of the production of the basic drugs should be made available to non-associated Indian formulators.

11. So far as formulations are concerned, in order that there may not be a gap between production and market demand and thereby creating a shortage in the market, the Indian companies applying for the manufacture of such formulations should be given licences liberally forthwith and the foreign companies should be asked to switch over within one year to the manufacture of bulk drugs and formulations to the extent of 50% of the production of basic drugs by them and the balance 50% to be supplied to non-associated formulators.

ANNEXURE—IX

(Chapter V—Para 13-k)

Excess Production of Bulk Drugs by Drug Manufacturing Firms

Sl. No.	Name of the Company	Foreign equity %	Item	Unit	Licenced Capacity	Permissible Capacity	Production			Excess		
							1971	1972	1973	1971	1972	1973
1	2	3	4	5	6	7	8	9	10	11	12	13
1.	Burroughs Wellcome	100	Bephenium Hydroxynapthoate	T	5	6.25	8.46	11.91	9.99	2.21	5.66	3.74
			Cyclizine Hcl. . .	Kgs	250	312	419	534	392.30	107	222	80.30
			D.C.C. . . .	T	2	2.5	6.3	7.4	6.612	3.8	4.9	4.112
			Isoprenaline Sulphate .	Kgs.	100	125	303	114	252.42	178	—	127.42
			Paracetamol . .	T	3	3.75	7.6	10.7	0.868	3.85	6.95	—
			Succinyl Gholinechloride	Kgs.	5	6.25	89.7	71.5	53.70	83.25	65.25	47.45
			Zinc Undecylewate .	Kgs.	200	250	302	485	259.77	52	235	9.77
2.	May & Baker Limited.	100	Metronidazole	Kgs.	602	750.5	5941	6922	7662	5190.5	6171.5	6911.5
			Promathazine Hcl	Kgs.	500	625	1028	858	2055	403	233	1430
			Promethazine S-Chlorotheophylline	Kgs.	300	375	216	396	461	—	21	86
			Di-iodochlore Hydroxy Quinoline	Kgs.	4200	5250	1572	5938	4573	—	668	—
			Neptal	Kgs.	136	170	175	186	272	5	16	102
3.	Roche Products	89	Dehydroametine	Kgs.	95	118.75	199	300	19.0	80.25	181.25	—
			Vitamin A	MMU	15	18.75	23.52	27.81	26.79	4.77	9.06	8.04
4.	Pfizer Limited	75	Chlorpropamide	T	1.5	1.87	11.97	12.90	9.08	9.10	11.03	7.21
			Oxytetracycline	T	9	11.25	30.82	39.00	33.79	19.57	27.75	22.54
5.	Glaxo Labs.,	75	Beta Ionone	T	60	75	96	103	100.07	21	28	25.07
			Calcium Sennosides	T	3	3.75	4.73	3.28	2.29	0.98	—	—
6.	Wyeth Lab. Limited	74	Methyl Testosterone	Kgs.	44.40	55.50	50.70	67.90	73	—	12.40	17.50
7.	Cyanamid Lab.	65	Tetracycline	T	10	12.5	16.7	20.1	18.23	4.2	7.6	5.73
8.	Ciba of India Limited	65	Sulphonnamides	T	95	118.75	146.8	136	81.69	28.05	17.25	—
			Nepresol	Kgs.	500	625	763	573	637	138	—	12
			Crude Quinone	Kgs.	2850	3652	2185	4125	4618	—	562.4	966
			Salt Antreryl	Kgs.	415	503.75	629	467	369	125.25	—	—
9.	Merck Sharp & Dohmed	60	Vitamin B12	Kgs.	72	90	94	142	123.60	4	52	33.60
10.	Bayer India Limited	57.45	Chlorequin Phosphate	T	4	5	22.3	22.8	10.32	17.3	17.0	5.32
			Entodoi	Kgs.	200	250	126	500	Nil	—	250	Nil
11.	Searle India Limited.	57	Aldaotane	Kgs.	28	35	N.A.	36.55	41.9	—	1.55	6.9
12.	Hoechst	50	Tolbutamide	T	36	45	60.47	57.99	65.54	15.47	12.99	20.54
13.	Wander Ltd.	49	PAS & Its Salts	T	120	150	146.4	150.7	135.82	—	0.7	—
14.	Synbiotics	48	Streptomycin	T	62	77.5	92.89	94.73	80	15.39	17.23	2.5
15.	Suhrid Geigy	47.5	Tanderil	T	6	7.5	7.9	7.3	7.23	0.4	—	—
16.	Geoffrey Manners & Co.	45	Al-hydroxide Gel.	T	216	270	251.4	293.2	323	—	23.12	53
17.	Cibatul Ltd	30	Sulpha drugs	T	160	200	243	252.21	N.A.	43	52.21	N.A.
18.	Atul Products Limited	Nil	Menadione Bisulphate	Kgs.	150	187.5	232.1	199.3	366.4	44.6	11.0	178.9
19.	Sarabhai M. Chemicals	Nil	Vitamin C	T	120	150	242	259	261	92	109	111
20.	Cipla	Nil	Diosgenin	Kgs.	2400	3000	4812	2369	2200	1812	—	—
			16-D-hydropregnelone	Kgs.	1200	1500	1074	1618	1300	118	—	—
			Testo terone	Kgs.	120	150	175.1	4.1	—	25.1	—	—

APPENDIX—I

Chapter V, Para 12

(Note : The classification of industries follows the First Schedule to the Industries (Development and Regulation) Act, 1951. Items of manufacture reserved for the [illegible] or allied Schedules. Excluded Note: [illegible] for production in the small-scale sector [illegible] be notified from time to time [illegible] be excluded from the [illegible] list).

1. Metallurgical Industries
   (1) [illegible] alloys
   (2) Steel castings and forgings
   (3) Special steels
   (4) Non-ferrous metals and their alloys.
2. Boilers and Steam Generating Plants
3. Prime Movers (other than Electrical Generators)
   (1) Industrial turbines
   (2) Internal combustion engines
4. Electrical Equipment
   (1) Equipment for transmission and distribution of electricity
   (2) Electrical motors
   (3) Electrical furnaces
   (4) X-ray equipment
   (5) Electronic components and equipment.
5. Transportation
   (1) Mechanised sailing vessels up to 1000 DWT
   (2) Ship ancillaries
   (3) Commercial vehicles.
6. Industrial machinery.
7. Machine tools.
8. Agricultural machinery
   Tractors and power tillers
9. Earthmoving machinery.
10. Industrial instruments: indicating, recoding and regulating devices for pressure, temperature, rate of flow, weights, levels and the like
11. Scientific instruments.
12. Nitrogenous and phosphatic fertilisers falling under (1) Inorganic fertilisers' under 'Ins. Fertilisers' in the First Schedule to ID&R Act 1951.
13. Chemicals (other than Fertilisers)
   (1) Inorganic heavy chemicals
   (2) Organic heavy chemicals
   (3) Fine chemicals, including photographic chemicals
   (4) Synthetic resins and plastics
   (5) Synthetic rubbers
   (6) Man-made fibres
   (7) Industrial explosives
   (8) Insecticides, fungicides, weedicides and the like
   (9) Synthetic detergents
   (10) Miscellaneous chemicals (for industrial use only).
14. Drugs and pharmaceuticals.
15. Paper and pulp including paper products.
16. Automobile tyres and tubes
17. Plate glass.
18. Ceramics
   (1) Refractories
   (2) Furance lining bricks—acidic, basic and neutral.
19. Cement Products
   (1) Portland cement
   (2) Asbestos cement.

CHAPTER—VI

RAW MATERIALS FOR BULK DRUG MANUFACTURE

The raw materials required for bulk drug manufacture cover a very wide field. They consist of substances of vegetable origin like medicinal plants and plant products, of animal origin like glands and organs of slaughered animals, a host of organic chemicals and intermediates besides inorganic acids and bases and nutrient media and solvents for the antibiotics industry. The measures for improvement in the supply of plant products have been deal with in Chapters III & VII. As regards glandular products this is dependent on the setting up of modern slaughter houses and facilities for collection and storage of glands and organs to prevent deterioration of the active principles before they are transported to pharmaceutical units. Action on these lines has been taken in Bombay by setting up a modern abattoir in Deonar. The Committee understands that several expert bodies have examined in details the possibilities of setting up of facilities in other parts of the country and have made comprehensive recommendations. The Committee is of the opinion that these valuable raw materials which are being wasted in large quantities, could be profitably used for biological products, sutures etc.

2. We have dealt in this chapter with some of the important solvents and nutrients for antibiotics and chemical raw materials for synthetic drugs in the supply of which the industry is experiencing difficuly. The list of nutrients and other raw materials required by the antibiotics industry is given in Annexure-I. Nutrients are mainly agricultural products and their supply is dependent on the overall agricultural production. But, even if the availability improves a lot depends on the standardisation of these products to get optimum yields. The industry has had to change its sources often resulting in different qualities which affect the yields. The list also gives the chemical raw materials and solvent requirements as well for the antibiotics industry. Requirements of important intermediates and chemicals for antibiotics and syntehtic drugs are shown in Annexure II and requirements of the same for other chemical based industries along with their total anticipated availability.

3. As regards solvents, chemicals and chemical intermediates excepting the inorganics the problem is quite complex. Many of the chemical based industries including drugs were established even before the locally manufactured organic chemicals and intermediates became available and they still depend on imports to some extent. Many of these intermediary products are interrelated in diverse ways to those required by the plastics, dyes, pesticides, paints, aromatic chemicals and rubber chemical industries. Several of them have common starting raw materials and several others are those which are obtained in a complex manufacturing chain and hence form co-products. This calls for an integrated development of all the chemical raw materials for the chemical-based industries. The large expansion that is taking place in the manufacture of basic chemicals as also in the chemical based industries are being linked at the stage of producing intermediary chemicals which are the starting point of chemical-based industries. In other words, the development of production of the chemical intermediates has been a series of exercises on import substitution which has been achieved in serveral instances. This is a continuous process and not only the existing production has to be increased but also new ones will have to be taken up as more and more basic chemicals become available and the expansion of the chemical-based industries make it possible to set up economic units of production of the other intermediates. A rough idea of the expansions necessary in the filed of organic chemicals and intermediates required to feed the chemical-based industries can be visualised by the following approximate break-up of imports of these products that are at present being made :—

Chemicals and intermediates :

for Drugs	Rs. 10 crores
Dyes	Rs. 10 crores
Pesticides	Rs. 5 crores
Plastics, fibres, rubber etc.	Rs. 20 crores
TOTAL	Rs. 45 crores.

Over and above this, the finished products are also being imported and when they are also made in the country, the requirements of the intermediates will go up further thus increasing the scope for indigenous production of intermediate chemicals.

4. There are certain areas in this filed where the small-scale industries, especially those set up by the technical entrepreneurs can play a very important role. Guidance from both the users of such intermediates as well as the research laboratories in the country are required in setting up units for their production. The State Governments and

financial institutions who are offering spcieal concessions for these young entrepreneurs need to be also greatly streamlined for accelerating this development. There is also a mistaken impression that their efforts should be utilised for making finished products only, starting from bulk materials made by the larger industries. Such activities need large marketing abilities and facilities which the small entrepreneurs hardly possess. Therefore, very often, they come to grief and blame the larger units who have such facilities in not being able to market their products.

5. In the recent past, large developments have taken place to increase the supply of basic organic chemicals which form the starting point for the various chemical intermediates required by the chemical-based industries. In several instances, these have been linked also within the major producing units, with the production of chemical intermediates and certain finished products. Several plants have also come up to make the intermediates starting from these basic chemicals to supply the same to chemical-based industries. Certain captive units have also been set up by the chemical-based industries themselves to meet their own requirements of intermediate. Still, several of them have yet to be linked with basic chemical production to provide their requirements and those that are already being made have to be expanded to reduce the imports. To give a general idea of the various basic chemicals produced and where they have been linked with the production of intermediates for chemical-based industries, they are dealt with under the following groups :—

A. Chemicals based on alcohol.

B. Chemicals based on coal.

C. Chemicals based on petroleum.

A. Chemicals based on alcohol

6. From the sugar industry, ethyla alcohol to the extent of 4,00,000 tonnes per annum is obtained by the fermentation of molasses. A number of basic organic chemicals based on alcohol is produced in the country and they are shown in Annexure III.

7. Unfortunately, several of these units have not been able to produce to capacity because of diversion of alcohol obtained from fermentation of molasses for potable use. Potable spirits can be made from alcohol obtained from other alternative raw-materials and there is no justification for diverting low priced molasses-based alcohol for such purposes. Unfortunately, many States are giving priority for supply of molasses based alcohol to potable spirits mainly from revenue considerations and are starving the alcohol-based chemical plants which have been set up at considerable cost resulting in under-utilisation of their capacity and shortage of the concerned chemical products which, in turn, have resulted in shortages of chemicals and intermediates required by the chemical-based industries. The same is true of ethyl alcohol required as a solvent in the pharmaceutical industry. The difficulty in obtaining alcohol for pharmaceutical and other industrial uses arises presumably because of the existing system of pricing and distribution control in regard to molasses. This system which originated in the treatment of molasses as a waste product, has now become out-dated considering the very large demand for molasses for the production of alcohol needed for industrial use. The Committee understands that this question has received the attention of government but because it happens to be a State subject, there have been dificulties in evolving a more rational and effective system of pricing/distribution controls on molasses which would protect the supplies for industrial use. The Committee recommends that this question should be pursued vigorously, so that the essential requirements of alcohol, particularly of the chemical-based industries are met with, irrespective of the fluctuations in the output of sugar and, therefore, of molasses.

8. It has been brought to the notice of this Committee that different States charge different rates of excise duty on alcohol with the result that there is disparity in prices and availability. The Committee recommends that Government should examine this question and ensure that this disparity is eliminated.

B. Chemicals based on Coal :

9. Chemicals based on Methane and Methyl alcohol are shown in Annexure IV. Here also, difficulties are encountered as, today, there is only one source for methyl alcohol, namely Fertilizer Corporation of India, Trombay It is necessary to have an alternate source to ensure regular supplies of methyl alcohol, which forms the starting point for a number of chemicals required by the chemical-based industries.

10. The present position of coal based chemicals is given in the enclosed statement Anneuxre-V. From the coke ovens of steel plants, 25,000 tonnes of benzene and corresponding quantity of toluene is obtained but hardly 15,000 tonnes are made available to the chemical industry. The rest gets burnt in the steel plants themselves. Alternative substitutes should be used in the steel plants and valuable chemicals like benzene and toluene should be released for the various intermediate producing plants in the country, which are set up for the purpose. An important source of organic bases is the acid sludge obtained from the acid wash of coke oven gases as they contain valuable

pyridine bases. If these are pooled from all the coke-ovens of Steel plants, valuable by-products like pyridine lines, and quinolines can be recovered. They will provide starting materials for a number of other chemicals re by the chemical-based industries. At present the acid sludge is a total waste. Steps should also be taken to that in the coke ovens of the new Bokaro Steel Plant, where 45,000 tonnes of benzene and the corresponding a of toluene could be obtained thereform, are recovered and made available to organic chemical industries.

C. Chemicals based on Petroleum :

11. With the discovery of petroleum resources in the country and the installation of large number of refi a very rich source for organic chemicals has become available. Several petro-chemical units have been set produce a large number of organic chemicals. These petro-chemical industries have been set up near the re and are clustered around with a number of other chemical based units. This is because certain primary manufa processes such as reforming and cracking give rise to a number of different gaseous fractions which cannot be ported over long distances and must be converted at adjacent locations and economic uses for others have to be by recycling them to petroleum refineries for conversion to petroleum products.

12. The total quantity of crude distilled in the oil refineries amounts to 22 million tonnes, out of which 7 n tonnes are obtained locally and 15 million tonnes are imported. When the crude oil is obtained from the oi' associated gases largely methane and ethane are also botained which are today largely used as fuel or for generation. There are also certain off-gases obtained from petroleum conversion operations at the refinerey and are mostly flared and intome instances used in the fertilizer plants. Among the light fractions obtained fro refineries there are again gaseous compounds. The earlier ones which are mostly methane and ethane are us captive heating and steam generation in the refineries.

13. The others which are propane and butane are liquified and used as domestic fuel after filling in cyl. (LPG). Out of the liquid fractions, those with low boiling points between 25° and 60° C are used as petroleum as a solvent in the extraction of active principles of plant materials and for other purposes. The most impo fractions for the petro-chemical industry are the fractions which have boiling points between 60° and 125° C (Na and are the source of petrol or motor-spirit and also petro-chemical and fertilizer feed stock. The interm fraction between 125* and 180* C is also used as petro-chemical feed stock but progressively more as fertilize stock. These fractinns comprise 15% of the crude distilled and roughly amount to 3.3 mil. tonnes. The p chemical industry uses less than 1 million tonnes, of this today but with the expansions that are taking place, thi be increased considerably.

14. There are at present two petro-chemical reformers and four petro-chemical crackers, of which the la cracker is under construction. Various primary and down-stream products that are obtained and planned for pro tion are given in Annexure-VI.

15. In addition, several drug manufactues produce their own intermediates for their captive requirements could, if necessary, increase their production to meet other's demands. One of the examples is INDIAN DRUGS A PHARMACEUTICALS LIMITED's intermediate plant at Synthetic Drugs Plant, Hyderabad. There other firms in the private sector, who make intermediates which are given in Annexur VII.

16. It is seen from the various statements, which are illustrative and not exhaustive, that a large numb intermediate chemicals are being made. The main problem is the supply of basic chemicals to increase their pro tion and expansions in their capacities. With more refineries that have been planned and associated reformers crackers that will come up, there will be an increasing supply of the petro-chemicals. Similarly, for coal based in tries and alcohol based industries, a better rationalisation in the use of the basic raw-materials will result in b utilisation of their capacities. Linking of basic chemicals with intermediates required by chemical based indus not yet produced in the country is a continuous process and a challenge that will have to be taken up both by the in tries and the R & D institutions in the country. Wherever technologies are available in this filed, there should b hesitation in obtaining the best. Our efforts should be concentrated in improving them further. Harnessing potentialities of the technologists that are coming out of the educational institutions, is another important fa in this direction. The integrated development of chemical raw materials and intermediates is the main factor will increase the technical base of the country and that makes all the difference between a developing and develc country in so far as chemical industry is concerned. Once this is achieved a two way flow of chemical prod and know-how with developed countries could be established. Processing a large number of imported prod does not build the required base even if it be by mainly Indian owned firms but on the other hand only incre our dependence on other countries. Hence, whatever facilities are available in this direction in all sectors of industry, should be fully utilised to raise the technical base of the country which only can increase our barga power and put us on the map of production of chemical and chemical-based products including drugs.

17. As will be seen from Annexure II the demand for intermediates by the chemical based industries including drugs will be large and indigenous production of more of the intermediates will have to be planned. In many instances the requirements of drug industry from only a small percentage of the total demand. The two major raw materials required for making the intermediates are benzene and toluene, especially the former. Even with the full capacities of the petro-chemicals reformers in operation and complete recovery of these from the coke Ovens, the production will fall short of country's requirement by the end of the Fifth Plan period. As all the naptha produced is not being fully utilised, reformer units should be set up another existing refineries and also those proposed to be set up for recovering aromatics like benzene, toluene and xylene. This will enable more intermediates being produced for the drugs and other chemical-based industries.

18. At present 48 bulk drugs including a few intermediates and chemicals are imported through State Trading Corporation. This system of canalisation was introduced from April, 1970, with a view to :—

(i) check the possible over-pricing of drugs by some companies ;

(ii) assist the small-scale manufacturers who are large in number in the procurement of raw materials ;

(iii) obtain the drugs at cheaper prices as a result of bulking imports, and

(iv) regulate excessive imports by the actual users direct to protect the growth of the local industry engaged in the manufacture of such items.

Drugs falling within the production range of Indian Drugs and Pharmaceuticals limited are handed over by State Trading Corporation to Indian Drugs and Pharmaceuticals Limited for distribution along with the quantum produced by them. In other cases like Vitamin-C and Chloramphenicol, State Trading Corporation, itself distributes the drugs imported by them and also issues release orders on the indigenous manufacturers of the concerned drugs taking their production into account. The remaining canalised items imported are also distributed by the State Trading Corporation itself.

19. The release orders for canalised items, except for a few chemicals as mentioned in the import Trade Control Policy book, are issued to the various formulators-those registered with the Directrate General of Technical Development under the industries (Development and Regulation) Act and in the small scale sector, based on the recommendations made by the concerned State Drug Controllers. In the case of units registered under the Industries Development and Regulation Act, the raw materials are released on the basis of the best of past two years consumption of the individual items. In the case of small scale unit, some incremental allocations are made over the past consumption on the following pattern :—

(a) Additional 30% to units having a turnover of less than Rs. 1 crore ;

(b) Additional 15% to units having a turnover of Rs. 1 crore and more per annum, and

(c) Additional 50% to the small scale units situated in the State of West Bengal, irrespective of their turnover. DGTD units are also entitled to claim more releases if the allocations made to them fall below their requirement as per licensed/approved capacities for the production of the concerned formulations. Additional releases are also made for meeting Government Orders, subject to their being certified by the Drug Controllers of the States.

20. Besides, some bulk drugs and chemicals are also canalised through State Trading Corporation. In additions to this, the actual users in both the settors-organised and small scale, are given import licence for other drugs and chemicals on actual users basis.

21. As is well known the number of manufacturing units is more than 2,500 and each one needs different raw materials and bulk drugs depending upon their production pattern. While it would be ideal to canalise the import of all the chemicals, solvents and drugs consumed by the entire industry through a centralised agency, it would be practically un-manageable to handle such canalisation effectively.

22. The Committee, however, feels that it is necessary that there should be a central agency for import of all bulk drugs and intermediates needed for the 117 essential formulations indentified by the Committee. This should be done by the National Drug Authority sugguested by us separately in this Report. It would be one of the functions of this Authority to import raw materials and also the ingredients required for these drugs and distribute them to the manufacturers. The N.D.A. will stipulate the quantities of formulations that should be produced by firms out of the bulk drugs supplied to them and ensure that the manufacturers utilise the bulk drugs properly. Although, it would be desirable to regulate the import of raw materials for all formulations, the Committee, feels that a beginning should be made in regard to 117 formulations indentified as essential by the Committee. It is also hoped that as the National Drug Authority expands, it would progressively undertake the distribution of all drug formulations manufactured in the country.

23. As regards the bulk drugs produced indigenously, the Committee, understands that while many of the are themselves consuming drugs for captive use, some other manufacturers do not find a market for the bulk d produced by them. It would, therefore, be desirable to have a centralised agency which would advise various m facturers to regulate their production in accordance with the demand pattern and would also control the distribu of the drugs so produced among formulators. It has to be appreciated that the task involved in this operation w be stupendous considering the number of the bulk drugs involved and the formulators requiring them. The drugs indigenously produced and the chemicals required for the production of 117 items identified by this Commi should be pooled by the National Drug Authority and distributed to the manufacturers according to their requirem Ultimately the bulk drugs produced in our country, which are necessary for production of drugs other t those indentified by the Committee should also be pooled and distributed by this Authority.

24. Presently, there is no organised distribution system in respect of the chemicals, solvents or basic materials produced in the country and consumed by this industry. Each drug manufacturer has to arrange for requirements and in the case of any difficulty experienced by any manufacturer in obtaining his raw-materials nitric acid, glycerine, alcohol etc., assistance of government is sought. Government, in turn, assists such en preneurs by asking the concerned manufacturers of chemicals etc., to help. Such efforts, however, have yiel very little results. In a few cases like alcohol the efforts have failed. Ultimately, however, the National D Authority should take up the responsibility of coordinating the production and distribution of the chemicals wh are exclusively used for the drugs manufactured in the country. In the case of alcohol, this Authority sho persuade the State Governments to ear-mark the bonafide requirements of the drugs industry.

25. Similarly the same organisation should look after the requirements of packaging materials like glass/plas bottles, rubber stoppers, cellophare/aluminium strips and such other essential packing materials required by drug industry.

Summary of Recommendations

The Committee understands that several export bodies have examined in detail the possibilities of setti ng up facilities in various part of the country, like modern slaughter houses, facilitises for collection and storage of glan extraction of active principles etc. The Committee is of the opinion that these valuable raw materials which are n being wasted in large quantities could be used profitably for biological products, sutures etc.

(Chapter-VI. Para 1)

2. In regard to manufacture of chemical intermediates, the small scale industries expecially those set up by th technical entrepreneurs can play a very important role. Guidance from both the users of such intermediates as we as the Research laboratories in the country are required in setting up uints for their production. The State Goverr ments and financial institutions who are offering special concessions to these young entrepreneurs need to b streamlined for accelerating this development.

(Chapter-VI. Para 4)

3. The Committee understands that the question of distribution of molasses for the production of alcohol ha received the attention of the Central Government but becuase it happens to be a State subject, there have been diff culties in evolving a more rational and effective system of pricing/distribution controls on molasses which would pro tect the supplies for industrial use. The Committee recommends that this question should be pursued vigorousl so that the essential requirements of alcohol, particularly of the chemical-based industries are met with, irrespectiv of the fluctuations in the output of sugar and, therefore, of molasses.

(Chapter-VI. Para. 7)

4. It has been brought to the notice of this Committee that different States charge different rates of excise duty on alcohol with the result that there is disparity in prices and availability. The Committee recommends that Govern ment should examine this aspect and ensure that this disparity is eliminated.

(Chapter-VI. Para 8)

5. Presently, there is only one source for Methyl alcohol. It is necessary to have an alternate source to ensure regular supply of methyl alcohol.

(Chapter-VI. Para. 9)

6. Valuable chemicals like Benzene and Toluene should be made available to the chemical industry and these should not be used as a fuel as is done in the Steel plants. Steps should also be taken to ensure that in the coke over of the new Bokaro Steel Plant where 45,000 tonnes of benzene and the corresponding amount of toluene can be obtained from the coke ovens should be recovered and made available to organic chemical industries.

(Chapter-VI. Para 10)

7. The acid sludge, obtained from the acid wash of coke oven gases contain valuable pyridine bases and this should be pooled from all the steel plants, for recovery of valuable items like pyridine, picolines, and quinolines.

(Chapter-VI. Para. 10)

[illegible] required by chemical-based industries not yet produced in the [illegible] will have to be taken up both by the industries and the R & D institutions [illegible] are available in this direction, there should be no hesitation in [illegible] for improving them further. Harnessing the potentialities of the technologists that are coming out of the educational institutions, is another important factor in this direction. The integrated development of chemical raw materials and intermediates is the main factor that will increase the technical base of the country. Processing a large number of imported products does not build the required chemical base even if it be by mainly Indian owned firms but on the other hand only increases our dependence on other countries. All available facilities, in this direction, should be fully utilised to raise the techical base of the country.

(Chapter-VI. Para.16)

9. All the naptha produced should be fully utilised by setting up recovery units near the refineries for recovering the aromatic chemicals like benzene, toluene and xylene. This will enable more intermediates being produced for the drugs and other chemical based industries.

(Chapter-VI. Para. 17)

10. Although it would be desirable to regulate the import of raw materials for all formulations, a beginning should be made, whereby a central agency imports all bulk drugs and intermediates needed for the 117 essential formulations identified by the Committee. This should be done by the National Drug Authority, who will also import raw materials and the ingredients required for these drugs and distribute them to the concerned manufacturers. The NDA will also stipulate the quantities of formulations that should be produced by the firms out of the basic drugs supplied to them and ensure that the manufacturers utilise them properly. The Committee also hopes that as the NDA expands, it would progressively improve and expand its activity in this direction.

(Chapter-VI. Para. 22)

11. NDA would advise various manufacturers to regulate their production in accordance with the demand pattern and would also control the distribution of the drugs so produced among formulators. To begin with, the bulk drugs indigenously produced and the chemicals required for the production of 117 items as identified by this Committee, should be pooled by the NDA and distributed to the manufacturers according to their requirements.

(Chapter-VI. Para 23)

12. NDA should take up the responsibility of coordinating the production and distribution of the chemicals which are required for the manufacture of drugs in the country. In the case of alcohol, this Authority should also persuade the State Governments to earmark the bona-fide requirements of the drugs industry.

(Chapter-VI. Para 24)

13. NDA should also look after the requirements of packaging materials, like glass/plastic bottles, rubber stoppers, colophane aluminium strips and such other essential packing materials required by the drug industry.

(Chapter-VI. Para 25)

ANNEXURE I

Requirement of Raw Materials for the Manufacture of Antibiotics for Achieving Targets for the year 78-79 in respect of the Antibiotics as indicated below

(Chapter VI Para 2)

Penicillin	780 mmu
Streptomycin	825 tonnes
Tetracyclines	280 tonnes
Neomycin	10 tonnes
Raw Materials :—	
Carbohydrates	
Strach	2800 tonnes
Dextrin	400 tonnes
Dextrose	15800 tonnes
Cane Sugar	9600 tonnes
Protein Sources	
Soya Flour	6620 tonnes
Corn Steep Liquor (50%)	6750 tonnes
Ground nut meal	232 tonnes
Salts	
Ammonium Sulphate	3330 tonnes
Sodium Sulphate	990 tonnes
Ammonium Chloride	70 tonnes
Manganese Sulphate	10 tonnes
Zinc Sulphate	2.2 tonnes
Sodium Bi-phosphate	0.825 tonnes
Sodium Chloride	190 tonnes
Potassium Acetate	190 tonnes
Potassium Dihdrophosphate	610 tonnes
Acids	
Sulphuric Acid (Tech)	9500 tonnes
Nitric Acid (Tech)	580 tonnes
Hydrochloric Acid (Tech)	3400 tonnes
Oxalic Acid (Tech)	280 tonnes
E.D.T.A.	115 tonnes
Alkalies	
Calcium Carbonate (Tech)	585 tonnes
Sodium Hydroxide (Tech)	9900 tonnes
Potassium Hydroxide (CP)	320 tonnes
Calcium Oxide (Tech)	135 tonnes
Gases	
Ammonia	225 tonnes
Chlorine	14.6 tonnes
Nitrogen	2150 tonnes
Carboxide	78 tonnes
Solvents	
Butanol	2120 tonnes
Butylacetate	2340 tonnes
Methanol	1275 tonnes
Isopropyl Alcohol	56 tonnes
Octanol	15 tonnes

Quaternary Ammonium Compounds

[illegible]	750 tonnes
[illegible]	10 tonnes
[illegible]	[illegible]
[illegible]	[illegible]

[illegible]

[illegible]	1360 tonnes

Resins (Replac[illegible])

	82.5 tonnes
IRC 50	25 tonnes
IR 45 or equivalent	52 tonnes
IR 4[illegible]-124 or equivalent	50 tonens
Deacidite FF	24 tonnes
Zeocarb - 225	

Antibiotics

Wax Emulsion	1136 tonnes
Vegetable oil	4300 tonnes

Miscellaneous

Formaldehyde (30%)	355 tonnes
Potassium Phenyl Acetate	949 tonnes
Phenylacetamide and Phenylacetic acid	400 tonnes

ANNEXURE II

REQUIREMENTS OF IMPORTANT INTERMEDIATES AND CHEMICALS

(Chapter VI - Para 2)

Unit- Tonnes

Name of Chemical/Intermediate	Availability (anticipated)	Estimated demand 1978-79	Estimated demand 1978-79 the Di Industr
1	2	3	4
A. *Alcohol based*			
1. Acetic Acid	33,200	36,000	2(
2. Acetic anhydride	12,156	13,000	
3. n-butanol	9,500	10,000	
4. Butyl acetate	7,230	70,000	2
5. 2-Ethyl hexanol	3,000 (+10,000 others)	20,000	
6. Ethyl acetate	According to demand.	8,000	
B. *Methane & Methanol based*			
1. Methanol	1,90,000	1 20,000	5.
2. Formaldehyde	1,20,000	75,000	
3. Methylamine	4,000	6,000	
4. Dimethyl sulphate	1,500	2,000	1.
5. Methylene dichloride 6. Methyl chloride	7,000		1 1.
C. *Other derivatives based on alcohol*			
1. Monochloroacetic acid	6,000	5,000	1
2. Aceto acetic ester cyanoacetic ester	1,500	2,000	1
3. Methyl dichloro acetate	170	300	
4. Aceto acetic ester	1,500	2,000	1.
5. Diethyl malonate	1,000	1 000	1,0
D. *Coke-oven products & their derivatives*			
1. Benzene	30,000	2,30,000	2.
2. Toluene	3,000	15,000	2.0
3. Phenol	6,000	30,000	3.8
E. *Petro chemicals products*			
1. Benzene	92,000	2,30,000	2,1
2. Toluene	14,000	15,000	2,0
3. Orthoxylene	31,000	35,000	
4. Ethylene oxide	30,000	40,000	
5. Acrylo Nitrile	24,000	24,000	
6. Acetonitrile	600	1,200	1,2
7. Butanol	6,000 (+ 9,000 from alchol)		2,4
8. Acetone	20,000	36,000	
9. MIBK	3,700	4,000	1,2
10. Ethyl chloride	1,500	1,500	
11. Phenol	15,000 (+ 6,000 from coal)	30,000	

1	2	3	4
Products from H. O.C			
12. NO	[illegible]	[illegible]	
	(+ 18,300 others)		
13. Meta amino phenol	750	600	600
14. M.C.B.	4,250	10,000	1,700
	(+ 2,000 others)		
15. Aniline	6,000	15,000	6,000
	(+5,000 others)		
16. Acetanilide	2,300	4,000	4,000
17. Para-nitro tolene	1,100	1,500	300
18. Meta Nitro toluene	90	1,000	
19. Ortho Nitro Toluene	1,900	2,500	
Other products based on Toluene & Benzene			
20. Acetophenone		1,000	760
21. Amino chlorobenzophenone		15	12
22. C & P nitro phenol		1,000	600
23. p-Chloro phenol		10	5
24. p-Chlorobenzene sulfonamide		50	40
25. 2-5-dichloro nitrobenzene		2,000	1,5
26. Methyl benzene sulfonate		2,500	2,400
27. p-nitro aceto phenone		1,000	750
28. Benzaldehyde		1,200	600
29. Benzoic acid		1,000	10
30. Benzyl chloride		2,000	250
31. Benzyl cyanide		1,000	1,000
32. p-chloro benzoic acid		25	15
33. 2:4-Dichloro benzoic acid		15	10
34. p-nitro benzoic acid		250	200
35. m-nitrobenzoic acid		50	40
36. p toluene sulfonamide		100	200
37. Phenyl acetamide	80	300	300
38. Phenyl acetic acid & its salts	100	1,500	750
Other miscellaneous products			
1. Beta Picoline		500	5
2. Alpha picoline		50	
3. Pyridine	500	300	15
4. Gamma picoline		350	35
5. Phosgene	150	4,000	150

ANNEXURE III

ETHYL ALCOHOL BASED CHEMICALS (TONNES)

(Chapter VI—Para 6)

	Acetic Acid	Acetic Anhydride	Butyl Acetate	Remarks
1	2	3	4	5
Indian Organic Chemicals, Khapoli	6,000		500	From Butanol obtained from ether pl
Somaiya Organo Chemicals (Godavari Sugars) Kanhegaon, Maharasthra	1,800			Also acetaldehyde supplied for sale.
Sirsilk, Hyderabad	3,800	2,900		Major part of acetic anhydride acetic used for conersion to Celiulose Ace
Mysore Sugars, Mandya Karnatak, Mysore Acetate	3,600	1,800		Major part of acetic anhydride us Mysore Acetate for producing Cell Acetate.
Andhra Sugars, Tanku, A. P.	1,080	750		For sale.
A.P.I.D.C. Hyderabad	1,680			For sale.

	Acetaldehyde acetic acid	2-Ethyl Hexanol	Butyl Alcohol	Butyl Acetate	Remarks
Union Carbide, Bombay	1,363	3,000	3,000	2,730	Part of acetaldehyde and acetic acid sold.
Somaiya Organics, Barabanki, U.P.	2,400	—	3,000	3,000	
Kolhapur Sugars	2,400	—	1,500	1,000	Also sell acetic acid.

	Polyethylene	P.V.C.	Styrene		Remarks
Chemplast, Mettur	—		12,000	—	From ethylene obtained from alcohol thro ethylene dienloride and vinyl chlori
A.C.C.I., Rishra	13,000		—	—	From ethylene obtained from alcohol
Hindustan Polymers, Vizag	—		—	10,000	Based on ethylene from alcohol and benz from coke ovens.

Four manufacturers made esters like ethyl acetate to the extent of 3,950 tonnes.

OTHER DERIVATIVES BASED ON ALCOHOL CHEMICALS (TONNES)

	Mono-chloro Acetic Acid
Sardesai	2,050
Cellulose Products, Bombay	1,000
Hico Bombay	

	Acetic Anhydride	Pyrazolone	Aceto-Acetic Ester	Remarks
Colour Chem.	200	As required	1,500	Pyrazolone is obtained by treating diket with phenyl hydrazine. Aceto acetic e is obtained by treating diketene with cohol.

	I.D.P.E.	S.B.R. Rubber	P.V.C. Styrene	Remarks
Synthetic & Chemicals, Bareilly	—	30,000	—	This is based on ethylene from alco which in turn is converted to styre with benzene. Butadiene is also tained from alcohol thro' acetaldeh stage and condensed with styrene making SBR rubber.

ANNEXURE IV

METHANE AND METHYL ALCOHOL BASED CHEMICALS (TONNES)

(Chapter VI -Para 9)

F.C.I., Bombay has a capacity to produce 37,500 tonnes of methanol.

	Formal-dehyde	Chloro-methanes	Methyl amines	Dimethyl Sulphate	Remarks
Standard Chemicals, Bombay	—	5,000	—	—	
Mettur Chem. Mettur Dam	—	5,000	—	—	
F.C.I., Bombay	—	—	4,000	—	
Several Units (HOC, Atul Drug House, Allied Resins & Chem. Newchem. etc.)	85,000	—	—	—	
Ganesh Chemicals Industrial Solvents and Chemicals P. Ltd., Bombay	—	—	—	1,500	

	Penta Erythri-tol	Hexamine	Remarks
Atul Drugs, etc.	2,400	900	Penta-erythritol is made starting from Acetaldehyde & formaldehyde. Hexamine is made starting formaldehyde and ammonia.

ANNEXURE V

COKE OVEN PRODUCTS AND THEIR DERIVATIVES

(Chapter VI--Para 10)

	Benzene	Naphth-alene	Toluene	Pyridine picoline & quinoline	Remarks
Hindustan Steel	25,000	6,000	Corres-ponding qty.	—	
Bokaro Steel	45,000	3,000	-do-	—	Under planning.
Pooled resources of Hindustan Steel & Bokaro, Acid sludge				500	Recovery units to be set up.

PRODUCTS BASED ON COAL-BASED PRODUCTS

	M.C.B.	Phenol	Pentach-lorophe-nol	Phthalic anhydride	Remarks
Durgapur Chemicals, Durgapur . . .	Matching for phe-nol.	6,000	900	3,300	(expansion by 6,000 based on Oxylene).

ANNEXURE VI

PETROCHEMICAL REFORMERS (TONNES)

(Chapter VI—Para 14)

	Benzene	Toluene	O-xylene	P-xylene	Mixed Xylenes
Udex Plant Baroda Refinery	45,000	14,000	—	—	—
I.P.C.L. Baroda	—	—	21,000	17,000	2,500

PETROCHEMICAL CRACKERS

	Ethylene	Propylene	Butadiene	Benzene
NOCIL, Bombay	60,000	35,000	7,000	14,000
Union Carbide, Bombay	22,000	5,000		6,000
I.P.C.L., Baroda	1,30,000	78,000	22,000	24,000
Plastics & Resins Tuticorin	12,000 (Ethylene & Acetylene)			

DOWNSTREAM PRODUCTS MADE BY PETROCHEMICAL UNITS

I.P.C.L.

	Ethylene oxide	Ethylene Glycol	L.D.P.E.
Ethylene	5,000	20,000	80,000

	Acrylonitrile (HCN by products) Methyl Methacralate Sod. Cyanide	Acetonitrile	Poly propylene
Propylene	24,000	600	30,000

	Ploybutadine
Butadine	20,000

	Detergent Alkylate
Benzene	As per demand.

Using Alpha paraffin from Superior Kerosene obtained from the refiner.

NOCIL

	Ethylene oxide	Ethylene glycol	Vinyl Chloride	P.V.C.
Ethylene	12,000	10,000	30,000	20,000

	Butanol	Octanal	Acetone	Di-Aceton	MIBK
Propylene	6,000	10,000	11,000	2,800	3,700

	Styrene	Polystyrene
Benzene	14,000	10,000

UNION CARBIDE

	L.D.P.E.
Ethylene	2,000

PLASTIC & RESINS

	P.V.C.
Ethylene & acetylene	12,000.

DOWNSTREAM UNITS BY PETROCHEMICAL REFORMERS

I.P.C.L.

	DMT	Polyester
Xylene	24,000	3,500

DOWNSTREAM OTHER THAN PETROCHEMICAL UNITS (TONNES)

ETHYLENE BASED

	H.P.D.E.	Remarks
P.I.L.	30,000	

	Styrene	Polystrene	
Polychem	14,000	10,000	Using also Benzene.

	Ethyl Chloride	
Standard Mills	1,500	

PROPYLENE BASED

	Acetone	Phenol	
Herdillia	6,000	10,000	Using also beazene via cumene. Acetophenone obtained as a by product.

BENZENE BASED

	Nitrobenzenes		Chloro-benzenes		M.A.P.	B.H.C.	Aniline	Acetanilide	Nitro-cholro-benzene
H.O.C.	MNB	11,000	MCB	4,250	750	3,500	6,000	2,000	2,320
	DNB	350	ODCB	300					
	NBSA	2,250	PDCB	600					
			ONCB	1,500					
			BNCE	1,500					

	S.B.R.	Remarks
Synthetic & Chemicals	30,000	Using benzene Butadiene.

	Styrene	Caprolactum	
G.S.F.C.	30,000	20,000	Sytrene using ethylene.

TOLUENE BASED

	O.N.T.	P.N.T.	M.N.T.	D.N.T.
H.O.C.	1,900	1,100	90	350

	Benzyl Cyanide	Phenyl acetamide	Phenyl Acetic Acid
D.C.M. Daurala	Mostly capative	80	100

ANNEXURE VII

DRUG INTERMEDIATES

(Chapter VI—para 15)

Indian Drugs & Pharmaceuticals Ltd.	
Hydrazine hydrate 50%	160—200 tonnes
Phenylhydrazine	
Pyrazolone	
Paraphenetadine	225
Para Amino phenol	Under implementation.
Thiosemicarbazide	
Acetyl Sulfanilamide	1300
Cyano Acetic Ester	10—30
Acetyl Acetone	300
Acetobutrolactone	75
Diethylamine	220
Triethylamine	30
Monoethylamine	500
Malonic ester	119—125
Sulfaguanidine	875
Diethyl Carbamly chloride	18
Trichloroacetone	6
Warner Hindustan	
	(Tonnes)
1. Beta Picoline	200—500
2. Alpha Picoline	50
3. Pyridine	200—300
4. Gamma Picoline	50—350
Atul Products	
1. Methyl dichloroacetate	170—220
2. Phosgene	100—150
3. P. Toluene sulphanamide	100
4. Etnyl chloroformate	50
Hico Products	
1. Quaternary Ammonium Compounds	2000

CHAPTER VII

DEVELOPMENT AND FLOW OF TECHNOLOGY

Technology, economy and social utility are very much dependent upon the scale of production, physical r quirement, market capacity and government policies. The present structure of the drug industry being ... geai to the market mechanism from which vast majority of the Indian population is excluded, it cannot serve the broa social goals envisaged.

2. It is necessary in the Indian drug industry to identify a radically new direction to fulfil the social needs an enhance its technological efficiency. Technology is closely linked up with its social role. In the Indian drug in dustry, introduction of a new drug or a new process by a unit is decided on the profitability to an individual entre preneur. Problems of technology in the drug industry are complex, not only due to the rigorous experiments t be conducted first in the laboratories, on animals and then on human beings, but also due to the involvement c various sections in the community and their interlinks in the use of drugs. In a country like India, where the averag technical knowledge of the consumer is rather low and technical guidance for him is scarce, the role of Governmer becomes highly important. The drug manufacturing units, in general, are credited with the ingenuity and exper tise to cozen not only millions of citizens, but also the governments and even the most advanced and technicall powerful societies could not escape this. Unless the very activities through which such influence could be exer cised are eliminated, it is difficult to bring out any marked change in the prevailing system.

3. Technological development in any industry has to be comprehensive and it has to be aimed at achievin specific goals. In the present situation in India, acquisition of process know-how is only one aspect, though impor tant, of the many problems in the technological development in the rug industry. The other aspects of the whole innovation chain are so characteristic of each society that foreign examples or institutions can play a limited role.

4. Technology for the production of bulk drugs is closely interwoven with that needed for the production of basic chemicals. Indeed, in the West, drug industry followed the establishment of the basic chemicals industry. Europe, led by Germany, had an early start in the establishment of the fine chemicals industry and actually Ehrlich's pioneering work was inspired and supported by this industry. Later, other countries in Europe entered this arle of production of fine chemicals and they were followed by U.S.A. and Japan. Long years of concerned effort have provided all these advanced countries with a tradition of high level sophistication in the field of production of all chemicals and, all drugs are in essence chemicals. All these countries have, over the decades, worked out refine ments in each technology to permit bulk production at economic levels. Usually, each country and sometimes, even an individual complex within a country, diversifies its base in bulk chemicals production to feed a diverse variety of chemical-based activities such as synthetic polymers, dyestuffs, drugs and pharmaceuticals for human and animal consumption, etc. Also, many of the large complexes base their drug lines either on their own discoveries or on such critical intermediates, as they may produce, and which have application in more than one of the above areas. It must be emphasized, however, that it is unusual for the same complex to produce all the basic raw materials and intermediates that they may need for their individual lines of production in bulk drugs and pharmaceuticals.

5. In India, chemical industry was almost non-existent at the down of our independence and our effort in drug production amounted really to only large scale preparation of simple extracts, and injectibles and the latter two groups were often prepared from imported materials.

6. Chemical industry has come a long way during the past 27 years and we have today a reasonable base to pick up challenges in this technology-intensive industry with confidence. Indeed, working of Hindustan Organic Chemicals Ltd. (H.O.C.) and Indian Petrochemical Corporation Ltd. (I.P.C.L.), the Durgapur complex and as number of units in the private sector manufacture today a large variety of chemicals based on down-stream products of coal-tar distillation, molasses-based alcohol, petroleum, etc. These is, of course, need for increased productivity in a rationalised manner of all that we produce now and diversification of production to cater to national needs on a priority basis. Quite apart from working out and establishing large scale technology, there is now in existence a substantial number of competent chemical engineers, design engineering consultants, other technologists and plants for manufacture of sophisticated chemical equipment. And, barring very high pressure re-action vessels and related equipment, most of the equipment needed for production of drugs is now being fabricated in India.

7. We have, over the years, imported technologies for the production of important antibiotics and a number of bulk synthetic drugs both in the public and private sectors. Many of these technologies have been substantially refined by indigenous effort, for better economy in production. Besides, technology for several products has been developed within the country. [illegible] challenges have been met with confidence and our base of technological competence as on date is quite [illegible]. Both [illegible] country is now poised not only to absorb technology of any complexity that may be imported but also to improvise and innovate production technologies with competence and complete confidence.

8. There are two broad areas where flow of technology [illegible] in the field of pharmaceuticals in our country. The first is with regard to the existing drugs, to produce the essential items in quantities adequate to meet our increasing requirements and maximise production from available resources and manufacturing facilities already established. This, of course, presupposes that it should be of the required quality, i.e. well formulated and effective in its therapeutic action and is made available at reasonable prices. These drugs should cover specific areas where both prophylactive and curative action have to be taken to treat common diseases that affect large population of country.

9. Secondly, there are areas where existing drugs are not really very effective or where no curative drugs exist for certain diseases in the country. In this case, technology has to deal with research and introduction of better and more efficacious remedies for treatment.

10. It is natural that the first part, i.e. maximising production for improvement of manufacturing technology rationalising resources etc. takes comparatively shorter time than the second part i.e. discovery and introduction of new drugs to treat diseases which still do not have effective remedies.

11. The pattern of consumption of drugs in this country does not follow the pattern in other advanced countries. This is because of the different climatic conditions, lack of proper supply of potable water in rural areas, nutritional deficiencies in our diet and lack of hygienic conditions of living resulting from want of proper housing facilities, lack of proper collection and disposal of sewage and other wastes. In Annexure I are shown 42 basic drugs which would make roughly 80% of value of the items required by the end of the Fifth Plan period as worked out by the Task Force. They comprise anti-infective agents to a large extent, anti-diarrhoeals, analgesics and nutritional supplements like vitamins. Technology for the manufacture of most of these drugs are already available in the country as several commercial units are producing them. 29 of these drugs are covered by the essential drugs identified by this Committee.

12. Increasing supply of raw materials for increasing production, specially for synthetic drugs is essential. Large efforts have been made to increase the production of basic chemicals, both by the expansion of the production of mineral acids and inorganic salts and also in the production of organic chemicals by setting up of recovery units in the coke ovens attached to Steel Plants, alcohol based chemicals and petrochemicals obtained from refinery operations. These need to be linked in a large way with the production of chemical intermediates required not only by the drug industry but by other allied chemical based industries like dyes, pesticides, plastics, synthetic fibres, rubber chemicals etc. We have dealt this in some detail in the chapter on raw materials enumerating the various steps that have been taken on hand in this direction and that have yet to be taken up in the future and the part the national laboratories and the part the large and small scale entrepreneurs have to play in this connection.

13. Stepping up production of the existing units by improvement of technology through R & D activities and efforts of the State owned research laboratories are, no doubt, very important. This should not, however, preclude obtaining from abroad crucial technology for the purpose. Harnessing our limited resources of R & D facilities will definitely yield better results by concentrating on selected fields and also on improvement of imported processes. In this way, we will be able to shorten the period during which we have to depend upon imports of drugs essential to the community, maximise the effectiveness and development of domestic research and in the long run build up competence for export of technology developed by us.

14. Some of the advantages in following this procedure are very glaring in the field of antibiotics. With better strains and improvement of environmental conditions for the growth of the miro-organisms which produce the antibiotic molecule, much higher production can be attained from the existing plants.

15. The improvement of technology in the field of synthetic drugs involves the improvement of the different unit processes and operations and sometimes by reducing the number of steps in the process itself. This again, requires intensification of R &D activity carried out within the country. With the progressive improvement of the technical base in the country coupled with any improvement in the processes obtained from abroad, several of the

bottlenecks which affect production could be overcome. This along with our own ingenuity can mean a total new process which we can even offer to other countries. It should be borne in mind that bargaining power of a country for obtaining new technology is entirely dependent on our technical base. The amount of foreign exchang that can be saved by these efforts is evident from the major imports of drugs, which in many cases, are necessitate because of inadequate indigenous production (Annexure II).

16. With improved technology and better utilisation of capacity not only can imports be reduced but als exports of drugs, which amount to Rs. 16.41 crores in 1973, can be increased several-fold. Even improved tech nology can be offered to other countries to generate a two-way flow of technology.

17. Another important field where this country can take advantage of the special climate and soil conditio is the Scientific cultivation of plants required for the drug industry. This potential has not been tapped to an appreciable extent so far. Cinchona, poppy, ipecac, ergot, etc. are mainly cultivated by Governmental agencie while some other plants like mentha, eucalyptus, citronella, dioscorea, etc., are cultivated largely by the privat sector. This is because large investments have to be made in conditioning the soil, importing the required seed and adopting other agronomic practices for commercial viability. This aspect has been dealt with separately Chapter III. Today, there is considerable demand for plant products in the world inspite of the advances in chemic technology and development of cheaper synthetics and antibiotics.

18. The following drugs derived from plant materials have been identified in the essential drugs mentioned in Chapter X:

Quinine, Morphine, Emetine, Digoxin, Methyl ergomatrine, alkaloids of Ergot, Reserpine, Atropine, Physostigmine, Hematropine, Prednisolone, Noscapine, Vitamin A, Camphor, Menthol, Oils of Clove, Eucalyptus, Peppermints, Anethi, Anisi, Caraway and Cajeput and Belladonna.

The Committee notes that most of these products are manufactured at present in the country and therefore there should ordinarily be no need of importing any technology for any of these. However, vitamin A, prednisolone and other steroids, digoxin, belladonna alkaloids and emetine are produced largely by the foreign equity holding units. The Committee recommends that the National Drug Authority (NDA) should plan and supervise the development of indigenous know-how by utilising the relevant CSIR laboratories, namely Central Drug Research Institute, Regional Research Laboratory, Jorhat, Department of Chemistry, Indian Institute of Science, Bangalore, Department of Chemistry, College of Science, University of Calcutta for developing the indigenous know-how for these products on an economic scale. The NDA should also plan and supervise the streamlining of production technologies of other natural products listed in this group. The NDA should also take over the responsibility for the production of an important drug, Quinidine, (which does not appear in the list of identified essential drugs but is Important) from Cinchona febrifuge or from quinine itself.

19. The Committee feels that it may be necessary to import the technologies for the economic production of ergot alkaloids and of the therapeutically active steroids if these are not worked out by the above group of laboratories within a period of two years.

20. Belladonna is being processed by a large number of units in the private sector and camphor, menthol, oil of eucalyptus, etc. are produced by units outside the drugs and pharmaceutical field and, therefore, there is no need for import of any technology. However, there is need for their cultivation on a large scale.

21. Three steroidal drugs are required for family planning pill *e.g.* ethinyl estradiol, norethisterone and norgestrol. Ethinyl estradiol is being produced in this country at present in the private sector both by Indian and foreign equity companies and ethisterone and norgestrol are not produced in this country at present. The Committee is of the opinion that the public sector unit at Hyderabad in collaboration with the Department of Chemistry, Indian Institute of Science, Bangalore, Indian Institute of Experimental Medicine, Calcutta, Central Drug Research Institute, Lucknow and other Institutions engaged in phytochemical research, may be asked to develop the technology for these drugs within the next 3 years. In the meantime, the Committee feels that since there is urgent need for these steroins in the country, purchase of technology for these products may be considered. Norgestrel is a synthetic product add no separate mention of this will be made in the synthetic group of products.

22. Research and development require large resources. We should, therefore, concentrate on mostly those drugs which are essential for diseases prevailing in our country. Some of the essential categories are

(i) Anthelmintics
(ii) Anti-leprotics
(iii) Anti-filarials
(iv) Anti-malarials

23. The situation in respect of the availability of technology for the different classes of drugs and pharmaceuticals is outlined hereunder:—

Immunological agents

The Committee has identified the following immunological agents among the essential drugs, as under:—

Sera	(i) Tatanus antitoxin (ii) Diphtheria antitoxin (iii) Anti-venom serum
Vaccine	(i) D.P.T. (Triple vaccine) (ii) Polio (Types I, II, III) (iii) Typhoid-Paratyphoid A & B (iv) Cholera (v) Smallpox (freeze dried)
Toxoid	(i) Tetanus (ii) Diphtheria

The Committee notes that the technology for production of sera, vaccines, antitoxins and toxoids including those identified as essential drugs, in Chapter X, has been evolved and further improved in this country. As at present, there is therefore, no need to import any technology for this line of endeavour.

24. Out of 117 essential medicines identified by the Committee 44 are synthetic drugs. The Committee notes that the following 13 of these essential drugs are produced in the public sector:—

Piperazine salts, Folic acid, Sulphadimidine, Phenobarbitone, Vitamin B1, Vitamin B2, Analgin, Diethyl Carbamozine Citrate, Para amino Salicylic Acid, Thiacetazone, Nicotinamide, Sulphacetamide and Paracetamol.

The last 6 drugs are also produced in several units of the Indian sector and by some foreign equity sector units. It is obvious that the technology for all these is available in the public sector and the private Indian sector, and there is no need to import technology for any of these drugs.

25. The Committee is strongly of the opinion that while facilities should be provided to the purely Indian units to reach their licensed capacity for chloroquin, public sector must undertake production of this drug in a big way and fulfil the national targets for 1978-79 and 1983-84.

26. Acetyl salicylic acid and methyl salicylate are produced in the country in the indigenous sector in fairly large quantities. There is no need, therefore, to import technology for these 2 items.

27. Halogenated 8-Hydroxy quinolines are produced in this country in the private Indian sector from basic materials and though there is need to materially enlarge the production capacity for this drug, there is no need to import technology for this item.

28. Succinyl choline chloride, Tolbutamide, Chlorpromazine, Adrenaline, Metronidazole, Furosemide, Hydrochlorothiazide, Vitamin D2 and Mephentermine are being produced in the country by the foreign equity sector in some quantities. Lignocaine is produced in the Indian sector. Nor adrenaline is not produced in the country. There is need for indigenous technology to be developed for same of these items like Metronidazole, Nor-adrenaline etc.

29. The Committee recommends that in addition to R & D laboratories of the public sector, the following laboratories may be involved in developing these technologies:—

National Chemical Laboratory, Poona. Central Drug Research Institute, Lucknow. Regional Research Laboratory, Hyderabad.

Other institutions interested in this type of work may also be associated in this work.

30. Considerable amount of work has already been done for developing the technologies for the production of the above items in the laboratories of a public sector unit and the above mentioned laboratories. Pethidine is being produced by an Indian unit and, therefore, there is no need for the import of technology for pethidine.

31 (i) The following drugs are not at present manufactured in this country at all or are manufactured in only small quantitites:—

Nitrofurazone, Nitrofurantoin, Theophylline, Aminophylline, Phthalyl Sulphathiazole, Calcium Pentothenate, Chlorpheniramine maleate, Thipentol, Oxytocin, Primaquin diphosphate and Vitamin B6.

(ii) Laboratory scale know-how for the production of the above drugs except for thiopental, primaquin, calcium pantothenate and chlorpheniramine maleate are available in the public sector and in the national laboratories.

(iii) It is expected that these processes will be put through the pilot scale trials within the next 24 months. As at present, the Committee feels that we should await the results of these pilot scale trials. However, as mentioned in Chapter III, para 74, the Government/N.D.A. should assess the availability of indigenous technology in respect of Vitamin B6 and take necessary decision on the import or otherwise of technology for the same.

(iv) Technologies for the production of Thiopental, Primaquin, Calcium pantothenate and Chlorpheniamide should, however, be imported because they are not being produced in the country and are imported.

(v) Dapsone is being produced in the private sector by an Indian unit and also by a foreign equity unit. There is no need to import technology for this drug.

(vi) Isoniazid is being manufactured largely in the private Indian sector and there is no need to import technology for this item also.

(vii) At present ephedrine is being prepared by a foreign equity unit from imported intermediates. Ephedrine can be manufatured either by purely synthetic or semi-synthetic processes. The Committee understands that the production of ephedrine by semi-synthetic process is economical. A process for this has been developed by Central Drug Research Institute (CDRI) and is, at the moment, being scaled up, by an Indian unit. There is no need, therefore, to import the technology for the production of ephedrine.

(viii) Vitamin C is being produced at present by two Indian units and a plant has been set up for the production of this item in the public sector also with the assistance of the National Chemical Laboratory, Poona. The Committee feels that there is no need to import technology for production of Vitamin C. The Committee, however, wishes to emphasise that the public sector should give the highest priority to the production of Vitamin C to avoid heavy imports.

32. Diethyl ether, ethyl chloride, salicylic acid, glycerine, glucose, carbolic acid, benzoic acid, trinitroglycerine, etc., are large bulk items which find major application outside the drugs and pharmaceutical industry. These are produced in the country and, therefore, import of technology is not necessary.

33. Nearly, all the inorganic chemicals (Annexure III), except for iodine in the essential drugs list, are being produced in the country and, therefore, it is not necessary to import technology for any of these. In respect of iodine, the Committee feels that for the present, this chemical has to be imported.

34. The Committee has identified four antibiotics among the essential drugs. These are penicillin, tetracycline, streptomycin, and chloramphenicol. Penicillin, tetracycline and streptomycin are being produced in the private sector and public sector and chloramphenicol which is being manufactured synthetically, is produced entirely in the private sector. Whereas the basic technology for the production of penicillin, tetracycline and streptomycin is available both in the public sector and Indian units of the private sector, there is urgent need to obtain high yielding strains of the micro-organisms. One of the public sector units has obtained a high yielding strain of streptomycin and the Committee recommends that urgent steps should be taken to optimise the production at other public sector units also by making the new high-yielding strains available to them. It is immediately necessary to acquire high yielding micro-organisms of Penicillin and Tetracycline along with the associated balancing technology.

35. Chloremphenicol is being produced in the private sector at present and that the productivity in the Indian unit, in the private sector, has been low due to technological difficulties. Chloramphenicol production is fairly complicated and the Committee feels that in order to produce the quantity of chloramphenicol required in the country, steps should be taken to develop this technology indigenously starting from basic raw materials. This work should be entrusted to the National Chemical Laboratory (NCL) and the Indian Institute of Science, Bangalore and Central Drug Research Institute, Lucknow.

36. Sufficient technological skill is available in the public sector and the indigenous private sector to carry out formulations of almost any sophistication. The Committee does not, therefore, consider that there is need to import any formulation technology whatsoever. The Committee, however, recommends that the public sector units should set up a formulation R & D unit as early as possible.

37 The Committee recommends that in order to reduce dependence on import of technology in general, urgent steps should be taken to equip the public sector units of the industry as also the laboratories mentioned above, with such R&D and pilot plant equipment as may be necessary for this work. This would include low-temperature, high pressure and high-temperature equipment including the vapour-phase reaction equipment. The Committee strongly recommends that in consultation with the above laboratories, the specialised equipment may be provided at least at two centres to begin with.

38. The Committee is of opinion that there is urgent need to strengthen the R &D laboratories and pilot plant units with men and materials. The Committee strongly recommends that early steps should be taken to strengthen the available facilities in the public sector units, care being taken that there is a strong design and engineering component established in the R & D structure, so that a chemical process that the developed may be indigenously tested and upscaled by employment of the necessary component of indigenous and competent design and engineering skill. It is of course understood that wherever necessary, the public sector units should seek assistance from other public sector or private design and engineering organisations in respect of unscaling of a given process. The proposed N.D.A. should co-ordinate all these Research and Development activities.

39. We have identified in this Chapter areas where the technologies are existing and also such areas where there is need to develop and import technologies. We, however, feel that in general wherever it becomes necessary for economic reasons or for pressure of time to import a technology or an improvement thereon and/or it is available without onerous conditions attached to it, such technologies might be accepted.

Summary of Recommendations

1. There is need for increased productivity in a rationalised manner of all that we produce now and diversification of production to cater to national needs on a priority basis.

(Chapter VII, Para 6)

2. There are two broad areas where flow of technology is important in the field of Pharmaceuticals in our country. The first is with regard to the existing drugs, to produce the essential items in quantities adequate to meet our increasing requirements and maximise production from available resources and manufacturing facilities already established. Secondly, there are areas where existing drugs are not really very effective or where no curative drugs exist for certain diseases in the country. In this case, technology has to deal with research and introduction of better and more efficacious remedies for treatment.

(Chapter VII. Para 8 & 9)

3. Stepping up of production by the existing units by imporvement of technology through R & D activities and efforts of the State owned research laboratories are very important. This should not, however, preclude obtaining from abroad crucial technology for the purpose. Harnessing our limited resources of R & D facilities will definitely yield better results by concentrating on selected fields and also on improvement of improted processes.

(Chapter VII—Para 13)

4. Another important field where this country can take advantage of the special climate and soil conditions is the scientific cultivation of plants required for the drug industry.

(Chapter VII—Para 17)

5. The National Drug Authority should plan and supervise the development of indigenous know-how of natural products by utilizing the relevant National laboratories, Educational institutions, etc. on an economic scale. It should also plan and supervise the streamlining of production technologies. The National Drug Authority should also take over the responsibility for the production of an important drug-Quinidine-from cinchona febrifuge or from quinine itself.

6. It may be necessary to import the technologies for the economic production of ergot alkaloids a therapeutically active steroids if these are not worked out by the above group of labroatories within a peri years.

(Chapter VII–

7. There is need for the cultivation of menthol, eucalyputs oil bearing plants on a large scale.

(Chapter VII–

8. The Public Sector unit at Hyderabad in collaboration with the Department of Chemistry, Indian In Science, Bangalore, Indian Institute of Experimental Medicine, Calcutta and Central Drug Research Institu now, may develop the technology for ethinyl estradiol, nor ethisterone and norgestrel.

(Chapter VII—

9. R & D efforts should be concentrated towards the development of techlology for new drugs req treatment of diseases prevailing in our country, such as (i) Anthelimintics (ii) Anti-leprotics (iii) Anti-fil Anti-malarials.

(Chapter VII—

10. Indigenous technology should be worked out for succinyl choline chloride, chlorpromazine, adi metronidazole, furesemide, hydrochlorothiazide and nor adrenaline.

(Chapter VII—Pa

11. In addition to the R & D laboratories in Public Sector the following laboratories may be involved i loping these technologies :—
National Chemical Laboratory, Poona
Central Drug Research Institute, Lucknow
Regional Research Laboratory, Hyderabad.

(Chapter VII—P

12. In regard to the drugs mentioned in paragraph 31, laboratory scale technology is available and it is ex that these processes will be put through pilot plant scale trials within the next 24 months. The results of thes plant trials should be awaited. Govt./NDA, should , however, assess the availability of indigenous techno respect of Vit. B and take necessary decision on the import of technology. Technologies for the produc thiopentai, primaquin, calcium pantothenate and chlorpheniramine should be imported.

(Chapter VII—Pa

13. There is an urgent need to botain high yielding strains of micro-organisms. One of the public unit has obtained a high yielding strain of streptomycin and the Committee recommends that urgent steps sho taken to optimise the production at other public sector unit also by making the new high-yielding strains avail them. It is immediately necessary to acquire high yielding micro-organisms for Penicillin and Tetracycline alon the associated balancing technologies.

(Chapter VII—Pa

14. In order to produce the quantities of chloramphenicol required in the country, steps should be ta develop this complex technology indigenously starting from basic raw materials. This work should be entrus N.C.L. and the Indian Institute of Socience, Bangalore and Central Drug Research Institute, Lucknow.

(Chapter VII—Pa

15. The public sector unit should set up a formulation R & D unit as early as possible.

(Chapter VII—Pa

16. In order to reduce dependence on import of technology in general, urgent steps should be taken to equip the public sector units as also the laboratories already mentioned, with such R & D and pilot plant equipment as may be necessary for this work. This would include low temperature, high pressure and high-temperature equipment including the vapour phase reaction equipment. The Committee strongly recommends that in consultation with the above laboratories, the above specialised equipment should be provided at least at two centres to begin with.

(Chapter VII—Para 37)

17. Early steps should be taken to strengthen the available facilities in the public sector units, care being taken that there is a strong design and engineering component established in the R & D structure so that a chemical process that may be developed may be indigenously tested and upscaled by employment of the necessary component of indigenous and competent design and engineering skill. Wherever necessary, the public sector units should seek assistance from other public sector or private design and engineering organisations in respect of upscaling of a given process. The proposed N.D.A. should coordinate all these Research and Development activities.

(Chapter VII—Para 38)

18. The Committee has indentified areas where the technologies are existing and also such areas where there is need to develop and import technologies. The Committee, however, feels that, wherever it becomes necessary, at any point of time, for economic reasons or for pressure of time to import such a technology or an improvement thereon and/or it is available without onerous conditions attached to it, such technologies might be accepted.

(Chapter VII—Para 39)

ANNEXURE I

(Chapter VII, Para 11)

PRODUCTION OF BASIC DRUGS

	1978-79		
	Units		P Cr
1. Penicillin	780	MMU	3
2. Streptomycin	825		2
3. Chloramphenicol	590		1
4. Tetracycline	200		1
5. Nicotinic Acid/Amide	600		
6. Sulphadimidine	1010		7
7. Vitamin C	900		7
8. Analgin	400		2
9. PAS	1000		5
10. Ampicillin	35		4
11. Oxytetracycline	80		4
12. Vitamin B1	100		4
13. Oxyphenyl Butazone	50		2
14. Vitamin A	80	MMU	3
			14
B ITEMS			
1. Chloroquin	150		3
2. Isoniazid	265		
3. Halogenated Oxyquinolines	450		
4. Vitamin B12	300	Kg	3
5. Aspirin	1900		2
6. Sulfadiazine/Sulphadimidine	1230		1
7. Vitamin B6	50		2
8. Phenacetin	500		1
9. Panthenol	60		1
10. Phenylbutazone	200		1
11. Vitamin B2	24		1
12. Insulin	3000	MMU	1
			3
C ITEMS			
1. Paracetamol	400		
2. Metronidazole	50		1
3. Folic Acid	75		1
4. Phthalyl Sulfathiazole	150		0
5. Thiacetazone	70		0
6. Sulfacetamide	80		0
7. Diethylcarbamazine	45		0
8. Tolbutamide	75		0
9. Phenobarbitone	34		0
10. Neomycin	10		0
11. Vitamin E	9		0
12. Piperazine	118		0
13. Ether	530		0
14. Sulfamerazine	34		0
15. Sulfamethozy Pyridazine	17		0
16. Amidopyrine	20		0
			19

ANNEXURE II

(Chapter VII, Para 15)

MAJOR EXPORTS OF DRUGS MANUFACTURED IN INDIA

1973-74

Product	Quantity (Tonnes)	Value (Rs/lakhs)
1. Ampicillin	24.6	161.0
2. Vitamin C	306	113.0
3. Chloramphenicol	65	86.0
4. Tetracyclin	54	74.0
5. Analgin	219	65.0
6. Streptomycin Sulphate	52	63.1
7. Chloroquin	[illegible]	60.0
8. Phthalyl Sulphathiazole	122	40.0
9. Metronidazole	25.0	[illegible]
10. Phenyl Butazone/Oxyphenyl Butazone	[illegible]	29.4
11. Vitamin B2	[illegible]	[illegible]
12. Vitamin B1	27	25.0
13. Pantothenates/Panthenol	33	23.0
14. Sulphamethoxy-Pyridazine	18.8	17.0
15. Neomycin	4.5	15.0
TOTAL :		831.5

ANNEXURE III

(Chapter VII, Para 3.5)

INORGANIC CHEMICALS

1. Aluminium Hydroxide
2. Magnesium Hydroxide
3. Magnesium Trisilicate
4. Sodium Chloride
5. Iodine
6. Potassium Iodide
7. Sodium Bicarbonate
8. Potassium Permanganate
9. Zinc Oxide
10. Boric Acid
11. Chlorinated Lime (Bleaching Powder)
12. Caustic Soda
13. Magnesium Sulphate
14. Sodium Sulphate
15. Potassium Chloride
16. Potassium Sulphate
17. Ammonium Mercuric Chloride
18. Ferrous Sulphate

CHAPTER-VIII

Pricing of Drugs and Pharmaceuticals

One of the terms of refernce of the Committee is "to examine the measures taken so far to reduce prices of drugs for the consumer and to recommend such further measures as may be necessary to rationalise the prices of basic drugs and formulations." In order to assess the impact of the measures taken so far and also to consider what further steps if any, are needed in public interest, it would be useful to refer briefly to some of the special characteristics of this industry ; and in the light of these chracteristics to clarify the main objectives of Governmental action affecting the working of this industry including the pricing of its products.

2. The modern pharmaceutical industry is of relatively recent origin. Essentially, the production of synthetic drugs and pharmaceuticals based on research is a post-World War-I phenomenon ; but during the half a century since the modern pharmaceutical industry was born, and particularly after World War-II, it has grown at a phenomenal rate. According to an Organisation for Economic Cooperation and Development (OECD) Survey in 1969, the total market for pharmaceutical products in the OECD countries i.e. North American Continent, Western Europe, Japan etc. was of the order of $ 10 billion. By 1974, it would have increased still further, and currently, it is likely to be nearer $ 15 billion at current prices. Compared to this huge turnover, the production and consumption of modern pharmaceuticals in India is still minuscule.

3. Unlike some other modern industries such as automobiles or aluminium, the pharmaceutical industry consists of several thousand units ranging from very small establishments which are engaged in manufacturing specialised chemicals to enormous manufacturing empires with turnover as high as $ 1 billion i.e. roughly about Rs 800 crores. The wide range in terms of size arises because beyond a certain minimum size which is not very large, the economices of scale in production are not important in the pharmaceutical industry. Nevertheless, it has been common experience all over the world that in every country a large number of small firms which are locally owned account for roughly about 20% of the total sales of drugs and pharmaceuticals. The remainder of the market is controlled by mostly multi-national units which are much larger in size and resources. The reason why large units generally dominate this industry is because the pharmaceutical market is extremely heterogenous and really consists of a large number of products each differentiated from the other and often protected by patents. In the result, the industry is highly competitive particularly in the matter of formulations; but this competition is not in terms of price but rather in the form of persuading doctors or in the case of house-hold remedies, consumers, to patronize a particular brand of drug and formulation. An important characteristic of this industry is a quick product change or product adaptation technique which is only partly based on proven imporvements is the effectiveness of production combinations. In large part, the Product adaptation/innovation is essentially a marketing technique with a view to retaining or augmenting one's share of the market for a particular pharmacopoial product group. Such a marketing technique, of course, necessarily involves substantial selling costs which in turn have to be added to the costs of the drug. In advanced industrial countries, the pharmaceutical industry also spends substantial amounts—around 10% of total turnover—on drug research and product development. But these expenditures are relatively less significant in developing countries, including India, and by and large the multi-national corporations use their research outlays in the parent company to introduce new drugs/formulations by their subsidiaries in developing countries. The use of brand names as opposed to generic names also enables the industry to sell essentially similar drug formulations at widely varying prices. Quite often, it is difficult for the doctor and almost impossible for the patient to have, at their disposal, informatio which would enable them to compare prices of drugs which are virtually identical. Advertisements rarely mention prices and, in general, the medical representatives canvass the superiority of their particular brands of medicine with the doctor not on grounds of prices but on other grounds such as therapeutic effectiveness or advantages of the new or improved drug. In short, the success of the larger units in the modern pharmaceutical industry is dependent mainly on their ability to develop new products based on research and to create and sustain a demand for their product; and this is done by effective selling techniques and by product adaptation/innovation with a view to help the effective marketing.

4. This particular characteristic of the industry implies that in judging the growth or performance of the industry, reliance merely on the value of output can be misleading. Even if, as in India, prices of drugs have been under control over a number of years, the increase in output could well reflect the introduction of new products at higher prices; and, in any case, in judging the social utility of the industry, what is important is the product composition and not only the value of output. This is particularly important in a country like India where general poverty and the

wide disparities in levels of incomes between different sections exist, special efforts need to be made to ensure the pharmaceutical industry devotes adequate attention to producing the drugs and medicines which are most c to the large mass of people and that these are marketed at prices within the reach of common man. There is evidence to suggest that while the growth of the pharmaceutical industry over the last 15 years has been impressive in terms of growth of output, it has been less so, if one takes into account the product compositio the pricing policies of the industry. It has been brought to the notice of the Committee that according to c medical opinion, in a large number of cases the therapeutic usefulness of particular drug combinations is som doubtful ; and indeed there are cases where the usage of pharmaceutically effective ingredients are irrational or ful in terms of therapeutic value.

5. In the context of the structural charateristics of the drug industry and keeping in view the social objec of Government, it is important to clearly define what it is that we want to achieve through governmental acti the field of drug prices. The per capita consumption of modern drugs and pharmaceuticals in India is curr estimated to be Rs. 6 per year and according to some estimates, only about 20% of the population use modern d On a rough estimate it would appear that the total annual expenditure on drug formulations will probably be b Rs. 30 per family where the family income is Rs. 4200 per year. The pricing of drugs is thus a socially importar sue not because of its effect on the family budget but for certain other considerations. High prices of drugs, fc stance, would effect the ability of the public hospitals to cater to the needs of the poor; but even here, it has recognised that the cost of medicines constitutes a relatively small proportion around 12 to 15 per cent of the cost of the public health services. The reduction in the price of drugs, by itself, therefore, will not make much d ence to the ability of the municipal or state agencies to provide medical facilities. The concern about drug pri therefore, really arises from the fact that many of them are essential to the health and welfare of the commun and that there is no justification for the drug industry charging prices and having a production pattern which is ba not upon the needs of the community but on aggressive marketing tactices and created demand. In other wo the main objective of policy has to be to secure a better convergence of commercial considerations and sc needs and priorities. The emphasis has to be on increasing the social utility of the industry particularly in the c text of extreme proverty and the urgent need for extending as rapidly as possible certain minimum facilities in te of preventive and curative medicines to the large mass of people both urban and rural.

6. It is in this somewhat broader perspective that one needs to view the efforts made so far to reduce the pr of drugs for the consumer. Prior to 1962, there was no statutory control over prices of drugs and formulatic Prices were brought under statutory control, for the first time in 1962 in the wake of Chinese aggression and the claration of emergency. The Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 19 were promulgated under the Defence of India Act. These orders had the effect of freezing prices of medicines on 1st April, 1963.

7. The industry was highly critical of the freeze order on the ground that the prices of various raw materials a inputs were not similarly frozen. It was also claimed that the blanket freeze was adverseiy affecting the growth Indian firms of medium and small size. Government introduced a system of selective increases of prices in 196 and further, 17 essential drugs were identified and were referred to the Tariff Commission for investigation of the cost structure in August, 1966. Drug Prices (Display and Control) Order, 1966 made it obligatory for the man facturer to obtain prior approval of Government before increasing the prices of any formulations in their lists as o June 30, 1966. By an amendment, items with pharmacoppoeial names were exempted from price approval. E emption was also made in the case of new drugs i.e. which had been evolved as a result of original research and we marketed for the first time. In such cases, the manufacturer could fix the prices after submitting necessary data and it was open to Government to fix revised prices, if necessary, within 4 months.

8. As a result of their study of the cost structure of 17 selected essential drugs and their formulations and som other related matters, the Tariff Commission recommended their fair selling prices and also made certain othe related recommendations (43 in number). The Commission came to the following two broad conclusions :

(a) "The domestic prices of the selected drugs are generally very much lower in most cases in other countrie (24.5).

(b) "By and large the prices in the Indian market of formulations compare favourably with the prices of simi lar formulations in the domestic markets of other countries." (24.7).

The higher prices of essential drugs as compared to those in developed countries were said to be due to th following more important factors (i) the high cost of equipment, inter-mediates, and raw materials, a good part o which was imported (ii) the small size and lower capacities of production as compared to other countries, and (iii the Patent Law and related conditions for the transfer of know-how.

9. The Commission took all these aspect into account and adopted generally the principle of weighted average for arriving at fair ex-works price for each essential bulk drug where more than one manufacturer was involved. The price of each individual costed unit was built up after a careful analysis of the data collected by them in respect of the years 1965-66 and 1966-67 for the units and after determining the costs on account of materials, manufacturing expenses, packing, royalty, research and selling expenses incurred by them. Provision was also made for a pre-tax return of 15 per cent on capital employed.

10. The Commission's findings in respect of selected formulations was that the prices can bear some reduction even after allowing for all costs and a reasonable return on investment. For arriving at the fair retail prices for the selected formulations of each firm, the Tariff Commission computed the factory cost comprising of costs of materials and packing materials, conversion cost and packing cost. As regard selling expenses the Commission found that their incidence varied from company to company and was "rather on the high side". Accordingly, they restricted it to 15 per cent of the total factory cost. The outward freight and excise duties were added on the basis of the then existing rates. They recommended selling prices included in addition to the above items, a 15% mark-up on the total cost of sales, i.e. total factory cost plus freight and the selling expenses corresponding to 15 per cent on capital employed in the case of essential drugs, the commission of the retailers, the wholesalers and other intermediates at differential rates for ethical drugs and non-ethical drugs (i.e. drugs saleable against a doctor's prescription and those saleable without such a prescription).

11. The Drugs (Prices Control) Order, 1970 was promulgated on 16th May, 1970. The principal objective of the order was to effect a measure of rationalisation in the prices of drugs and to build up a rational system of price control. The order was also designed :

(i) to bring down the prices of those essential drugs where prices generally remained very high,

(ii) to provide sufficient incentives to the industry to maintain/facilitate its growth from the basic stages and to develop research facilities and expansion in a planned manner,

(iii) to promote diversification of entrepreneurship in the future development of this industry, and thereby provide better opportunities, for Indian personnel with requisite technical qualifications, and

(iv) to curb excessive profits.

12. The Drugs (Prices Control) Order, 1970 was subsequently amended from time to time in the light of the experience gained in its working and suggestions received from the indsutry and trade. The salient features of these amendments and Order are as follows :—

(i) Selling prices for 17 essential bulk drugs in different forms were fixed by Government taking into account the recommendations of the Tariff Commission.

(ii) Selling prices of other bulk drugs frozen at the level prevailing immediately before the promulgation of the order. No manufacturer, importer etc. were to be permitted to increase the selling prices of the bulk drugs without prior approval of the Government for which details are required to be furnished in the prescribed form.

(iii) In regard to formulations, certain norms for conversion charges and packing charges were prescribed for reworking the costs and a formula was devised for calculating the prices of all formulations having due regard to products of original research and development.

Under the usual scheme, the formulations were priced with a mark-up of 75% on the total ex-factory cost. The mark-up includes provision for :

(i) Outward freight,

(ii) Distribution costs and the trade commission,

(iii) Promotional expenses, and

(iv) Manufacturers' margin.

13. In case of formulations involving original work and research, higher rate of mark-up upto 100% was permissible. In respect of formulations involving original research in India on basic drug a mark-up upto 150% was permissible. This order also provided for an alternative scheme of pricing. This alternative scheme provided some flexibility in the fixation of prices, subject to certain conditions relating to mark-up on [illegible] and other formulations and overall profitability not exceeding 15 percent on sales turnover.

It was provided under alternative scheme that gross profits made by this industry (gross profit before tax) will not exceed 15% of turnover in any year; and any excess thereof; if earned, shall be funded* separately which can be utilised, with the prior approval of Government, for following purposes :

(a) Research and development expenditure.

(b) Adjustments against future profits or losses: and

(c) Such other purposes as may be specified by the Central Government from time to time.

*During four years of operation of the Drugs (Prices Control) Order, 1970, only two companies have funded Rs. 22.52 lakhs. These two companies have also not come up so far with any proposal in regard to the utilisation of the amount so funded.

14. Incidental provisions, such as issue of price lists, marking of prices on containers of drugs, sales of split quantities of drugs, proper maintenance of accounts etc., have also been made for the effective implementation of the Order. Prior approval of Government is necessary for revision of prices of formulations once fixed, as well as for fixation of prices of new packs and new formulations. However, small units with a sales turnover of Rs. 5 lakhs or less were exempted from getting prior Government approval. This was provided to help small scale manufacturers.

Implementation of Drugs (Prices Control) Order, 1970

15. The Order provided certain time limits for submission of revised price lists supported by complete data for approval by the Government. When it was found that there was rise in the selling prices of certain products, Government issued an order on 18th August, 1970 whereby the prices of such products where increases had been effected by the industry after 1st of August, 1970, were "frozen" at the level prevailing immediately before the commencement of the Order, pending scrutiny of the pricing data by Government.

16. Subsequently, necessary approvals after scrutiny of the detailed cost data, were issued in December, 1970. There are over 2,500 drug manufacturing units of various sizes in the country. As, it was obviously not possible for the Government to examine the detailed price calculations of all these units in respect of the formulations within the time-limit specified in the Price Control Order, a beginning was made by fixing the prices of the drugs produced by the more important units numbering about 110. It was considered that as a result of operation of the market forces, the prices of formulations manufactured by other units would have to move in sympathy with those of the aforesaid leaders in this industry.

17. Details of cost structure of 11,732 packs of formulations as produced by the manufacturers were examined on a quick basis by the Ministry of Petroleum & Chemicals During a short period by constituting a Drug Prices Review Cell .As a result of this exercise, prices of about 44.9% of the formulations/packs were reduced, 36.15% were kept at the earlier level, and increases were permitted only in respect of 11.45% of packs of finished formulations. At the same time new introductions accounted for 7.5% of the total number of packs examined. It was then estimated that as a result of the above exercise, the community would have benefited to the extent of Rs. 20 crores in a total turnover of about Rs. 220 crores.

18. In September, 1970 a Working Group was set up by the Ministry of Petroleum & Chemicals under the Chairmanship of the Chairman, Bureau of Industrial Costs & Prices to examine the cost structure of 24 bulk drugs and other allied matters. This Working Group also investigated the cost structure of certain formulations and developed norms of conversion and packing charges of different packs of these formulations. The Working Group submitted its report in four volumes, the first three relating to bulk drugs and the fourth to formulations.

Reports of the Working Group were submitted to Government between April to October, 1972. In April and May, 1974, Government announced its decisions in respect of the recommendations pertaining to norms of conversions and packing charges. As costs of production had undergone a significant change since the initial investigation by the Working Group, Government asked the Bureau of Industrial Costs and Prices to examine whether and to what extent, the earlier recommendations needed modification. In the light of this examination, Government also announced its decisions in regard to the prices of 24 bulk drugs. No decision, however, had been reached on the recommendations of the Working Group in regard to the basis of pricing of formulations by the time the Committee on Drugs and Pharmaceuticals was appointed on the 8th of February, 1974.

19. The price control on the Drugs and Pharmaceutical industry has thus been in force in one form or another for more than a decade. Since 1970, virtually all changes in the prices of drugs and formulations required prior [illegible] The operation of the control, however, had less impact on the structure and level of prices [illegible] would have expected in view of the very large proportion of items in respect

of which reductions in prices were effected. As pointed out earlier, the Drug Price Review Cell undertook a quick examination of the cost structure of 11,752 packs and formulations and after discussions with the manufacturers, certain price adjustments mainly downward were effected. In such an exercise, however, it was only to be expected that manufacturers agreed to reduce the prices of those items where the sales value was small and/or growth prospects were limited. While the price reductions covered nearly 45% of the formulations in terms of numbers, in terms of total sales of the 110 companies, the proportion was less than 30%. Similarly, in the case of more than 1/3rd of the formulations, prices were allowed to be kept at the earlier levels. In a large number of cases, these items which together constitute about 6% of the sales were also products which carried a much higher mark-up ; and, therefore, had a significantly higher margin of profit.

20. The review of the trends in profitability on manufacture of formulations since these were brought under statutory control by the Drugs (Prices Control) Order, 1970, shows certain interesting results. Firstly, there has been a general decline in the ratio of profitability on sales over the 3 years ending 1972-73. The results are summarised below :

TABLE

(Percent)

	1969-70	1971-72	1972-73
(i) 31 firms with more than 50% foreign equity	19.15	11.59	9.79
(ii) 11 firms with less than 50% foreign equity	14.62	9.01	8.34
(iii) 15 firms with no foreign equity	9.11	7.77	5.70
(iv) Aggregate of 58 firms	15.47	10.19	8.53

This general decline in profitability, however, covers a fairly wide variation as between units. For instance, while the average profitability of companies with majority foreign equity participation has come down from 19.15% to 9.79% the analysis shows that even in this sector there was a fair number of units with rates of profitability which were significantly higher than the average. Thus, in 1969-70, 20 units had a profitability rate which was 12% and above on sales and even in 1972-73, there were still 10 units in this category. Similarly, in 1969-70, 4 units had a profitability rate which was lower than 6%. This number has gone upto 7 in 1972-73. Secondly, the profitability of Indian companies with no foreign share-holding has generally been lower than that of companies with foreign share-holding. There are several reasons for this trend but in large part the difference arises from the fact that the pharmaceutical industry generally is based on aggressive and competitive selling. Companies and foreign share holdings, are generally older and better established and even after the institution of price control in 1970, they have a product range which continues to have a wide market acceptability and fairly attractive profitability. Newers entrants--mostly Indian companies--have had to face the handicap of being late comers in the field but even in the case of Indian companies it has to be noticed that in 1972-73, the profitability rates among profit making companies varied from 1.6% of sales to 10.7%; two units incurred losses. Thirdly, profitability does not seem to be related to the size of the units except to the extent that generally units with a turnover in excess of Rs. 5 crores annually seem to have a somewhat better profitability record. Otherwise, there is no firm trend suggesting that profitability of smaller units or units of intermediate size is any different from profitability of other units both in terms of levels of profits as well as the variations as between units. This would suggest that except for very large firms—and these are also the older established units—the profitability record is more dependent on the productc omposition of units and their ability in terms of marketing rather than on scale of production.

21. The analysis of profitability in the preceding paragraph is based on returns received from the companies as required under the Drugs (Prices Control) Order, 1970, and relate to pre-tax profitability in relation to the sales turnover of formulations only. In order to assess the profitability of the industry, however, it is necessary to look at the performance of the industry not merely in terms of pre-tax profits as a percentage of sales but also other indicators such as the rate of profitability in relation to capital employed or net profits (*i.e.* profits after payment of tax as a proportion of net worth *i.e.* paid-up capital *plus* the reserves). The only source of information for this kind of assessment is the analysis of Balance-sheets periodically published by the Reserve Bank of India; and the coverage of companies is somewhat different from the companies included in the analysis in the above paragraph. The following table summarises the results of Reserve Bank of India's analysis of Balance-sheets:

TABLE

(Rs. lakhs)

	39 Companies			42 Companies		
	1968-69	1969-70	1970-71	1970-71	1971-72	1972-73
1. Net worth	5956	6677	7422	7618	8477	9063
2. Capital employed	8493	8917	10320	10691	12015	12922
3. Net Sales	14278	16450	18414	18315	21422	24183
4. Gross Profit	2708	3394	3289	3347	3564	3831
5. Pre-tax Profit	2448	3164	3023	3070	3203	3388
6. Net Profit	1069	1358	1222	1250	1363	1411
7. Gross Profit to						
(a) Capital employed	31.9	38.1	31.9	29.7	31.3	29.6
(b) Net Sales	19.0	20.6	17.9	18.3	16.61	15.8
8. Net profit to capital employed	12.59	15.23	11.84	11.69	11.34	10.92
9. Net profit to net worth	17.9	20.3	16.5	16.4	16.1	15.6
10. Net profit to net sales	7.49	8.26	6.64	6.83	6.36	5.83

It will be seen that the profitability after tax measured as a return on capital employed or as a return to the shareholders on their own funds i.e. paid-up capital plus reserves, have not declined as sharply as in the case of profits as a proportion of sales. Of course, in 1973-74 and in 1974-75, there would have been a somewhat more pronounced decline in profitability because of the rise in manufacturing and other costs which were off-set only partially by the the revision of prices. But the fact remains that the industry was able to off-set part of the decline in profitability on sales by the increase in the volume of sales. Between 1968-69 and 1972-73 the total sales of formulations by foreign companies with more than 50 per cent foreign equity, increased by 69.2 per cent. The corresponding increase in the case of the Indian companies, however, was only 32.9 per cent and this is one of the reasons for the relatively sharper reduction in the profitability of some of the Indian companies.

There is also another factor which needs to be borne in mind in comparing the profitability as derived from the analysis of Balance Sheets and profitability on the sale of formulations reported by the companies as required under the Drugs (Prices Control) Order, 1970. The latter relates only to the formulation activity and the profits are shown as a percentage of sales turnover including excise duty, but in calculating the profits, payment of interest and bonus are treated as elements of cost. Thus, the concept of profitability is somewhat different than the one traditionally used in the analysis of balance sheets. Moreover, in many of the larger companies, particularly foreign companies, the non-drug activity constitutes a significant part of the total turnover. In the case of 25 companies,

19 foreign majority and six with a measure of foreign ownership, which accounted for 48 per cent of total sales of formulations in 1972, non-drug activity accounted for 24.5 per cent of their total sales and most of the non-drug products were not covered by any price control. In assessing the impact of price control on the drugs and pharmaceutical industry, it is necessary, therefore, to take a comprehensive view of the entire activity.

22. While the operation of price control so far [illegible] or excessive profits by the drug and pharmaceutical industry, it does not appear to have contributed materially to the emergence of a product or price pattern which is more in consonance with social needs or national objectives. For instance, in spite of the fact that the industry has been under some form of price control for over two decades there are still fairly wide variations in the prices charged by different units for same or similar formulations. Even more disturbing, however, is the fact that the structure of product pricing appears to have a bias in favour of greater profitability in respect of less essential formulations which are consumed by the more affluent sections. This is, of course, implict in the alternative scheme of pricing referred to in para 13 and the procedure adopted in enforcing price reductions when the Drugs (Prices Control) Order came into force in 1970.

23. An important element of cost which needs particular attention is the cost of packing. It has been brought to the notice of the Committee that in many insances, the cost of packing materials constitutes a fairly high proportion of the costs of pharmaceutical products. It has also been noticed that in respect of the same formulation and type of pack, there are fairly wide variations as between units in regard to cost of packing. It is recognised that in some preparations like eye- drops, eye ointments, transfusion solutions, sterile preparations, the cost of packing material could be much higher than the ingredients used because it is necessary to keep the ingredients free from even a trace of impurity. In certain other cases also, therepeutic properties of the medicines need to be protected and this can be done only by resorting to somewhat special packing materials which are relatively expensive. Nevertheless, the Committee feels that greater attention needs to be paid than at present to standardization and economy in the use of packing material consistent with the protection of consumers' interest.

Economy in packing costs can be achieved through bulk packings which would enable the cost to be reduced very considerably for large consumers such as hospitals, health centres and institutional users. Special attention needs to be paid to discouraging non-functional packing which is often resorted to not in order to maintain the quality of the product but to make the product look more attractive. The Committee feels that it would be desirable to keep under continuous review the modes of packing and the materials used for packing purposes by the drugs and pharmaceutical industry with a view to evolving, appropriate packing standards, rationalising material usages and ensuring that competitive packing is not resorted to as a salespromotion measure. The system of price fixation which is based on computation of material cost, conversion costs and packing costs, together with the mark-up thereon, as laid down in paras 6 & 7 of Drugs (Prices Control) Order, 1970 sometimes tended to reduce the incentive to the manufacturers to keep packing costs to the minimum necessary.

24. Rigid control on prices of drugs and formulations had to be modified and selective increase in prices permitted on the merits of each case to take account of any substantial variations in costs of materials including packaging material. But the extent to which such modifications were required was relatively small, until the last quarter of 1973. For instance, the total number of applications received for refixation of prices was 759 in 1971, 2710 in 1972 and 2653 in 1973. With the oil crisis and the subsequent spiralling up of world prices and also the high rate of domestic inflation, the situation was radically altered by the end of 1973. During the first quarter of 1974, the number of applications for price revision went up to 1469 and it increased further to 2151 in the quarter ending June, 1974. It was evident that with the steep rise in production costs, the revision of prices both of bulk drugs and formulations was necessary if supplies in the market were to be maintained.

25. In July 1974, Government after detailed discussions with representative associations of manufacturers evolved a system under which manufacturers could apply for price increases but the extent of such increases was to be limited to the actual increase in costs of materials including packaging materials only. Other cost increases such as those due to increase in wages, electricity rates, freight charges, distribution costs etc. were not to be taken into account. The salient features of the guidelines are :—

1. A basis for calculation of escalatory effect due to rise in the prices of raw and packing materials over the prices used in the cost data of 1970/the latest cost data approved for price revision prior to May, 1974.

2. A simplified procedure for adoption and acceptance of prices for drugs and excipients used in the formulations duly certified by Chartered/Cost Accountant in the prescribed proforma.

3. Notified rates besides norms for Conversion Costs, Packaging Costs and process loss for overages for working out current ex-factory costs.

4. Provision of an additional mark-up on the escalatory effect to provide for the increased cost of commission, transport and miscellaneous selling and distribution expenses as under :—

(i) 50% on escalatory effect wherever the existing mark-up is 75% or less.

(ii) 25% on escalatory effect wherever the existing mark-up is between 75% to 100%.

(iii) Mark up on escalatory effect up to a maximum of 25% wherever the existing mark-up is between 100 –150% limited to a maximum mark-up of 100% on the revised ex-factory cost.

(iv) No mark-up on escalatory effect for items where the existing mark-up is more than 150%. In such cases even the escalatory effect would be so restricted as to limit the revised mark-up to 150%.

Further, in order to assist smaller units which, in any case, would have to price their products in relation to the prices charged by the larger manufacturers in the industry, Government also decided to raise the exemption limit from Rs. 5 lakhs to Rs. 50 lakhs.

26. As a result of these measures, it was possible to deal with the large number of applications received for price revisions much more expeditiously. In general, decisions on applications were taken within 4 to 6 weeks although the total number of applications was very large. Thus, the monthly receipt of applications which was on an average of 221 in 1973 went up to 603 in the first half of 1974. As a result of the revised procedures, in the course of 3 months between September and November, 1974, it was possible to deal with as many as 1466 price revision cases. 27. The procedure laid down in the guidelines for price revision, however, is intended to be a stop-gap arrangement in order to provide interim relief to the industry in an expeditious manner. The main purpose of this revision was to ensure that there was no serious disruption in supplies on account of the spiralling of production costs and the continuation of an uneconomically low price. This purpose was, by and large, achieved. The more important and longer term problem of evolving arrangements to ensure that the drug industry operates in a framework which ensures adequate supplies of essential drugs and pharmaceuticals at prices which are fair an reasonable both to the producers and to the consumers, however, still remains. It is to this problem we will now turn.

28. In order to evolve a long-term policy, it is necessary to identify, in the first instance, the main objective of such a policy, taking into account the socio-economic conditions in the country and the declared objectives of planned development in the field of health services. In this backgroungd, it would appear that any scheme of price/production regulation should be: (i) to ensure that the country's dependence on imports of basic drugs is reduced as quickly as possible by encouraging, wherever possible, an economically viable domestic production of such bulk drugs. The primary objective of policy in this field should be larger production and lower costs so that in the long run, these may be reflected in adequate availability and lower prices (ii)) In the field of formulations, the main thrust of policy should be to take measures which will reduce or eliminate the social costs involved in competitive product adaptation or aggressive selling. The recommendation of the Committee in Chapter X regarding the abolition of brand names in respect of 13 drugs will be an important initial step in this direction. In addition, the administrative regulation and licensing should be geared to ensure that greater emphasis is laid on production of the 117 essential medicines listed in Annexure-II to chapter X of the report. In this area, the policy objective should be to ensure that prices are fair and reasonable to the producer and to the consumer. But this will need to be supplemented by appropriate administrative action to strengthen the production base by ensuring adequate supplies of materials, both domestic and imported, and adequate arrangements to ensure that extraneous factors such as shortage of power, allotment of materials such as alcohol etc. do not interfere unduly with production; and (iii) apart from these, it would still be necessary to have some arrangements to monitor and regulate where necessary, prices of important drugs and formulations with a view to ensuring that the drugs and pharmaceutical industry does not generally act to the detriment of the consumer.

29. If these are accepted as the primary objectives of the regulatory framework, it seems necessary to have a certain shift of emphasis in regard to the existing regulatory arrangements including the present basis of price control. Firstly, in order to encourage the production of bulk drugs which are currently imported in significant quantities, it would be necessary to list out items which can and should be produced within the country in a specified period of time. Having identified these items, all necessary assistance should be provided to enable the industry to produce them. To the extent that the public sector and/or the wholly owned Indian units are able and willing to produce these bulk drugs, they should receive preference. If, however, for any reason, production plans of these units do not materialise, other units in the industry including those with foreign equity may be permitted to set up production capacity. As long as the country is dependent on net imports of a basic drug, the existing unit or a new unit may be free to determine the selling price provided it is not higher than the selling prices of State Trading Corporation which are based on average landed costs of imports and handling and other charges.

30. In the case of bulk drugs in which production is already established and in which imports are no longer necessary, greater attention should be paid to ensure that the cost of production is kept to the minimum. This involves the use of efficient technology and process know-how; an adequate scale of production and also special care

to ensure that some of the essential ingredients are not excessively high priced as compared to international price either because of high import duties or other tax measures or because of under-utilisation of productive capacity or inefficient management. It would also be desirable to exempt from price control items in which there are no imports and which in terms of total sales of the bulk drug do not exceed Rs. 25 lakhs annually. In respect of other bulk drugs, a system of price regulation based on detailed cost investigation should continue subject, however, to the price being so fixed that an efficient unit is able to get a return on his capital employed which is a little higher than is available on formulations for the industry as a whole.

31. The Committee has given serious consideration to the question of the rate of return on investment required for production of bulk drugs. The Tariff Commission had come to the following conclusion in their report regarding the return on capital employed on the basic activity :-

"Considering that the durg industry is oriented to humanitarian services it should not hanker after the high profits and we have assumed a low rate of dividend and consider that the stability of the companies as well as higher margins earned their side activities would be conducive to the attraction of the requisite capital. We have therefore, arrived at the figure of 15 per cent of the employed capital as fair return for the industry in respect of its manufacture of basic drugs."

This aspect was also examined by the Working Group on Drugs and Pharmaceuticals set up by Ministry of Petroleum & Chemicals under the Chairmanship of Shri N.N. Wanchoo, the then Chairman of BICP and came to almost similar conclusion, as follows:

"It seems to us that with a return at 12% many units of this industry may not even be able to declare a dividend at 10% on the share capital, let alone find adequate funds from internal sources for the growth of the industry. The importance of having a well developed drug industry and the need for self-sufficiency cannot be over-emphasised from the point of view of the health of the community. In these circumstances, we are of the view that a higher return would be justified in this case and, accordingly in our calculations of fair selling price, we have allowed return at 15% on the capital employed."

It is interesting to note that while the return of 15% was allowed on sales turnover in case of formulation activity, the return on bulk drug activity was calculated at 15% on capital employed. It is also necessary to note herethat the ratio of turnover to capital employed is 2.6 : 1 in formulation activity and hardly 1 : 1 in case of bulk drug activity. It need therefore be emphasized that in the past the drug manufacturers have put up more stress on the production of formulations which were more profitable than on the bulk drug activity. In order to set the things right, the return on capital employed in case of bulk drug activity should now be made as attractive as possible to encourage more basic production, and to realise the targets laid down in the Task Force Report of the The Planning Commission. The Committee, therefore, recommends that a return-post tax between 12 to 14% with reservation from Shri K.S. Chavada who wanted 90% post taxr eturn on capital employed, on equity i.e. paid up capital plus reserves may be adopted as the basis for price fixation, depending on the importance and complexity of the bulk drug. For the purpose of determining the rate of return, on this basis, taxation should be calculated on the basis of statutory rate of tax. Otherwise, the benefits on any specific corporate tax concessions will be denied to the units in the industry.

32. In respect of formulations, it will be seen that the control over prices has evolved over the years in a somewhat *ad hoc* manner. Under the existing arrangements, prices of all formulations in different packs manufactured by all units in the industry having a total sales turnover of over Rs. 50 lakhs are subject to control. Any change in the prices has to be with the prior approval of Government. In effects, therefore, the present price regulation extends to over 6000 packs distributed amongst 2800 products. Though the system of price regulation is comprehensive, as pointed out earlier, it has not succeeded fully in bringing about equitablility as between units or contributed to a socially desirable structure of prices. The present arrangement for price fixation costs an enormous administrative burden on the agency responsible for fixation/revision of prices. The operation of the alternative scheme of pricing referred to in para 13 has meant that for the same or similar products, variation in prices between different producers could be considerable.

33. The general inflationary trend and more particularly the recent steep escalation in some of the costs input and manufacturing expenses which have been only partially compensated in the form of an adjustment of prices has, in effect, meant that the ceiling of 15% on sales turn-over prescribed under the alternative scheme has become notional for most of the units in the industry. At the same time, the way in which the cost increases and price revisions have affected the units in the industry have not been uniform. In general, units which started with a relatively high mark-up on growth items in their production structure — and many of these have been foreign dominated units— been less adversely affected than those units which started with a relatively lower average mark-up. This is true of many Indian units and also those units which had a high proportion of their output in the form of generic name drugs or life saving drugs which were deemed essential to the life of the community, and, therefore, the mark-up had been kept deliberately on the lower side. Altogether, the situation today is that the structure of drug prices has tended to be distorted both in relation to the original intentions of the Drugs (Prices Control) Order, 1970 and also in terms of any objective or rational criteria for evolving a pricing policy in respect of drugs and formulations.

34. In this background, the first question to ask oneself is: is it necessary in terms of public interest to have a price control system which covers each and every formulation; or is it better to introduce some selectivity in regard the formulations which are to be brought under price control ? Given the characteristics of the industry and keeping in view the need to have an effective system which is administratively workable, the Committee has come to the conclusion that more selectivity in the system of price regulation, with a view to ensuring fair prices in respect of drugs and formulations, would be desirable rather than all drugs and formulations irrespective of their importance. Regulation of prices is essentially a device to ensure that public interest is protected. In the drug industry, effective competition is often vitiated by the prevalence of brand names and the strong brand preference which has been created over the years through aggressive marketing. In respect of formulations based on thirteen drugs, the Committee has recommended that brand names should be abolished. Provided there are no artificial restrictions placed on increase in production in respect of formulation sold under a generic name, there will be adequate competition and the Committee recommends that these should be free from price regulation. It will be recalled that as pointed out in para 7, formulations sold under a generic name were originally exempt from price control order. Adequate production and the abolition of brand names in the case of particular drug formulations would, in the view of the Committee, provide sufficient protection to the consumer in terms of availability and price.

35. In the case of other formulations, selectivity could be (a) in terms of size of the units (b) in terms of selection of items and (c) in terms of controlling the prices only of market leaders in particular products for which price control is contemplated. An appropriate combination of these criteria is also feasible. The essential point, however, is that the new system of price control should be one which does not require a prior approval of Government in respect of each formulation, irrespective of its importance, nor should it involve having to examine costs and prices of each manufacturer of a product, irrespective of whether or not the unit accounts for a significant share of the market.

36. On this basis, there is a good case for exempting from the purview of price regulation all units with a turnover of less than Rs. 1 crore, as against the present exemption limit of Rs. 50 lakhs for this purpose. There are about 2500 units in the drug and pharmaceutical industry but according to the available information only 42 of them have presently a turnover in excess of Rs. 2 crores annually and another 15 have a turnover in excess of Rs. 1 crore. These 57 units between them account for over 3/4ths of the total production of drugs and pharmaceuticals. In order to ensure that this relaxations not misused, the Committee feel that the exemption should not be applicable in respect of those units which come within the purview of the Monopolies and Restrictive Trade Practices Act.

37. It is possible that in exceptional cases, units with a total turnover of less than Rs. 1 crore may still be important from the point of view of price regulation, because they account for a substantial proportion of the total output of a drug which is essential to the community and which in terms of total sales is significant in volume. In order to ensure that all formulations (other than those which have to be marketed under generic names only) which have a substantial volume of sales turnover are within the ambit of price regulation, the Committee suggests that all formulations which have an annual all-India sale in excess of Rs. 15 lakhs (including excise duty) should be within the ambit of price regulation whether or not the total annual turnover of the unit is in excess of Rs. 1 crore. At the same time, even large firms may have items of manufacture which are minor elements in their production programme and have a small turnover. According to the available data, the pharmaceutical industry in 1974 had 2791 products (each with several pack sizes) which it marketed. Of these, only 453 products had an annual sales turnover, individually, of more than Rs. 15 lakhs. In other words, if price control is limited to products with sales in excess of Rs. 15 laks annually, it would be possible to minimise the product coverage of control by nearly 80%, and yet the 453 products which will continue to be under control will account for 70% of the total turnover of the industry. In this way, the administration of the control can be made more manageable and, therefore, more effective. If necessary, Government may, in exceptional cases, decide to add any particular product to the list of price controlled items, in public interest. But, ordinarily, in any product group only those manufactures which individually have a total sale of their specific formulation in excess of Rs. 15 lakhs will be brought under control. The ceiling price will be determined taking into account the production costs and a reasonable return for the units which are the market leaders; and all other units will be free to decide on their own prices provided they are not inexcess of the ceiling price determined by Government.

38. Another variant of selectivity, which could also be considered, would be to identify product groups which individually are important and which collectively constitute the bulk of the output of the drugs and pharmaceutical industry. In respect of each item on this list, it would be possible to identify the leading producer who, between them, account for, say 60%, of the sales. On the basis of the cost analysis in respect of these units, maximum prices may be prescribed and all other units may be free to fix their prices. But in practice they will have to adjust their prices to keep in line with those charged by the market leaders. Under this arrangement, all the major units will find themselves in a situtation where a few of their products are market leaders and the selling price is based on an examination of their costs. But in respect of other products some other firm would be recognised as a market leader and although they may have the freedom to price their product, it will be circumscribed by the fact that the leading producers of that product have to sell it at a price which is based on a claculation of reasonable costs of production including a margin of profit. Such an arrangement will considerably reduce the volume of detailed cost investigation and will still ensure that the consumers get the formulations at prices which are fair and reasonable. Such an

arrangement, however, will work only provided there are no constraints on the market leaders increasing their output so as to meet emergent demand at the controlled price. Otherwise, a situation can arise when in the absence of adequate volume of production by the market leaders, there is a thriving black market for their products and the other manufacturers are also able to charge prices higher than the ceiling prescribed by Government, to the detriment of the consumer. On balance, the Committee is of the view that this particular variant of selectivity may be administratively simpler.

39. In any of these variants, however, it is necessary to provide for a reasonable margin of profit which will provide the industry— both private and public sector — not only to maximise production by utilising existing capacity but also to incur additional investment for a sustained growth of the industry. Starting from a relatively small base as we do, it is important to ensure that regulation of prices is not such as to discourage the planned rate of growth. At the same time, it has to be recognised that the profitability of the drug industry and particularly in respect of formulations has traditionally been higher than in most other industries; and this is true in most parts of the world. The return of 15% on sales, including excise duty and exclusive of bonus and interest payments, provided for under the Drugs (Prices Control) Order, 1970 is, in the view of the Committee, excessively generous. Translated in terms of return on capital employed, this would mean a grooss return of between 35 to 40% (or even more) on capital employed and in most cases, this would imply a rate of return in excess of 20% after payment of tax on equity i.e. paid up capital plus reserves. Of course, in practice, profitability with very few exceptions, has been much lower than this level partly because of administrative action taken by Government in fixing lower mark-ups on certain essential products and partly because generally cost increases have been offset only partially by revision of prices. In the last year or so, the profitability of the industry has been further reduced as a result of the sharp escalation in costs and only part of the increase has been taken into account in the readjustment of prices. The Committee feels, therefore, that in determining fair and reasonable return to the industry, the basis should not be the one provided under the DPCO. The Committee is inclined to the view that a ceiling on profitability as recommended by the Working Group under the Chairmanship of Shri N.N. Wanchoo adjusted for the significant increases in longterm interest rates would serve the purpose and would ensure an adequate return.

40. The main recommendations of working group on Drugs and Pharmaceuticals under the Chairmanship of Shri N.N. Wanchoo on return on formulation activity under the alternative schemes were as follows : -

Type of Unit	Ceiling on profits as percentage of sales turnover
1. *Large units with sales turnover exceeding Rs. 6 crores per annum and*	
(a) having no basic drug manufacturing activity nor any researech activity	6
(b) having basic drug manufacturing activity corresponding to 5% or more of sales turnover, but no research activity	7
(c) having basic drug manufacturing activity at 5% or more of the sales turnover and engaged in approved research and development work relating to new drug	8
2. *Medium size units with sales turnover between Rs. 1 crore to 6 crores per annum and:*	
(a) having no basic drug manufacturing activity nor any research activity	7
(b) having basic drug manufacturing activity corresponding to 5% (or more) of the sales turnover but no research activity	9
(c) having basic drug manufacturing activity at 5% or more of sales turnover, and engaged in approved research and development work relating to new drugs	11
3. Unit with sales less than Rs. 1 crore per annum	10

When the sales turnover of a medium size unit exceeds Rs. 6 crores per annum, it would shift out of the class and the ceiling on profit would be reduced to the levels applicable to large units indicated above. In order that a medium size unit having a ceiling at 7%, 9% or 11% as recommended above may not suffer adversely, we would recommend marginal adjustments. Accordingly, when such units shift out of the class, the rule of ceiling on profit recommended for large units should be so applied that the profit left with these units would be not less than Rs. 42 lakhs, Rs. 54 lakhs or Rs. 66 lakhs as may be appropriate. Similarly, when a small size unit shifts into medium size, a marginal adjustment should be allowed, so that the ceiling rule would operate when profit exceeds Rs. 10 lakhs.

The above percentages were suggested on slab basis taking into consideration the size of the units and also turnover in September, 1972. In the light of the subsequent changes that have taken place since then in the economy due to oil crisis and unbridled increase in the cost of inputs and the increase in bank rates etc., it is suggested that the percentage of 6-11% may be amended to 8-13% by adding 2% to each of the percentages suggested against the category of each activity listed under the large, medium and small groups. In order to ensure that the profitability ceilings as above, do not work to the disadvantage of manufacturing units particularly those in the Indian sector, the Committee would further suggest that as an alternative criterian the ceiling on profitability may also be specified in terms of the rate of return, after taxes on equity i.e. paid-up capital and reserves. Depending on the type of unit, this ceiling, in present circumstances, may be kept between 10 to 12.5 per cent post-tax on net worth.

In para 21, the general profitability of the industry was discussed. It may be observed therefrom that the industry on an average was making a profit of 15% on the net worth after taxes. It was also stated that the decline in profitability would have been more pronounced in 1973-74 and 1974-75. In order to promote a healthy growth of the industry, it has been suggested that the rate of return permissible may be between 10 and 12½% post tax on net worth. In view of the flexibility allowed in adjusting the price structure of the products in line with those of market leaders, the range of products that come under direct price control, will be limited, and the manufacturer will therefore, have much more freedom to adjust the prices of other products according to market conditions. In some cases, the manufacturers may even be in a position to earn profits in excess of the ceilings suggested above. There should, therefore, be a provision, as at present, for funding the excess profits and these should be utilised for the purposes to be specified by the Central Government. However, the provision for ajdjusting the funded amount in the future profits or losses should be deleted as suggested by the Working Group.

41. The above suggestion, it needs to be emphasised, would involve a radical departure from the existing system of price regulation in this industry. Instead of the present comprehensive control on all products of each firm above certain size, the proposed system will be a much more selective and will be confined to the determination of fair prices in respect of important pharmaceutical product groups. Even in respect of these products, the basis for determination of fair prices would be an investigation in the costs of production of two or three leading manufacturers which between them, account for say 60% or more of the total sales of that product. Similarly, the basis of price determination will also undergo a change. According to the Drugs (Price Control) Order, 1970, retail prices of products are based on a calculation of material costs, conversion costs and packing costs. In addition to these costs, a mark-up to a maximum of 75% on essential drugs and 150% on others is allowed. The quantum of the mark-up has varied even more widely for reasons explained in para 19. Under the new system, fixation of ceiling prices for leader products will be on the basis of a more detailed cost examination. There will be no mark-up on costs but all costs including legitimate selling expenses, trade commission, freight etc. will be taken into account. In addition, a return on sales on the lines suggested in para 40 will be permitted in arriving at the fair retail selling price. This price, as pointed out earlier, will be in the nature of a ceiling and all producers will be free to change their prices without prior approval of Government provided the retail price does not exceed the ceiling notified for that product. Such an approach to the fixation of prices will enable the price fixing authority to examine carefully the cost elements and also judge whether or not it is possible to reduce some elements of costs such as fancy packaging or exhorbitant expenditure on sales promotion. Such a uniform approach to the price fixation of major phramaceutical groups would also remove the disincentives for the production of essential drugs which have sometimes arisen in the past because mark-up on essential drugs was kept at a very low level. In additionl to the control of prices, the system will also have an overall limit in terms of profitability as pointed out in para 40. The Committee feels that the above proposals would be fair to the consumer and at the same time provide adequate incentive to the industry to minimise costs and increase production.

42. The preceding discussion has been specifically in the context of appropriate price regulation for this industry. Given the characteristics of the industry, however, the Committee firmly believes that in order to achieve national objectives and protect the consumer, price control, by itself, is not enough. What is needed is a multi-pronged approach. In order to ensure that the drug and pharmaceutical industry acquires adequate social content, the extension of the public sector, so that it acquires a dominant role in this industry is very important. In addition, however, the Committee feels that it is essential to evolve an effective and continuing system of monitoring, in respect of this industry, if social objectives are to be achieved. For instance, it is not merely enough to fix what are deemed to be fair and reasonable prices and revise them as and when manufacturers approach Government for an upward revision of prices on account of escalation in costs. In this way, prices tend to be revised only in the upward direction. It is

equally necessary for Government to have a suitable organisation which would be in a position to take *suo-moto* action to bring about a reduction in prices whenever circumstances so warrant. As a result of improved technology or larger scale of production or because of lower input prices, production costs of drugs and pharmaceuticals go down; and in all such cases, the consumer should benefit in the form of reduced prices.

43. The main objective is to make essential drugs and pharmaceuticals available to an increasing number of people at prices which they can afford. This objective cannot be secured merely by price regulation or even by giving the public sector a more dominant role. What should cause concern is not merely the high prices but even more importantly high costs. The drug industry in this country, like many other industries, suffers from a high cost structure which is attributable to several reasons. In some cases, the teachnology is poor or obsolete. In others, the scale of output is too small to be economically viable. Some of the essential materials which go into the production of drugs and pharmaceuticals are available at twice or thrice the prices prevailing abroad. High rate of duties including heavy customs duty on items which are not planned to be produced in the country in the near future also have contributed to the high cost structure.

44. The Committee understands that the Bureau of Industrial Costs and Prices to which the work relating to the revision of prices under the Drugs (Prices Control) Order was transferred since January, 1974, is presently engaged in evolving a computer programme which will maintain complete and up-to-date information on raw material and packaging costs; and which will also enable Government to build up, on a continuing basis, a detailed profile of the activities of all large units and of the industry as a whole. We recommend that high priority should be given to the building up of such an information/monitoring system. The primary purpose of the information system should be to provide, on a continuing basis and with minimum time lags, all the relevant information regarding production and stocks, costs, sales, profitability, raw material availability and the emerging shortages etc. This type of information will enable Government to act effectively and quickly. For this purpose the Committee feels that it would be desirable to have in Government a Central Co-ordinating Committee at an appropriately high level which will keep under review the trends and developments in this industry. This aspect has been dealt with in details in the chapter dealing with National Drug Authority (Chapter IV).

Summary of Recommendations

1. It has been common experience all over the world that in most countries a large number of small firms whic are locally owned account for roughly about 20% of the total sales of drugs and pharmaceuticals. The remainde of the market is controlled by mostly multi-national units which are much larger in size and resources.

(Chapter-VIII. Para 3)

2. An important characteristic of this industry is a quick product change or product adaptation technique whi is only partly based on proven improvements in the effectiveness of production combinations. In large part, the pr duct adaptation/innovation is essentially a marketing technique with a view to retaining or augmenting one's sha of the market for a particular pharmacopoeial product group. Such a marketing technique, of course, necessaril involves substantial selling costs which in turn have to be added to the cost of the drug. In advanced industrial coun tries, the pharmaceutical industry also spends substantial amounts—around 10% of total turnover—on drug researcl and product development. But these expenditures are relatively less significant in developig countries, including India and by and large, the multi-national corporations use their research outlays in the parent company to introduc new drugs/formulations by their subsidiaries in developing countries. The use of branch names as opposed to gener names also enables the industry to sell essentially similar drug formulations at widely varying prices. Quite often it is difficult for the doctor and almost impossible for the patient to have, at their disposal, information which woulc enable them to compare prices of drugt which are virtually identical. Advertisements rarely mentioned prices and in general, the medical representatives canvass the superiority of their particular brands of medicines with the docto not on grounds of prices but on other grounds such as therapeutic effectiveness or advantages of the new or improve drug. In short, the success of the larger units in the modern pharmaceutical industry is dependent mainly on the ability to develop new products based on research and to create and sustain a demand for their product; and this i done by effective selling techniques and by product adaptation/innovation with a view to help the effective market ing.

(Chapter-VIII. Para 3

3. There is some evidence to suggest that while the growth of the pharmaceutical industry over th e last 15 yea has been quite impressive in terms of growth of output, it has been less so, if one takes into account the product con position and the pricing policies of the industry.

(Chapter-VIII. Para 4

4. The per capita consumption of modern medicine in India is currently estimated to be Rs. 6 per year and accor ding to some estimates, it would appear probably below Rs. 30 per family where the family income is Rs. 420(per year. The Committee feels that the main objective of policy has to be to secure a better convergence of commer cial considerations and social needs and priorities. The emphasis has to be on increasing the social utility of the industry particularly in the context of extreme poverty and the urgent need for extending as rapidly as possible certain minimum facilities in terms of preventive and curative medicines to the large mass of people both urban and rura

(Chapter-VIII. Para 5)

5. While the operation of price control so far has certainly helped in preventing the emergence of very large or excessive profits by the drug and pharmaceutical industry, it does not appear to have contributed materially to the emergence of a product or price pattern which is more in consonance with social needs or national objectives.

(Chapter-VIII. Para 22)

6. An important element of cost which needs particular attention is the cost of packing. In some of the prepa rations like eye-drops, eye ointments, Transfusion solutions, sterile preparations, the cost of packing material coul be much higher than the ingredients used because it is necessary to keep the ingredients free from even a trace of im purity. The Committee feels that greater attention should be paid, than at present, to standardization and economy in the use of packing materials consistent with the protection of consumers' interest.

(Chapter-VIII. Para 23

7. It would be desirable to keep under continuous review the modes of packing and the materials used for packing purposes with a view to evolving appropriate packing standards, rationalising material usages and ensuring that com petitive packing is not resorted to as a sales promotion measure.

(Chapter-VIII. Para 23

8. The administrative regulation and licensing should be geared to ensure that greater emphasis is laid on the production of the 117 essential medicines identified by the Committee. In this area, the policy objective should be to ensure that prices are fair and reasonable to the producer and to the consumer. But this will need to be supplemented by appropriate administrative action to strengthen the production base by ensuring adequate supplies of materials, both domestic and imported, and adequate arrangements to ensure that extraneous factors such as shortage of power, allotment of materials such as alcohol etc. do not intefere unduly with production.

(Chapter-VIII. Para 28)

9. If these are accepted as the primary objectives of the regulatory framework, it seems necessary to have a certain shift of emphasis in regard to the existing regulatory arrnagements including the present basis of price control. Firstly, in order to encourage the production of bulk drugs which are currently imported in significant quantities, it would be necessary to list out items which can and should be produced within the country in a specified period of time. Having identified these items, all necessary assistance should be provided to enable the industry to produce them. To the extent that the public sector and/or the wholly owned Indian units are able and willing to produce these bulk drugs, they should receive preference. If, however, for any reason, production plans of these units do not materialise, other units in the industry including those with foreign equity may be permitted to set up production capacity. As long as the country is dependent on net imports of a basic drug, the existing unit or a new unit may be free to determine the selling price provided it is not higher than the selling prices of STC which are based on average landed costs of imports and handling and other charges.

(Chapter-VIII. Para 27)

10. In the case of bulk drugs in which production is already established and in which imports are no longer necessary, greater attention should be paid to ensure that the cost of production is kept to the minimum. It would also be desirable to exempt from Price Control items in which there are no imports and which in terms of total sales of the basic drug do not exceed Rs. 25 lakhs annually.

(Chapter-VIII. Para. 30)

11. In respect of other bulk drugs, a system of price regulation based on detailed cost investigation should con tinue, subject, however, to the price being so fixed that an efficient manufacturer is able to get a return on his capital employed which is a little higher than is available on formulations for the industry as a whole.

(Chapter-VIII. Para. 30)

12. The Committee after taking into consideration the question of the rate of return on investment required for production of bulk drugs, made by the Tariff Commission and also the Working Group headed by Shri N.N. Wanchoo recommends that a return post-tax between 12 to 14 % on equity i.e. paid up capital plus reserves may be adopted as the basis for price fixation, depending on the importance and complexity of the bulk drug. For the purpose of determining the rate of return, on this basis, taxation should be calculated on the basis of statutory rate of tax. Otherwise, the benefits of any specific corporate tax concessions will be denied to the units in the industry.

(Chapter-VIII. Para 31)

13. The Committee has come to the conclusion that more selectivity in the system of price regulation with a view to ensuring fair prices in respect of drugs and formulations would be desirable rather than on all drugs and formulations irrespective of their importance. As a first step, Committee recommends that the formulations based on 13 drugs, as identified by the Committee for the purpose of generic name usage should be free from Price Regulation.

(Chapter-VIII. Para 34)

14. In the case of other formulations, selectivity could be (a) in terms of size of the units (b) in terms of selection of items and (c) in terms of controlling the prices only of market leaders, in particular products, for which price control is contemplated. The Committee considers:—

(i) Units having annual turnover of less than Rs. 1 crore, may be exempted from the purview of Price Regulation. This however should not be applicable in respect of the units which come under the purview of MRTP Act.

(ii) Alternatively all formulations, other than those marketed under generic names which have an annual all-India sale in excess of Rs. 15 lakhs (including excise duty) should be within the ambit of price regulation, whether or not the total annual turnover of the unit is in excess of Rs. 1 crore. If necessary, Government may in exceptional cases decide to add any particular product to the list of price controlled items in public interest. The ceiling price will be determined taking into account the production costs and a reasonable return for the units which are the market leaders.

(iii) Another variaut of selectivity, which could also be considered would be to identify product groups which individually are important and which collectively constitute the bulk of the out-put of the drugs and pharmaceuticals industry. In respect of each item on this list, it would be possible to identify the leading producers who, between them, account for, say, 60% of the sales. On the basis of the cost analysis in respect of those units, maximum prices may be prescribed and all other units may be free to fix their prices. On balance the Committee is of the view that this particular variant of selectivity may be administratively simpler.

(Chapter-VIII. Paras 35 to 38)

15. The Committee feels that the recommendation of the Working Group on Drugs and Pharmaceuticals under the Chairmanship of Shri N.N. Wanchoo, on forumulation activity, under the alternative scheme of pricing, may be adopted with the revised rates of ceiling on profits, as 8% to 13% on sales turnover, by adding 2% to 6 to 11%, to cover the recent increase in the cost of inputs, bank rates etc. following the category of firms having the activities listed under the large, medium and small groups. Marginal adjustments would need to be made when an unit shifts from one class to another. In order to ensure that the profitability ceilings as above do not work to the disadvantage of manufacturing units, particularly the Indian Sector, the Committee would further suggest that, as an alternative criterion, the ceiling of profit may also be specified as between 10 to 12.5%, post tax, on net worth i.e. paid up capital and reserves.

(Chapter-VIII. Para 40)

16. In view of the flexibility allowed in adjusting the price structure of the products in line with those of marke, leaders, the range of products that come under direct price control, will be limited, and the manufacturer will therefore have much more freedom to adjust the prices of other products according to market conditions. In some cases, the manufacturers may even be in a position to earn profits in excess of the ceilings suggested above. There should, therefore, be a provision, as at present, for funding the excess profits and these should be utilised for the purposes to be specified by the Government. However, the provision for adjusting the funded amount in the future profits o losses should be deleted as suggested by the Working Group.

(Chater-VIII, Para 40)

17. Instead of the present comprehensive control on all products of each firm above certain size, the proposed system will be a much more selective and will be confined to the determination of fair prices in respect of important pharmaceutical product groups. Even in respect of these products, the basis for determination of fair prices would be an investigation in the costs of production of two or three leading manufacturers which between them, account for say 60% or more of the total sales of that product. Under the new system, fixation of ceiling prices for leader product will be on the basis of a more detailed cost examination. There will be no mark-up on costs but all costs including legitimate selling expenses, trade Commission, freight etc. will be taken to into account. In addition, a return on sales on the lines suggested in para 40 will be permitted in arriving at the fair retail selling price. This price, as pointed out earlier, will be in the nature of a ceiling and all producers will be free to change their prices without prior approval of Government provided the retail price does not exceed the ceiling notified for that product.

(Chapter-VIII. Para 41)

18. In order to ensure that the Drug and Pharmaceutical Industry acquires adequate social content, the extension of the public sector to acquire a dominant role in this industry is very important. In addition, however, the Committee feels that it is essential to evolve an effective and continuing system of monitoring in respect of this industry if social objectives are to be achieved.

(Chapter-VIII. Para 42)

19. The Committee recommends that high priority should be given to the building up of an information/monitoring system which should provide, on a continuing basis and with minimum time lags, all the relevant information regarding production and stocks, costs, sales, profitability, raw material availability and the emerging shortages etc. This type of information will enable Government to act effectively and quickly.

(Chapter-VIII. Para 44)

CHAPTER IX

QUALITY CONTROL OF DRUGS

The Committee on Drugs and Pharmaceuticals Industry was constituted by the Ministry of Petroleum and Chemicals by their Resolution dated the 8th February, 1974 to examine various aspects of the drug industry. One of the terms of reference was also to recommended measures for effective quality control drugs and rendering assistance to the small scale units in this regard. While the work of the Committee was in progress, certain unfortunate and tragic incidents connected with the quality of drugs took place in the country which created a sense of urgency on the part of the Committee to look into the specific terms of reference. The Minister for Health was also concerned over this unfortunate incident. He had discussions with the Chairman and requested him to go into the problem on a priority basis. He also wrote a letter dated the 30th April, 1974 to the Minister for Petroleum and Chemicals to that effect. The Ministry of P&C desired that the Committee should examine this problem thoroughly and submit an interim report. Accordingly, the Committee which had already discussed this subject on the 29th March, 1974, met on 2nd of May, 1974 and appointed a Sub-Committee consisting of:—

1. Dr. Ranen Sen, M.P.

2. Dr. M. L. Dhar, Director, Central Drug Research Institute, Lucknow.

3. Shri M. K. Rangnekar, Commissioner, Food & Drug Administration, Maharashtra, Bombay.

4. Dr. B .B. Gaitonde, Director, Haffkine Institute, Bombay.

5. Dr. B. V. Ranga Rao, Jawaharlal Nehru University, New Delhi.

6. Shri P. S. Ramachandran, Drug Controller (India)—Convener.

2. The Sub-Committee held two meetings on the 14th and 15th May, 1974. The Report of the Sub-Committee as approved by the Committee on Drugs and Pharmaceuticals Industry, is appended (Appendix A). This was submitted to Government on 25th May, 1974 as an interim report.

3. We cannot conclude without expressing our warm appreciation for the full cooperation and assistance the Committee has received from the Directorate of Drug Control, Ministry of Health and Family Planning, Government of India and from Mr. P. S. Ramachandran and Mr. M. K. Rangnekar. The Directorate made available to the Committee all the previous reports, literature and important information. But for this valuable assistance, the Committee's task would have been difficult, especially when the Committee had to submit its interim report within a short time, looking to the urgency of the problem.

4. We sincerely hope that the Government will give due consideration to our recommendations made in this interim report and will take immediate steps to implement them so that the quality of drugs may be improved, standard-quality drugs may be made available to the community and the menance of sub-standard and spurious drugs may be combated effectively.

(This was submitted on 25th May, 1974 as an interim report)

APPENDIX A

CHAPTER IX

Report The Sub-committee on Quality Control of Drugs and Related Matter (as approved by the Committee on Drugs and Pharmaceuticals Industry)

Term of Reference:

To recommend measures for effective quality control of drugs and for rendering assistance to the small scale units in this regard.

This term of reference, in the opinion of the Committee, is the most vital for consideration at present. Development of the drug industry, the patronage that is exptended to it by the medical profession and the recognition that other countries give to the quality of drugs made in India are dependant on the image of the drug industry that is projected to the consumers of drugs in this country and abroad. The drug industry has undoubtedly made phenomenal progress over the last 25 years during which period its turnover has risen from Rs. 10 crores to Rs. 350 crores. However, while quality control measures are being enforced fairly rigidly by certain States, enforcement of these measures in many States is not satisfactory. This must, in our view affect the tempo of progress by the industry and what is more, the progress made in this important field by some States would be nullified. While the development of the industry in certain States has been carefully nurtured by experts who are fully competent to handle problems of drug manufacture and testing, other States have adopted the attitude that mere increase in the number of drug manufacturing units constitutes development of the industry. It is noteworthy that in the States where drug control is fairly rigid, the industry has received a great impetus and the products manufctured in those States command good support from the medical profession and consumers. On the other hand, in the States in which drug control has been lax, there has not been sufficient appreciation of the educative and developmental aspects of the drugs industry. Drug control, we would wish to reiterate, is not merely enforcement of the quality control measures but is intimately connected with the development of the ethical sector of the drug industry. Haphazared multiplication of drug units only. benefit, the unscrupulous elements who are inclined to get-rich-quick rather than help developing a real industry. Associated malpractices, such as unauthorised sale of raw materials, cannot be ignored. An aspect which is particularly deplorable is the tendency on the part of many States to extent special concessions to firms located in their States in making purchases of drugs without regard to the quality control measures observed by tendering firms. Such a course of action is obviously ill-advised and it is likely to endanger the health of the people.

2. The overall aim of the drug control organisation in the country should be to infuse a sense of confidence in the quality of drugs that are manufactured by firms, notwithstanding the size of operations of the unit. Today, a section of the industry feels that medical practitioners are not inclined to encourage products of firms which are wholly Indian in structure. This attitude of the medical profession is understandable as the interests of patients are of paramount importance to it and as its aim is to cure the patients quickly by administering those drugs in whose quality the profession has confidence. It is the responsibility of the drug control administration, both at the Central and State levels, to ensure that the quality of drugs manufactured by all firms is uniformally satisfactory. In the case of drugs, a little latitude shown to a manufacturer may spell all the difference between life and death. Unless concerted efforts are made by the Centre and the State Governments to improve the standards of inspection, licensing of drug firms and the weeding out of firms which are technically or otherwise incompetent to manufacture drugs, the medical profession cannot be expected to have full confidence in the quality of all the drugs that are available in the country.

3. Quality control of drugs assumes considerable importance when we have to compare the same drug made by different manufacturers. Some units in the industry have a built-in system for quality control right from the raw materials to the finished stage and also the requisite organisation to frequently the stability of the drug when it moves in the market and for recalling any drug from the market from different parts of the country whenever necessary. Others, however, lack these essential facilities without any built in quality control and without any regard to the keeping quality of the drug. The difference is obvious. It is not enough if a drug complies with the standards when it is made but it is equally important that its potency is guaranteed when it is consumed in any part of the country and under various climatic conditions. Such a quality control check can be enforced only if the officer in overall charge of the organisation and the Drugs Inspectors have the necessary background knowledge and are properly trained. Frequent inspections of manufacturing establishments and stability studies of products and enforcing stringent precautions at the first and subsequent inspections must constitute the most important duties of such officers.

4. The technique of manufacturing drugs is becoming more and more highly specialised and complex and new techniques in manufacture and testing of drugs are being introduced continuously. Organised manufacture of dru of high potency has greatly increased the social responsibility of the Drug Control Organisation and compels it t exercise rigid control over the practices of drug manufacturers and also act as an adviser to the industry to strive fc constant improvement of its performance. All these need an expert in the field of drugs and the responsibility cannc be assigned to personnel whose competence in this complex field is questionable.

Scope of the Drugs and Cosmetics Act

5. "Drugs Control" is a social measure intended to ensure that the community at large obtains drug of standar quality. With this object in view the Drugs Act was enacted in 1940, the Rules under it were framed in 1945 and er forcement of the legislation was started in 1947. The Act regulates the import into and manufacture, distribution an sale of drugs in the country.

Control Mechanism and Division of Responsibility :

6. *Central :*

Under this Act, the Central Drugs Standard Control Organisation, headed by the Drugs Controller (India) is responsible for :

(i) Controlling the quality of imported drugs, and drugs moving in inter-State Commerce;

(ii) Co-ordinating the activities of the States advising them on matters relating to the uniform administration c the Act in the country.

(iii) Laying down regulatory measures and standards of drugs, and

(iv) Granting approval to 'New Drugs' proposed to be imported into or manufactured in the country.

7. *States :*

The State Drug Control authorities are responsible for controlling the quality of drugs manufactured, sold or distributed in the country. This control is exercised through a system of licensing of manufacturing and sale premises through Drugs Inspectors.

8. *Drugs Control Organisation in the States :*

Although the Drugs and Cosmetics Act has been in force for nearly 26 years, the level of enforcement in most of the States is far from satisfactory. The main reasons for this unsatisfactory state are the varying standards of inspection and licensing of drugs firms and the lack of qualified officers in most of the States to supervise drug control operations. With a view to identifying the short comings in the Drugs Control Administration on an all-India basis, three Committees studied all aspects of enforcement of Drug Control in the States and recommended the nature of re-organisation that was necessary. The salient features of their recommendations were that for the Drugs Control Organisation to be effective the following pre-requisites are necessary (a) a full-time Drugs Controller with necessary qualifications and experience (b) adequate number of duly qualified Inspectors on attractive pay scales, (c) a fullfledged testing laboratory for testing all categories of drugs, (d) a legal-cum-Intelligence Cell for carrying on a campaign against spurious drugs and for processing legal cases, and (e) a machinery for maintaining "public Relations" which is vital in a field like drugs.

9. This Committee agrees that the Drug Control Organisation should be streamlined in the manner set out above. The position that obtains today in the various States is set out below together with our recommendations.

A full time Drugs Controller with necessary qualifications and experience :

At present the States of Maharashtra, Karnataka, Gujarat and Kerala have a full-time State Drugs Controller with necessary qualifications and experience in the field of drug manufacture and drug testing. West Bengal has a whole-time Officer but this officer belongs to Provincial Medical Service Cadre.

The Director of Medical or Health Services is incharge of the Drugs Control Organisations in Andhra Pradesh, Assam, Bihar, Haryana, Madhya Pradesh, Orissa, Punjab, Rajasthan, Tamil Nadu, Uttar Pradesh, Himachal Pradesh and the Union Territories of Delhi, Chandigarh, Pondicherry. In some of the States he is assisted by an Assistant Drugs Contr oller who is a full-time Officer.

Recommendations:

10. The officer in over-all charge of Drug Control in a State constitutes the king-pin of the Organisation. He should be responsible not only for enforcing the quality control measures over drugs but also for the development of the drug industry, having regard to the raw materials and natural resources available in the country. Lack of adequate technical knowledge on the part of the top officer will result in ill-equipped and ill-organised firms being

licenced to manufacture drugs. The check that is experienced over the first licensing or the renewal of licences mines the quality of products that are turned out by the firm though frequent inspections of the manufacturing are also necessary to ensure that the quality control discipline is ingrained in all the personnel working in the Considering these aspects, the need for laying down the qualifications for the 'Licensing Authority' needs no emp We understand that the Drugs Technical Advisory Board, constituted under the Drugs and Cosmetics Act recommended that the qualifications of the licensing authority in each State should be laid down in the Drug Cosmetics Rules and if necessary an enabling provision should be introduced in the Drugs and Cosmetics Ac this purpose. The qualifications should be the same as that required for Drugs Inspector under the Drugs and metics Rules, the idea being that experienced Inspector should be made eligible for appointment as the Drug C Authority. The overall authority in the State should also be the 'Controlling Authority' for Drugs Inspectors no Drugs Inspector should be permitted to institute a prosecution without the express order in writing from the trolling Authority'.

11. Apart from laying down the qualifications for the Licensing Authority, it is felt that in licensing firms, Licensing Authority should be guided by a small technical committee which among others should include a se officer from the Central Drugs Control Organisation. Indeed, the Committee would go a step further and rec mend that licensing of drug manufacturers in each state should be decided by a Board. This licensing Board sh consist of (i) Drug Control Authorities of the State concerned; (ii) Drug Control authorities of the State in the reg (iii) a senior representative of Drugs Control Authority of India; and (iv) if possible, one of the Drug Control Au rity from Maharashtra, Gujarat or Karnataka. This procedure of screening applicants for manufacturing licen would greatly help in weeding out firms which are incompetent or ill-equipped to manufacture drugs and also obv inter-state complaints. This Committee recommends that the Drugs and Consmetics Rules should be suita amended for this purpose. The Committee also feels that manufacturers of injectibles including glucose soluti anti-biotics etc. (Schedule C items) should not be licensed to manufacture unless they have their own arrangem for testing them. The present provision which permits such firms to get their finished products tested by a priv laboratory lends scope for abuse and should be amended in the manner recommended by us. Other items—n schedule C items may, for the present, be permitted to be got tested by manufacturers through commercial labo tories, even though, in our opinion this provision should also be withdrawn when the restrictions on imports of alytical equipment get eased. Such commercial laboratories should be required to maintain efficient standards w regard to technical staff, equipment and environments and should be approved by the Drug Control Organisatio the Centre.

12. Last and this aspect in the opinion of the Committee is of vital importance—the Drug Control Organ tion should be divorced from the Directorate of Medical and/or Health Services and constituted into a separate dep ment functioning directly under the control of the Ministry/Department of Health. Such a realignment of the Dr Control Organisation will be conducive to greater coordination between the Government and the Drug Cont Organisation, eliminate delays that are inevitable in an arrangement where the Drugs Controller functions und someone else's control and help in answering the criticism that the power to license drug manufacturing firms vested in the authority that also purchases drugs.

Adequate number of duly qualified Inspectors on attractive pay scales

13. Earlier, the Committee on Drugs Control, which was appointed by the Government to study the existi conditions of drug control organisation in the States and make recommendations for making the control measur more effective had recommended that there should be one Inspector for 200 selling premises. According to h recommendation, the minimum number of Inspectors that the States Drugs Control Organisations should have about 480, against which the actual number of Drugs Inspectors in the States is 369. The States of Gujarat, Kera Maharashtra and Tamil Nadu have now the full complement of Drugs Inspectors. However, more appointment Drugs Inspectors without concomitant efforts to bring their technical knowledge up-to-date will not help in toni up quality control measures. "Drugs" is a field where innovations in the techniques of manufacture and testin drugs are a daily feature and if the inspectors are not conversant with them they will cease to command the respe of the industry which engages top-grade technical personnel. A programme for training Inspectors, it is learnt, ha been organised by the Central Drugs Control Organisation though many States have not availed themselves of th facility.

Recommendations:

14. The States which do not have an adequate number of Drugs Inspectors, as per the scale recommended by the Committee on Drug Control should be helped to expand their Drugs Inspectorate. The Salary scale offered to Drugs Inspectors should be reasonable and sufficient to attract good talents to the profession. This is particularly necessary as the industry is prepared to pay very attractive salaries to technically competent personnel. In our opinion each State should have at least one Chief Inspector on a salary scale of Rs. 1100-1600 who should be well-conversant with the manufacture of antibiotics preparations, injectibles including transfussion solutions, sera, vaccines etc. This officer should carry out the inspection of firms which apply for the manufacture of these drugs. We also

strongly recommend that an Inspector from the Central Government should also be associated with the first inspection of firms. It is at the time of granting first licence for manufacture that utmost care should be exercised by the Drugs Control Authority. Once the manufacturing licence is granted, it would be difficult to make the manufacturer improve his quality control measures to the extent that is desirable. No Inspector should be posted by a State Government unless he has been trained. The training facilities for Inspectors should be augmented by the Central Government and the Committee recommend that for the benefit of the States in the northern and eastern regions, a second training course should be organised in Calcutta.

A Full-fledged testing laboratory for testing of all categories of drugs

15. At present, only three States namely Maharashtra, Gujarat and Tamil Nadu have facilities for testing all categories of drugs. Other States have limited facilities for testing of non-biological drugs, while some States and Union Territories have no testing facilities at all. The position in respect of various States is set out below :—

I. *States having facilities for testing all categories of drugs :*

1. Maharashtra
2. Gujarat
3. Tamil Nadu

II. *States having facilities for testing non-biological drugs:*

1. Andhra Pradesh
2. Bihar
3. Kerala
4. Madhya Pradesh
5. Punjab
6. Karnataka
7. West Bengal
8. Assam
9. Rajasthan
10. Haryana
11. Uttar Pradesh
12. Jammu & Kashmir

III. *States which do not have facilities for testing many drugs:*

1. Orissa
2. Chandigarh
3. Delhi
4. Goa
5. Himachal Pradesh
6. Manipur
7. Pondicherry
8. Tripura

The Centre has three laboratories, namely the Central Drugs Laboratory, Calcutta, the Central Indian Phamacopoeia Laboratory, Ghaziabad and the Central Research Institute, Kasauli for testing samples of drugs. A well designed modern laboratory building is being constructed to house the Central Drugs Laboratory and the Ghaziabad laboratory. The Central Research Institute, Kasauli is engaged in the testing of Sera, vaccines and immunological products. The testing facilities of the Central Government have been made available to such of the States/Union Territories who do not have their own testing laboratories or whose testing facilities are not adequate. Sixteen States and Union Territories are now availing of these testing facilities of the Central Government. The Committee is of the view that the work-load in the Central Drugs Laboratory, Calcutta has increased to such an extent that laboratory reports get delayed.

Recommendations:

16. Mere exhortation to the States advising them to build up testing facilities will not have the desired effect. The Centre, in our opinion, should assist the States in developing combined food and drugs laboratory by extending financial assistance to them. A scheme for this purpose, it is understood, has been accepted under the Fifth Five year Plan and that the intention is to build eight laboratories during this period. There may be States which may not have the resources to employ competent persons on adequate salary scales in the laboratory and to meet the recurring expenditure for running the laboratory. If such States ask for financial aid from the Centre for expending some of their departments, the Central Government should consider such requests favourably.

17. The Central Government have done well in providing a new building for the Central Drugs Laboratory. The Laboratory at Ghaziabad, in our opinion, will be pre-occupied with Pharmaceutical and National Formulary work. The Centre should have three more regional laboratories one in the South, one in the East and one in the West. In addition, to this, a laboratory for testing sera, vaccines and immunological products should also be set up by the Centre. A scheme for the establishment of a Central Biological Standardisation Laboratory, it is understood, is being examined. This scheme should be given high priority during the Fifth Five Year Plan.

Legal-cum-Intelligence Cell for carrying on campaign against spurious drugs and for processing legal cases.

18. The State Governments of Maharashtra, Karnataka, Gujarat and West Bengal have a 'Legal-cum-Intelligence Cell' for carrying on the campaign against spurious drugs and for processing legal cases. Other States have not so far created such 'Cells'.

Recommendations:

19. The States should constitute a legal-cum-intelligence Cell for carrying on the campaign against spurious drugs. Our recommendations setting forth the manner in which the compaign against spurious drugs should be organised are given separately. The Central Government should assist the States in organising this compaign by extending financial assistance to them.

20. There is need for maintaining close contact with the medical profession, consumer groups etc. Unless this contact is established, the public may not be aware of the governmental efforts that are being made in this directions.

Most of the States are remiss in this direction. Maharashtra, Gujarat and Karnataka have, however, made commendable strides in this connection.

Recommendations:

21. Enlistment of the co-operation of the public, the members of the medical profession and other social bodies such as Consumer Councils etc. in tightening drug control measures and in combating spurious drugs should engage the attention of the Central and State Governments. Today, there is little awareness among the public and the members of the medical profession about the working of the drug control agencies. While some of the States like Maharashtra, Gujarat, Karnataka and others have constituted State Drug Advisory Boards where representatives from the medical profession, the police department, social workers, the industry and the trade are represented, other States, despite repeated requests, have not been able to constitute such Boards. It is not enough that Drug Control Organisations function efficiently in States, The public must also be aware of the functioning of such organisations. The Committee would go to the extent of recommending that the constitution of Drug Advisory Boards should be provided for statutorily in the Drugs and Cosmetics Act so that it becomes mandatory on the part of the deficient States to constitute such Boards.

Spurious drugs and problems connected with the compaign against them

22. The term "Spurious Drugs" does not specifically occur in the Drugs and Cosmetics Act. However, the term 'misbranded drugs' defined in Section 17, covers what is commonly intended by the term 'Spurious Drug'. In brief, spurious drugs would include :—

(a) A drug whose label shows it to be manufactured by a firm which is non-existent.

(b) A drug which is found to be different from what is claimed on the label.

(c) A drug which is manufactured by a party other than the manufacturer shown on the label.

(d) A drug which is a close colourable imitation of a well established drug or brand of drug and which is likely to deceive the consumer into the belief that he is buying the established drug or brand of drug.

(e) Defective drugs which are treated in such a manner as to conceal the damage or defects of drugs which are made to appear of better or greater therapeutic value than they really are (Penicillin adulterated with other material and labelled as pure penicillin of certain potency is a case in point).

23. "Sub-standard Drugs" are those which do not conform to the standards laid down in the Drugs and Cosmetics Act. While the manufacture of spurious drugs is essentially a clandestine operation indulged in by unlicensed manufacturers or dealers, sub-standard drugs may be manufactured by licensed manufacturers. "Spurious drugs" is a law and order problem, just like any other illegal activity, such as counterfeiting of currency or smuggling of banned articles. The Drugs Inspector whose primary duty is to educate and assist honest and ethical drug manufacturers operating against valid licences to improve their quality and performance, is illequipped to tackle the problem of spurious drugs on his own. The reason for this is that the manufacture of spurious drugs is mainly an undercover activity and that for tracking down the hide-outs where drugs are faked, the operations should start from the end of dealers who are suspected to be selling or distributing such spurious drugs. The activities and the external 'Contacts' of such dealers should be kept under surveillance through plain clothed watchers or policemen. From the 'leads' that are obtained, the hide-out where the drug-faking activity is carried on should be traced and raids carried by the police or the Drug Control Organisation with the help of the police. Prosecutions may have to be launched, in many-cases, simultaneously under the provisions of the Drugs and Cosmetics Act, the Trade Marks Act, the Indian Penal Code etc., so as to ensure that the accused does not escape clutches of a single legislation on technical grounds. In short, the campaign against spurious drugs will be effective only if the Drugs Inspectors, apart from being fully conversant with the ins and outs of drugs manufacture and testing, are also well-acquainted with the provisions of other legislations such as the I.P.C., the Evidence Act, the Criminal Procedure Code etc. and also know the pitfalls in processing prosecutions. The secret of success of the campaign against spurious drugs lies in the maintenance of close liaison with the police authorities. This implies that an 'Intelligence-cum-legal' unit must operate in each State. This organisation should consist of 'watchers' who would be well-conversant with the drug trade and its practices. Barring a few States such as Maharashtra, Gujarat and Delhi, other States have not been able to organise these cells to counteract drug fakers. As already stated above, reports of movement of spurious drugs are more frequent in the State where drug control has been lax. The most disconcerting feature has been the lack of response on the part of several States to the information given to them about the positive clues relating to spurious drugs, such as the names of parties dealing with spurious drugs or the areas where they move. The Centre has to rest content watching this helpless state of affairs and can do very little with out the active support from the States. The value of maintaining a close liaison with the police officials at high levels has not been appreciated by most of the States. A few cases of spurious drugs were investigated and proceeded against by the Central Drugs Inspectors. Protracted legal procedures necessitated repeated visits to the State by the Central Drugs Inspectors with no commensurate results.

'Spurious Drug" problem assessed by Planning Commission's Task Force

24. The Task Force on Drugs and Food Adulteration appointed by the Planning Commission which had gone into the problem of spurious drugs in great detail recommended that special mobile squads for tracking down spurious drugs and food, must be constituted. Each squad was recommended to comprise a Drugs Inspector assisted by suitable police personnel. The Task Force had further recommended the establishment of 25 squads in the States with 4 squads at the Centre for coordinating the activities of the States mobile squads. As past experience has shown that the States may not be willing to establish such squads because of financial difficulties, the Task Force had specifically recommended that the scheme for setting up those anti-spurious drug squads should be centrally sponsored scheme with 100% central assistance.

25. Reports on the movement of spurious drugs indicate that the prevalence of such drugs is maximum in States where drug control is lax. Despite repeated exhortations to these States to tone up the Drugs Central Administration, the response, it should be stated, has not been encouraging. Unless Central Government assists the States in streamlining their Drug Control Organisation and setting up anti-spurious drug squads, it would be futile to expect any progress in this direction. The problem of spurious drugs should be tackled effectively and on a priority basis, as otherwise drug-faking activities may reach alarming proportions and pose a grave danger to the health of the nation. What is more, the confidence of the medical profession about the drugs which their patients secure will be shattered and the people at large will also develop a psychological distrust about the quality of medical relief available in the country. Lastly, our export prospects will suffer a serious set-back if wide-spread reports on the movement of spurious drugs continue to be published in the newspapers or are discussed in the Central and State legislatures.

The question also needs to be considered whether the penalties laid down in the Drugs and Cosmetics Act are inadequate.

Penal provisions of the Drugs and Cosmetics Act whether these are adequate or not

26. Under the existing provisions of Section 27 of the Drugs and Cosmetics Act, the punishment prescribed for manufacture, sale or distribution of certain categories of 'Misbranded Drugs' and 'Adulterated drugs' and also for manufacture of sale of drugs without valid licence is imprisonment for a term which shall not be *less than one year but which may extend to* 10 *years and also liable to fine.* The Court may, however, for special reasons to be recorded in writing, impose a sentence of less than one year. This is the enhanced penalty decided upon by the Parliament when the Act was last amended in 1964.

27. During the discussions of the Joint Committee in 1963. The punishments provided in the Act were thoroughly discussed. The Joint Select Committee enhanced the maximum punishment from three years imprisonment to ten years. The minimum punishment of one year's imprisonment and also the provision that the Court, for any specific reasons to be recorded in writing could impose a sentence of imprisonment of less than one year were retained by the Committee. Three members of the Joint Committee (Shri H.V. Kamath and Shri R.S. Khandekar and Shri P.C. Mitra) in two different minutes of dissent had expressed their views that the penal provisions :—

(1) should be such as life term if not capital sentence, confiscation of property, deprivation of civil rights and even flogging (views of Shri H.V. Kamath and Shri R.S. Khandekar).

(2) should not give any discretion to the Court to award punishments less than one year as no sympathy should be shown to person found guilty for misbranding or adulteration of drugs (views of Shri P.C. Mitra).

28. The Joint Committee, however, did not agree to these views of three members. The Parliament also had accepted into to the recommendations of the Joint Select Committee.

29. The Joint Committee had also made a new provision in the Drugs and Cosmetics (Amendment) Act of 1964 by which the implements and machinery used in the manufacture of misbranded and adulterated drug, also the animals and vehicles used in carrying these drugs would be liable to confiscation.

30. The Law Commission had also recently examined the penal provisions of the Drugs and Cosmetics Act and have found them adequate. The Commission however recommended that the existing provision in the Drugs and Cosmetics Act by which the Court may for any special reasons to be recorded in writing impose a sentence of imprisonment of less than 1 year should be modified so that for trifling reasons the court may not give lesser sentence of imprisonment.

31. Recently, the West Bengal Assembly passed a Bill recommending life imprisonment for persons found guilty of food and drug offences. The Courts have, however, been given discretionary powers to award a less severe penalty. This Committee's view is that merely amending the Act without streamlining the organisation to track down spurious drugs will not have the desired effects. It is recommended that a distinction should be made between offences relating to the manufacture and sale of spurious drugs and those offences relating to standards of drugs and that life imprisonment may be provided for the manufacture, sale stocking or exhibiting any drug which is deemed to be misbranded under clauses (a), (b), (c), (d), (f) and (g) of Section 17 of any drug that is adulterated under Section 17-B or for manufacture of a drug without a valid manufacturing licence. Elsewhere, in this report, we have indicated what amendments, in our opinion, are necessary in the existing Drugs and Cosmetics Act.

32. Summing up what is required is the establishment of an 'intelligence-cum-legal wing' in each State which can made use of the local police authorities in the campaign against spurious drugs and also process prosecutions quickly and efficiently. The constitution of 'State Advisory Committees' which should include representatives from the medical profession, consumer groups, the industry and the trade, should be considered so that the type of publicity measures that are needed to enlist the cooperation and goodwill of the public could be considered. Close liaison with non-official organisations such as the Citizens' Central Council and Consumer Councils are being maintained by the Drugs Control Organisation at the Centre and in the States. The main objective behind such liaison is to create a sense of awareness among the public as to the measures that the man in the street could protect himself from spurious drugs. A note (Annexure I) setting forth the manner in which the public can cooperate and assist the Drug Control Organisation in the compaign against spurious drugs is also attached.

The role of the Central Drug Control Organisation

33. The Committee of Economic Secretaries of the Government of India had considered the existing conditions in drug control in India in a meeting held in January 1970 and it was agreed that quality control of products manufactured anywhere in India was not solely the responsibility of the State in which the manufacturing unit is located since the product is sold all over the country. If a unit in one State was allowed to manufacture and market a product of substandard quality, this would nullify the measures taken by other States. It was essential that the Central Government should assume responsibility for ensuring statutory enforcement and control over the manufacture of drugs all over the country and also supervise their whole-sale distribution among the various States. Unfortunately these decisions have not been given effect to with the vigour that was necessary mainly because of financial and administrative reasons. Augmentation of the staff and testing facilities in the Central Drugs Standard Control Organisation, it must be admitted, has been slow.

34. Considering the overall coordinating role that the Central Drug Control Organisation has to play, this Committee would recommend that the following steps should be taken immediately to streem line the Central Organisation :—

(a) The complement of the Central Drug Inspectors should be augmented to at least 50 immediately and the Zonal Officers in Madras and Ghaziabad should be senior enough in status to enable them to discuss with the State Drug Control Authorities and Health Secretaries the problems relating to drug control.

(b) The facilities of screening 'New Drugs' should be reinforced by the inclusion of a medical officer with postgraduate qualification who should be able to advise on the Conduct of clinical trials with 'New Drugs'.

(c) The Central Drug Control Organisation is at present depending entirely on the veracity of the toxicity data on 'New Drugs' presented to it by firms, mainly the foreign ones. There are no facilities for counter-checking the toxicity data. Besides, Indian drug manufacturers are now taking an increasing interest in drug research and it is reasonable to expect that within the next five years there will be many new drugs developed by this sector of the industry. Carrying out toxicological studies on such new drugs will be beyond the resources of most of the Indian firms. The Central Government should therefore have a fully equipped toxicological laboratory for carrying out toxicity as well as teratology studies with new Drugs in particular. The Committee understands that the Bureau of Industrial Costs and Prices had recommended the establishment of such a laboratory for the Central Drug Control Organisation and had further suggested that a cess of 1% on the turnover of drug firms should be levied on the drug industry for this purpose.

(d) The library facilities should be augmented at the Zonal Offices and these facilities should be made available to drug manufacturers and State Drug Control Authorities.

(e) The facilities for training Drugs Inspectors (two such courses are recommended in Bombay and Calcutta) and Drug Analysts should be made permanent and whole-time senior officers should be appointed to conduct them.

(f) The 'Drug Standard Cell' for the publication of Pharmacopoeia and National Formulary is seriously handicapped for want of staff. This deficiency should be rectified immediately, as otherwise the Indian Pharmacopoeia and the National Formulary cannot be kept up-to-date.

(g) The Central Drug Standard Control Organisation should have its own library of books and journals. Likewise, the provision for travelling allowance for this organisation, including the Zonal Organisation, should be adequate. This is necessary as frequent discussions with the State Authorities at high levels will help improve the tone of Drug Control measures in the country.

(h) The Central Government should have its own 'Publicity Wing' so that suitable guidance could be given to the States/general public.

(i) Four mobile squads equipped with fast transport radio communication, police assistance and plain clothed watching staff should be attached to the four Zonal Officers to help the States in the campaign against spurious drugs.

(j) Lastly, the Central Drug Control Organisation should be separated from the Directorate General of Health Services and brought under the direct control of the Ministry of Health, Unless this is done, and the Centre sets an example, it will be futile to expect the States to create a separate department for drug control administration.

Financial aid to the States

35. Our salient recommendations covering the State Drug Control Organisations include :—

(i) The constitution of a separate drug control department and the appointment of a technically competent officer to head the State Drug Control Organisation.

(ii) The augmentation of the Drugs Inspectorate in the States and arrangements for keeping their technical competence upto-date such as provision of journals, pharmacopoeias, technical books etc.

(iii) Assistance to States for providing transport to at least Senior Inspectors.

(iv) The establishment of 25 mobile squads all over the country to tackle spurious food and drugs; and

(v) Financial assistance for the States in establishing a top-grade combined food and drug laboratory at the State level.

36. A statement showing the present status of the Drug Control Organisation in the States and the manner in which they should be streamlined if the organisations are to function effectively is attached (Annexure II). A proposal for extending financial assistance to the States for strengthening the Drug Control Administration with a view to enabling them to tackle the problem of sub-standard and spurious drugs more effectively is also attached (Annexure III). The scheme aims at extending financial assistance to the States on two counts, namely, (i) for reorganising the Drug Control Administration by appointment of a full time competnet Drugs Controller with adequate number of qualified inspectors and providing transport facilities; (ii) establishing anti-spurious squads with adequate facilities for quick investigation of the movement of spurious drugs. We have proposed financial assistance only for the additional staff that would be required to be recruited in the States to bring the Administration to uniform level throughout the country. The extent to which each state should be assisted has also been indicated.

37. Unless the Centre extends financial help for augmentation of the States Inspectorate and for the constitution of 25 mobile squads, States cannot be expected to make any headway in this direction. The Committee wishes to point out in this connection that while the States are being assisted financially in a liberal manner by the Centre to implement the Family Planning programme 'Drug Control' has not been accorded even that degree of importance, although this activity is vital for maintenance of public health. This Committee would also support the recommendation made by the Bureau of Industrial Costs and Prices that a cess of 1% should be levied on the pharmaceutical industry and that the funds so collected, which are expected to be of the order of Rs. 3.5 crores per annum, should be utilised primarily for the construction of the Toxicological Laboratory where 'New Drugs' could be got screened by the Drugs Controller at the Centre. The balance of funds should be utilised for strenghthening Drug Control Administration in the States, as well as for financing approved Research Schemes.

Coordination between the Centre and State Drug Control Organisation

38. Once the State Drug Control Organisation is streamlined in the manner recommended by us, the tone of drug control can be expected to improve. The standards of first inspection of manufacturing firms and inspection at the time of renewal of manufacturing licences must be stringent. The Committee would particularly recommend to the States that manufacturers of drugs which require special precautions namely the drugs. covered by Schedule C of the Drugs and Cosmetics Rules should be jointly inspected by Central and State Drugs Inspectors before licences are granted or renewed. Thereafter, States should draw up priorities for frequent inspection of drug manufacturing units, and firms which execute orders for goverment departments, and those which manufacture Schedule C drugs, including 'Blood Banks', should figure high in the priority list. Inspection of hospital stores and pharmacies throughout the states would not only have a salutary effect on their working but also raise the confidence of the common man in the quality of drugs made avialable by hospitals.

39. The Centre, in our view, should concentrate its attention on repeated inspections of firms manufacturing Schedule C drugs and also take for test samples, of life saving drugs on a planned basis. Test reports on drugs which are not of standard quality should be quickly pursued by the Central Drugs Standards Control Organisation with the concerned State Drug Control Authorities. Wherever the Central Drug Control Organisation feels that drug manufacturers who have been licensed are unfit to carry on the manufacture, it should be incombent on the Central Government to take up with the State Authorities (at a high level) and get the licences cancelled.

40. The Committee debated at great length on the advisability of the Central Organisation prosecuting firms located in the States if they are found to be marketing sub-standard drugs. Here again, we feel that such prosecustions if considered necessary should be resorted to by the State Authorities. The Central Organisation, in our opinion, will find itself hopelessly dependant on the police and prosecution facilities available with the State. the experience of a few prosecutions launched by the Centre, in some States makes us feel that the Centre should not waste its efforts in such activities single handed. Needless to say that close liaison between the Central and State Government Officers at the top level is called for to settle prosecution cases quickly and effectively.

Amendment of the Drugs and Cosmetics Act

41. The Committee has had close look at the existing provisions of the Drugs and Cosmetics Act. The experience gained by the Central and State and State Drug Control Administration over so many years of enforcement activity makes us recommend that amendments to many sections in the Act are called for. The penal provisions have been carefully examined, particularly in the context of life-imprisonment for drug. offences that has been provided by the West Bengal Government in its amendment Act. We are of the opinion that life-imprisonment should be made applicable only to offences relating to manufacture and sale of misbranded drugs which fall under clauses (a), (b), (c), (d), (f) and (g) of Section 17, to drugs which are adulterated under Section 17 (B) or for manufacture of drugs without a valid manufacturing licence. The present proviso to Section 27 (a) which permits the Court to award imprisonment for a period not less than one year have been amended and imprisonment for a minimum period of five years has been recommended. A list of the amendments recommended by us is enclosed (Annexure IV).

42. The Committee considered whether a separate definition for the term 'Spurious drugs' should be included in the Drugs and Cosmetics Act. Section 17 defines misbranded drugs. Section 17 (b) defines adulterated drugs. Hence the committee feel that it is not necessary to add a separate definition for spurious drugs as the existing definition covers all aspects of spurious drugs.

Hospital purchases of drugs

43. Government purchases of drugs are made against tender enquiries and from firms which quote the lowest prices. The quality of drugs manufactured by a firm depends upon the manufacturing facilities and conditions of manufacture, the competence of the personnel that supervise the production and testing of raw materials and finished products, product development research, the improcess checks and counter checks exercised by the firm, the monitoring arrangement maintained by the firm for following up the performance of their products when they move in the marekt and the extent to which they are able to recall a product from the market whenever necessary. These

'Good Manufacturing Practices' cost money and any firm which observes them meticulously cannot be expected to quote unduly low prices for their drugs. Besides, several States extend special preferences to drugs manufactured by the firms located in their states, ignoring the status of such firms or the nature of the quality control discipline exercised by them. We have reasons to believe that in some States firms are allowed to be floated specially for executing orders from hospitals. Such practices [illegible] with dangerous consequences to the quality of drugs supplied. All these factors combine to [illegible] rightly [illegible] many cases that the quality of drugs purchased [illegible].

44. While it is the responsibility of Central and State Drug Control Administrations to ensure that all drugs that move in the market are quality products, this cannot be achieved only by stringent inspection and licensing of firms by the Drug Control authorities. It is possible for firms to produce drugs which, when freshly made, will answer all the pharmacopoeial specifications. But if stability studies on the products were not properly carried out or if the conditions of manufacture were defective, deficiencies should manifest themselves in the product sometime after the drugs are manufactured. This underscores the need for every manufacturing firm to develop the quality control discipline and to safeguard the quality of their products.

45. The Committee would therefore recommend that States should have their own centralised arrangement for purchase of drugs and that manufacturers of drugs who tend for supplies should be screened with reference to the good manufacturing practices observed by them and controlled as potential suppliers. The procedure followed by the Maharashtra Government (Annexure V) and the D.G.S. & D. could be usefully adopted by other States. Deliveries against orders should be phased into convenient instalments so that hospitals are not saddled with large stocks of drugs or with drugs with limited life-periods. The Drugs should be subjected to thorough visual examination at the time of receipt in hospitals and whenever there are reasons to suspect their quality, samples should be got examined. The quality of drugs distributed to patients in hospitals is not only dependent on the precautions that are taken when drugs are purchased but also by the care with which the drugs are stored, issued and accounted for. We attach a note (Annexure VI) setting forth the manner in which Hospital Pharmacy Services should be organised. While the Committee note with satisfaction that inspection of hospital drug stores is being carried out in metropolitan centres, such inspections are all the more necessary in smaller towns as in the rural areas and public health centres. The Central and State Drug Control Organisations would do well to concentrate on this aspect. Likewise, the Drug Control authorities should subject firms which supply the drugs to hospitals to frequent inspections.

Quality Control and Small-Scale Units

46. The Committee has been specifically asked to examine, vide the terms of reference, as to what assistance can be rendered to small-scale units in the drug industry, for maintenance of quality control measures. We have given careful thought to this aspect and are of the view that in respect of drugs, where a slight carelessness on the part of a manufacturer of a minor defect overlooked by a manufacturing unit might make all the difference between life and death, there should be no special favour shown to any drug unit in regard to quality control measures, regardless of the size of the units. Though statements have been made by certain sections of the drug industry boasting that their quality is above questioning, the Committee feel that even well-organised firms have to be eternally vigilant about the quality of their products. The number of products recalled by the drug manufacturers in the U.S.A. and other advanced countries and the action taken recently against manufacturers of gross repute in the U.K. and U.S.A. lend support to this view. Indeed, the practice of recall from the market of drugs whose performance is not in accordance with the expectations of manufacturers is itself sufficient proof, that despite all the precautions taken by manufacturers things could go wrong.

47. Most of small scale firms find it difficult to get their drugs tested. Setting up of analytical laboratories by the units themselves, on a cooperative basis, seems to be one of the solutions. The small scale sector of the industry, we understand, is aware of this suggestion but apparently, it has not found favour with the industry. We would also recommend that the state Governments should place the testing facilities available with their analytical laboratories at the disposal of small scale firms on payment of prescribed fees.

48. The Committee, however, wishes to point out that in order to improve the performance of small scale manufacturing firms which are already operating in this country, the Central and State Government Drug Control Organisations should conduct special seminars, technical lectures etc. and issue bulletins emphasising on manufacturers the various aspects that have to be taken into considerations in maintaining quality control measures. In particulars, we feel that talks on subjects, such as, 'The maintenance of sterile areas in drug manufacturing units', Sterilization procedures for durgs', "Maintenance and house-keeping hints for manufacturers of sterile products, 'Problems relating to the production and quality control of ophthalmic preparations" etc. should be arranged. Some of the Zonal Organisations attached to the Central Drug Control Organisations have been circularising pamphlets which should benefit drug manufacturers. This practice should be followed by the other Zonal Officers and State Drug Control Organisations also.

49. We are also given to understand that the Ministry of Industrial Development may be in a position to start an organisations where prospective manufacturers of drugs particularly those whose financial resources are limited could be initiated into the subtleties of quality control measures inregard to durgs. Such an organisation should be started every soon.

Some general observations

The Drug and Equipment Standards Committee appointed by the Ministry of Health and Family Planning in 1965 had made valuable recommendations but unfortunately they have reminded unimplemented. Two specific recommendations namely the one suggesting that the Drug Control should administratively function independently under the Government concerned and not as an organisation attached to other departments and the other that offences under the Drugs and Comsetics Act and related legislation should be tried in specified Courts so that the latter might be fully conversant with the objectives of the legislation and technical aspects of the cases deserve special mention. As already mentioned by us earlier, we reiterate that the Central and State Drug Control Organisations should be independent of the Directorate of Medical and Health Services specially as the latter organisation and responsible for purchases of drugs. States will be reductant to carry out this separation unless the Centre sets an example. The second recommendation should also be pursued vigorously.

51. Most of the States have been extending all help to the drug industry. Special incentives for the industry are also offered by some States. We find however that in some States the industry has been suffering from certain handicaps, particularly because of water-shortage non-availability of alcohol and electricity etc. Units which are engaged in the production of drugs which are thermolabile and are sensitive to heat such as sera, vaccines, other immunological products and antibiotics should not be subjected to power cut as their production would be seriously hampered. The lack of power would effect refrigeration facilities and result in loss of valuable drugs. The Committee would particularly wish to bring this point to the notice of the Central and State Governments.

52. A Joint inspection by the local and Central Drug Controllers should be undertaken and completed with in a period of two months for all units in the small scale sector in respect of Schedule C items. This work should start immediately.

53. The general public in their own interest should also be aware of the precautions to be taken while purchasing drugs. They should also bring to the notice of the Drug Control authorities whenever the existence of any spurious drug comes to their notice.

Sd/- Jaisukhlal Hathi
Sd/- Yashpal Kapur
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Sd/- Ranen Sen
Sd/- K.S. Chavda
Sd/- C.M. Stephen
Sd/- M.L. Dhar
Sd/- S.S. Marathe
Sd/- Vinod Kumar
Sd/- P.S. Ramachandran
Sd/- B. Shah
Sd/- B.V. Ranga Rao
Sd/- M.K. Ranganekar
Sd/- B.B. Gaitande

New Delhi — Sd/- P.R. Gupta.

Recommendations

1. The officer in charge of the Drug Control in a State Constitutes the king-pin of the Organisation. He should be responsible not only for enforcing the quality control measures over drugs, but also for the development of the drug industry, having regard to the raw materials and natural resources available in the country. Lack of adequate technical knowledge on the part of the top officer will result in ill-equipped and ill-organised firms being licensed to manufacture drugs.

[Chapter-IX Para 10.]

2. The check that is exercised over the first licensing or the renewal of licence determines the quality of products that are turned out by the firm, though frequent inspections of the manufacturing firms are also necessary to ensure that the quality control discipline has become ingrained in all the personnel working in the firms.

[Chapter-IX para 10.]

3. As recommended by the Drugs Technical Advisory Board, the qualifications of the Licensing Authority in each State should be laid down in the Drugs and Cosmetics Rules and if necessary an enabling provision should be in troduced in the Drugs and Cosmetics Act for this purpose.

[Chapter-IX para 10.]

4. The overall authority in the State should also be the "Controlling Authority" for Drugs Inspectors and no Drugs Inspector should be permitted to institute a prosecution without the express order in writing from the "Controlling Authority".

[Chapter-IX Para 10.

5. The Licensing of firms in each State should be done through a Licensing Board consisting of (i) Drug Control authority of the State concerned, (ii) Drug Control authorities of the States in the Region, (iii) a senior representative of the Drug Control authority of India; and (iv) if possible, one of the Drug Control authority from Maharashtra Gujarat or Karnataka. The Drugs and Comsetics Act and Rules should be amended accordingly.

[Chapter-IX para 11.

6. The manufacturers of injectables including glucose solutions, antibiotics (Schedule C) items should not be licensed to manufacturer unless they have their own arrangements for testing them.

[Chapter-IX para 11.

7. The present provisions permitting such firms to get their finished products tested by private laboratory should be withdrawn when the restrictions imposed on import of analytical equipments gets eased. Meanwhile commercial laboratories should be required to maintain efficient standards with regard to technical staff, equipment and environments and should be approved by the Drugs Control Organisation at the centre.

[Chapter-IX Para 12.

8. The Drug Control Organisation should be divorced from the Directorate of Medical and/or Health Services and Constituted into a separate department functioning directly under the Department/Ministry of Health.

[Chapter-IX Para 12.

9. The State which do not have an adequate number of Drug Inspectors as per the scale recommended by the Committee on Drugs Control, should be helped to expand their drug Inspectorate.

[Chapter-IX Para 14.

10 The salary offered to Drug Inspectors should be reasonable and sufficient to attract good talents from the profession.

[Chapter-IX Para 14.

11. Each State should have alteast one Chief Inspector in the scale of Rs 1100-1600 who whould be well conversant with the manufacture of antibiotic preparations, injectable and vaccines, etc. including transfusion solutions. He should carry out the inspection of firms which apply for the manufacture of drugs also associating a inspector from the Central Government with the first inspection.

[Chapter-IX Para 14

12. At the time of granting first licence for manufacture, utmost care should be exercised by the Drug Licensing Board/Drug Control authority.

[Chapter-IX Para 14

13. No inspector should be posted by a State Government unless he has been trained. Training facilities for inspectors should be augmented and a second training course should be organised in Calcutta for Northern and Eastern Regions.

[Chapter-IX Para 14

14. The Central should assist the States in developing and /or expanding combined food and drug control laboratorien by extending financial assistance to them.

[Chapter-IX Para 16

15. In addition to the existing Central Drug Laboratory at Ghaziabad, the Central should have three more regional laboratories, one in the South, one in the East and one in the West.

[Chapter-IX Para 17

16. In addition, the Central should also set up a control laboratory for testing Sera, Vaccines and immunological products. The scheme of establishment of a Central Regional Standardisation Laboratory, should be given high priority on the Fifth Five Year Plan.

[Chapter-IX Para 17

17. The States should constitute legal-dum-intelligence Cells for carrying on the compaign against spurious drugs. The Central Government should assist the States in organising this compaign by extending financial assistance to them.

[Chapter-IX Pare 19

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17. The States should constitute legal-dum-intelligence Cells for carrying on the compaign against spurious drugs. The Central Government should assist the States in organising this compaign by extending financial assistance to them.

[Chapter-IX Pare 1

18. Enlistment of the co-operation of the public, members of the medcial profession, social organisations like Consmeers' Councils etc. in tightening Drug Control measures and in combating the menance of spurious drugs should be considered both by Central Government and State Governments.

[Chapter-IX Para 21.]

19. Setting up of State Drug Advisory Boards consisting of medical profession, Police Department, Social workers, the Industry and the trade should be provided for statutorily in the Drugs and Cosmetics Act and that this should become mandatory on the part of deficient States to constitute such Boards. Public should also be made aware of such organisations Boards.

[Chapter-IX Para 21.]

20. As recommended by the Task Force on Drugs and Food Adulteration, 25 special Mobile squads in the States should be organised for tracking down spurious drugs and food with 100% financial assistance from the Centre.

[Chapter-IX Para 24.]

21. Four special Mobile Squads should be established at the Centre for coordinating the activities of mobile squads in States.

[Chapter-IX Para 24.]

22. A distinction should be made between offences relating to the manufacture and sale of spurious drugs and those offences relating to standards of drugs. Punishment of life imprios nment may be provided for the manufacture, sale, stocking or exhibiting any drug which is deemed to be misbranded under clause (a), (b), (c), (d), (f) and (g) of Section 17 of any drug that is adulterated under Section 17 or for manufacture of a drug without a valid licence.

[Chapter-IX Para 31.]

23 The compl ement of the Central Drug Inspectors should be augmented to at least 50 immediately, and the Zonal Officers in Madras and Ghaziabad should be senior enough in status to enable them to discuss with the State Drug Control Authorities and Health Secretaries the problems relating to drug control.

[Chapter-IX Para 34 (a)]

24. The facilities for screening 'New Drugs' should be reinforced by the inclusion of a medical officer with post-graduate qualifications who should be able to advise on the conduct of clinical trials with 'New Drugs'.

[Chapter-IX Para 34 (b)]

25. The Central Government should have a fully equipped toxicological laboratory for carrying out toxicity as well as teratology studies with new drugs in particular.

[Chapter-IX Para 34 (c)]

26. The library facilities should be augmented at the Zonal offices and these facilities should be made available to drug manufacturers and State Drug Control authorities.

[Chapter-IX Para 34 (d)]

27. The facilities for training Drug Inspectors (two such courses are recommended in Bombay and Calcutta) and Drug Analysts should be made permanent and whole-time senior officers should be appointed to conduct them.

[Chapter-IX Para 34 (e)]

28. The Drug Standard Cell for publication purposes like the publication of Pharmacopoeia and National Formulary should be strengthened immediately to keep them up to date.

[Chapter-IX Para 34 (f)]

29. The Central Drug Standard Control Organisation should have its own library of books and journals. Adequate provision should also be made for this organisation towards travelling allowances and to improve the tone of drug contr ol measures in the country.

[Chapter-IX Para 34 (g)]

30. The Central Government should have its own publicity wing to enable it to give suitable guidance to the States.

[Chapter-IX Para 34 (h)]

31. Four mobile squads equipped with fast transport radio communication, police assistance and plain clothed watching staff should be attached to the four Zonal offices to help the States in the compaign against spurious drugs.

[Chapter-IX Para 34 (i)]

32. Drugs Inspectorate in the States and arrangements for keeping their technical competence upto date such as provision of journals, pharmacopoeias, technical books, etc. should be augmented. Transport facilities at least to the senior Inspector should be provided.

[Chapter-IX Para 35(ii)]

33. Financial assistance should be provided to the States in establishing top grade combined Food and Drug control laboratory.

[Chapter-IX Para 35(v)]

34. As recommended by the BICP, a cess of 1% should be levied on the pharmaceutical industry and the funs so collected which are estimated to be of the order of Rs. 3.5 crores should be utilised primarily for the construction of the Toxicological Laboratory at the Centre and the balance of funds should be utilised for strengthening the Drug Control measures at the Central and State levels, as well as for financing approved schemes of research.

[Chapter-IX Para 37.]

35. The standards of first inspection of manufacturing firms and inspection at the time of renewal of manufacturing licences must be stringent. Joint inspections by the Central and State Drugs Inspectors should be carried out before licences are granted or renewed.

[Chapter-IX Para 38.]

36. States should draw up priorities for frequent inspection of drug manufacturing units and firms which execute orders of Government departments and those which manufacture Schedule 'C' drugs including 'blood banks'.

[Chapter-IX Para 38.]

37. Inspection of hospital stores and pharmacies throughout the States should be frequently done.

[Chapter-IX Para 38.]

38. The Centre should concentrate on repeated inspections of firms manufacturing Schedule 'C' drugs, and also take out for test samples of life-saving drugs on a planned basis.

[Chapter-IX Para 39.]

39. The licences of the drug manufacturers who have been given licences and who are unfit to carry on the manufacture in the opinion of the Central Drug Control authorities should be cancelled in consultation with the State Drug Control authorities.

[Chapter-IX Para 39.]

40. The prosecution for offences under Drugs & Cosmetics Act should be initiated by States. There should be a close liaison between the States and the Centre to ensure quick effective prosecution.

[Chapter-IX Para 40.]

41. The present proviso to Section 27(a) which permits the court to award imprisonment for a period not less than one year has been amended and imprisonment for a minimum period of five years has been recommended. Further amendments as recommended vide Annexure V are suggested for implementation.

[Chapter-IX Para 41.]

42. The States should have their own centralised arrangements for purchase of drugs. The tenderers should be screened with reference to good manufacturing practices observed by them and enrolled as prospective suppliers.

[Chapter-IX Para 45.]

43. The procedure adopted by Maharashtra (Annexure V) should be followed for purchases of drugs by othe States. Hospital pharmacy services should be re-organised as per the manner set forth in Annexure VI

[Chapter-IX Para 45.]

44. The drugs should be subjected to a thorough visual examination at the time of receipt in hospitals and wher there are reasons to suspect their quality, samples should be got examined.

[Chapter-IX Para 45.]

45. In smaller towns and rural areas and Public Health Centres, frequent inspection of drugs is all the more necessary.

[Chapter-IX Para 45.]

46. The Drug Control authorities should frequently inspect the firms which supply drugs to hospitals.

[Chapter-IX Para 45.

47. Most of the small scale firms find it difficult to get their drugs tested. The State Government should place the testing facilities available with their analytical laboratories at the disposal of the small scale firms on payment of prescribed fees.

[Chapter-IX Para 47.]

48. The Central and the State Drug Organisations should conduct special seminars, technical lectures and issue builetins emphasising on manufacturers the various aspects that have to be taken into consideration in maintaining quality control measures.

[Chapter-IX Para 48.]

49. Talks on subjects such as maintenance of sterile areas in drug manufacturing units, sterilization procedures for drugs etc. should be held.

[Chapter-IX Para 48.]

50. An organisation where prospective manufacturers of drugs particularly those whose financial resources are limited could be initiated into the subteleties of quality control measures in regard to drugs should be started.

[Chapter-IX Para 49.]

51. As recommended by the Drugs and Equipment Standards Committee, the Central and State Drug Control Organisations should be independent of the Directorate of Medical and Health Services. The Centre should adopt this immediately to act as an example for the State to follow.

[Chapter-IX Para 50.]

52. Industrial units which are engaged in the production of drugs which are thermo labile and are sensitive to heat such as sera, vaccines, other immunological products and antibioties should not be subjected to power cuts as their production would be seriously hampered.

[Chapter-IX Para 51.]

53. A joint inspection by the local and central Drug Control authorities should be undertaken immediately and completed within a period of two months for all units in the small scale sector in respect of Schedule 'C' items.

[Chapter-IX Para 52.]

54. The general public in their own interest should also be aware of the precautions to be taken while purchasing drugs. They should also bring to the notice of the Drug Control authorities whenever the existence of any spurious drug comes to their notice.

[Chapter-IX Para 53.]

ANNEXURE I

Note on the Manner in which the Public can Co-operate and Assist the Drug Control Organisation.

(Chapter IX--Para 32 (APP. I)

The Drugs and Cosmetics Act which regulate the quality of drugs imported into, manufactured and sold in the country is a social legislation, its objective being to ensure that drugs are being manufactured under proper conditions and that the drug reaching the consumer is of standared quality.

The Drug Control Organisation at the Centre and in the States are responsible for enforcing the provisions of this Act. This law affords protection not only to consumers but also to law abiding manufacturers and dealers as it guards them against unfair competition by inferior or dishonestly-labelled products. It is, therefore, in the interests of the consumer, law-abiding manufacturers and dealers to co-operate and assist the Drug Control Organisation in the strict enforcement of this Act.

The gullible consumer is the main victim of an unscrupulous dealer dealing in spurious drugs. It is not possible for a consumer to have every drug purchased by him tested to ensure its quality. In some cases spurious durgs are made up so competently to resemble closely the genuine product that it is difficult for a layman to notice any difference between the genuine and the spurious product.

The racket of spurious drugs thrives mainly because of the greed of the manufacturer, dealer, and even the consumer. The desire to save money by purchasing drugs at a lower price without a cash memo, is in many cases the root cause for the prevalence of spurious drugs.

Generally, reputed manufacturers and dealers do not engage in the manufacture and sale of spurious drugs. It is generally the small chemist working on low margin of profits which deals in sale of spurious drugs.

The question that naturally arises is how should a consumer protect himself from this menace of spurious drugs. While there can be no fool-proof protection, nevertheless there are certain precautions which if taken by consumers could not only ensure their protection but also assist the Drug Control Organisation in their investigational activities. These precautions are:—

1. Buy drugs only from a reputed chemist preferably one known to you.
2. Insist on a cash-memo while purchasing the drug. The Drugs and Cosmetics Act requires a chemist to give a cash-memo and it is an offence for a chemist to refuse to grant a cash-memo.
3. Compare the price charged by the Chemist with that indicated on the lable. If the price charged is considerably lower than that indicated on the lable then there is a possibility that the drug supplied may not be genuine.
4. Beware of any shop which sells drugs at prices considerably lower than other competitors.
5. Examine the labels of the drugs purchased and do not buy drugs which have crossed the expiry date.
6. If the package of the medicine purchased appears different from that purchased earlier, forward the package to the nearest Drug Inspector for investigations. Similarly, if a medicine purchased tastes differently then report along with a sample of the medicine all to the nearest Drug Inspector.
7. Destroy all used containers of medicines particularly those where the name of the medicine or the manufacturer is indelibly marked on the container.
8. Associate the Drug Control Organisation in meetings of the Citizen Committee where quality control of drugs is being discussed.
9. Inform the State Drugs Controller of any cases of spurious drugs that have come to your notice. While furnishing this information please ascertain the facts correctly so that the time of the Drug Control Officer is not unduly wasted in fruitless investigations.

The steps set out above if followed by consumers would ensure not only protection but also assist the Drug Control Organisation in investigating cases of spurious drugs.

ANNEXURE II

SET UP OF THE DRUGS CONTROL ORGANISATION IN THE STATES AS ON 1-1-1974

(Chapter IX—Para 3C (App. I)

Sl. No.	Name of State	Whether whole time independent officer-in-charge of the Department	No. of Inspectors and scale of pay	No. of manufacturing premises as on 1-1-74	No. of sale premises as on 1-1-74	Intelligence-*cum*-legal wing for tracking down spurious drugs	Independent testing facilities available
1	2	3	4	5	6	7	8
1.	Andhra Pradesh	No, Director Health Services is the Drugs Controller & Licensing Authority.	16—Rs. 350—650 Rs. 250—500 (Gaz.).	Drugs—189 Cosmt.—13 Homeo.—8	12325,	A police wing consisting of one circle Inspector and one Sub-Inspector one head constable and two constables was done as an experimental measure and was ineffective and was withdrawn by the Police Deptt. in 1969. A proper pattern of police Wing has to be evolved where the police functions under the directtions of Drugs Controller.	(*a*) Yes, for non-biological products only (Institute preventive medicine, Hyderabad). (*b*) Biologicals products tested at C.D.L., Ghaziabad.
2.	Assam	No, Director Health Services is the Drugs Controller.	5—Rs. 350—950 (Gaz.) +35 part-time civil Surgeons of States Sub-Divn., Health Officer & Officer & Asstt. Surgeon as Ex-Officio Drugs Inspectors.	Drugs—10	1,987	—	No, The drugs testing Lab. have not yet been established and the samples are tested by C.D.L., Calcutta or Pasteur Instt., Shillong.
3.	Bihar	No, Director Health & Medl, Services is the Drugs Controller.	4—Full time Drugs Inspectors.	Drugs—79 Cosmt.—4 Homeo.—1	6,100 (Approx.)		(*a*) Yes, for non-biological ropducts (Bihar Drugs Control Lab., Patna). (*b*) Biological product tested at C.D.L., Calcutta.
4.	Gujarat	Yes, Director Drugs Control Admn.	50—Rs. 375—695 Rs. 245—515 (Gaz.)	Drugs—225 Cosmt.—131 Homeo.—2 Ayur.—10	3,691	Yes. Intelligence Branch Connecting of I Asstt. Director, 4 Drugs Inspectors and 10 Watchers.	Yes. (Drugs Lab., Baroda). Sample sent for test to Haffkine Instt., Bombay.
5.	Haryana	No, Dy. Director of H.S. is the Drugs Controller	6—Rs. 200—400 7C, M.O.'s working as ex-officio D.I.	Drugs—68 Cosmt.—7 Homeo.—1	1,031	—	No, samples sent for test to C.D.L., Cal., and Public Analyst, Chandigarh.

1	2	3	4	5	6	7	8
6. Himachal Pradesh	No. D.H.S. is the Drugs Controller.	2 - Rs. 250-900 (Gaz.)	Drugs - 31	531			No, samples sent to C.D.L., Calcutta.
7. Kerala	[illegible]	[illegible] (Gaz.)	Drugs - 57 Cosmt. - 10 Homeo. - 5		The State D.C. Orgn. has got an intelligence Branch under the charge of a Drugs Inspect. and a 'Legal Wing' in charge of a legal Asstt.	(a) Yes, for non-Biological products (Drugs testing Lab., Trivandrum). (b) Biological products at C.D.L., Calcutta.	
8. Madhya Pradesh	Yes, Drugs Controller under the Dir. of H.S.	32 - Rs. 190-315 (Non-Gaz.)	Drugs - 154 Cosmt.—43 Homeo. - 8	4,582	The Government have created four posts of Police Prosecutors in the State for conduction of Drugs Act case. Steps are also being taken to start an 'Intelligence-*cum*-Legal Wing.	(a) Yes, for non-Biological products (Drugs Testing Lab., Indore). (b) Biological product tested at C.D.L., Calcutta.	
9. Maharashtra .	Yes Commissioner, Food & Drugs Admn	107 - Rs. 250 - 715 (Gaz.)	Drugs - 909 Cosmt. - 692 Homeo. - 23	12,969	Yes, Intelligence Branch consists of 1 Sr. Drug Insp., 2 Drugs Insp. and 17 Watchers. This Branch is assisted by the Police staff consisting of 1 Inspector, 2 S.I., and 14 Constables.	Yes, Drug Control Lab., Bombay. Samples also tested at Haffkine Institute, Parel, Bombay.	
10. Manipur .	No, DHS is the Drugs Controller.	One full time Drugs Insp.	Nil	159	--	No, samples tested to C.D.L., Calcutta.	
11. Mysore . .	Yes, Drugs Controller	13 - Rs. 250—500 (Gaz.)	Drugs - 71 Cosmt. - 10 Homeo.	5,036	Yes, Legal Intelligence and prosecution branch formed.	(a) Yes, for non-Biological products (Drugs Testing Lab., Bangalore. (b) Biological product tested at C.D.L., Calcutta.	
12. Orissa .	No, Dir. H.S. is the Drugs Controller.	9 - Rs. 300 - 900 (Gaz.)	Drugs—60 Cosmt.—27 Homeo.—12	5,004	—	No, samples sent to Central Drugs Lab., Calcutta & C.I.P.L., Ghaziabad.	
13. Punjab . .	No, Dy. Director of H.S. (Food & Drugs) is the Drugs Controller.	12—Rs. 200 - 900 (Gaz.)	Drugs—49 Cosmt.—52 Homeo—6	2,198	--	(a) Yes, for non-Biological products (Public Analysis, Chandigarh). (b) Biological product tested at C.D.L., Calcutta.	
14. Rajasthan .	No, Addl. Dir of (Med. and H.S. is the Drugs Controller.	5 full time drugs Insp. appointed 19 Medl. Officer appointed as Ex-officio Drugs Insp.	Drugs—89 Cosmt — 13	3,176	—	(a) No, Prof. of Pharmacology S.M.S. Medl. College, Jaipur appointed as part-time Govt. Analysts. (b) Samples also sent for test to the DDL., Calcutta.	

1	2	3	4	5	6	7	8
15.	Tamil Nadu	No, Dir. of Medl. & Health Services is the Drugs Controller.	10—Rs. 525—900 59—Rs. 400—650	Drugs—303 Cosmt.—77 Homoeo.—6	13,044	--	Yes, King Institute, Guindy, Madras
16.	Tripura	No, D.H.S. is the Drugs Controller.	No, Drugs Insp.	Drugs—5	49	—	Samples sent to C.D.L., Calcutta
17.	Uttar Pradesh	Yes, a Drug Controller in the Dir. of Medl. and Health Services.	16—Rs. 300—900 Rs. 255—550	Drugs—154 Cosmt.—2	16,000	—	(*a*) Yes, Samples tested by the Public Analyst, Lucknow to the Govt. of U.P. (*b*) Samples also tested at the Central Research Institute, Lucknow. (*c*) Samples also sent to the C.D.L., Calcutta.
18.	West Bengal	Yes, Director of Drugs Controller Admn.	6—Rs. 325—1000 17—Rs. 275—650 (Gaz.)	Drugs—367 Cosmt.—101 Homoeo.—200	12,900	An Intelligence Cell has been set up under the State Drugs Control Orgn., in collaboration with the Enforcement Branch of the State Police.	Yes, Drugs. Calcutta. Samples also sent for test to the C.D.L., Calcutta.
19.	Chandigarh	No, Dy. Secy.,-*cum*-Dir. of HES.	One Inspector	Drugs—4	135	—	No, samples sent for test C.D.L., Calcutta.
20.	Delhi	No, D. H.S. is the Drugs Controller.	16—Rs. 350—900 (Gaz.)	Drugs—97 Cosmt.—136 Homoeo.—3	4,042	Two watchers have been appointed. Govt. has agreed for appointment of Police personnel to assist the Drugs Control Admn.	No, samples sent to C.D.L., Calcutta and C.I.P.L., Ghaziabad.
21.	Dadra & Nagar Haveli.	No, Chief Medl. Officer is the Drugs Controller.	N.A.	Drugs—4	N.A.	—	Samples sent for test to C.D.L., Calcutta. C.I.P.L., Ghaziabad.
22.	Goa	No, D.H.S. is the Drugs Controller.	No full time Drugs Insp. 5—Asstt. Drugs Controller appointed as Ex-officio Drugs Inspectors.	Drugs—12 Cosmt.—5 Homoeo.—1	163	—	Yes, Public Health Lab., Goa, CIPL., Ghaziabad.
23.	Pondicherry	Do.	One full time Drugs Inspector.	Drugs—21 Cosmt.—8	376	—	No, samples sent to King Institute, Guindy, Madras.

Total No. of Inspectors—405

Total No. of Manufacturing Premises : (as on 1-1-1974)

Drugs—2,935
Cosmetics—1,271
Homoeo. — 292

Total No. of sales premises : 1,07,876 (As on 1-1-1974)

N.A.—Not Available.
C.D.L.—Central Drugs Laboratory, Calcutta.
C.I.P.L.—Central Indian Pharmacopoeia Laboratory, Ghaziabad.
C.R.I.—Central Research Institute, Kasauli.
D.H.S.—Director of Health Services.

PRESENT POSITION REGARDING DRUGS INSPECTORS

(STATES)

S. No.	Name of the State	No. of Drug Inspectors as per the staffing pattern recommended by Committee on Drugs Control	Present strength of Inspectors
1	2	3	4
1.	Andhra Pradesh	31	16
2.	Assam	7	5
3.	Bihar	27	4
4.	Gujarat	27	50
5.	Haryana	9	6
6.	Himachal Pradesh	3	2
7.	Kerala	17	17
8.	Madhya Pradesh	30	32
9.	Maharashtra	78	107
10.	Mysore	19	13
11.	Manipur	1	1
12.	Orissa	14	9
13.	Punjab	15	12
14.	Rajasthan	29	5
15.	Tamil Nadu	38	69
16.	Uttar Pradesh	49	16
17.	Tripura	11	..
18.	West Bengal	63	23
19.	Chandigarh	..	1
20.	Delhi	17	16
21.	Goa	2	..
22.	Pondicherry	1	1
		478	405
	CENTRAL DRUGS STANDARD CONTROL ORGANISATION		
	Number of Drug Inspectors	50 (Expected strength at end of Fifth Five Year Plan)	17

ANNEXURE-III

BROAD DETAILS OF THE SCHEME TO BE IMPLEMENTED IN THE 5TH PLAN

(Chapter IX-Para. 36-App. I)

I. *Title of the Scheme :*

Financial Assistance to the States for strengthening the Drug Control Administration for combating the prevalence of sub-standard and spurious drugs.

II. *Objective of the Scheme :*

The objective of this scheme is to extend financial assistance to the States for strengthening the Drugs Control Administration with a view to enabling them to tackle the problem of sub-standard and spurious drugs more effectively. The Drugs and Cosmetics Act has been in force for nearly 25 years. However, it cannot be said that the prevalance of sub-standard and spurious drugs has been reduced considerably. The main reason why drugs standard control has not been able to make considerable headway is that the pre-requisites which are essential for effective enforcement of drug control measures in the States have been lacking. These pre-requisites are :

(1) Appointment of a whole-time officer with adquate background knowledge of drug manufacturing and drug testing as an overall officer in-charge of Drug Control in the State.

(2) Appointment of adequate number of Drug Inspectors with sufficient practical experience in drug manufacture and drug testing.

(3) Establishment of an "Intelligence-cum-Legal" Wing operating under the supervision of Drug Inspectors/ Control Officer possessing legal knowledge and commanding the support of the necessary police staff for tracking down spurious drugs.

The officer, who is in overall charge of Drug Control in each State and the Drugs Inspectors appointed under the Drugs and Cosmetics Act, constitutes the King-pin of the enforcement machinery. At present, only 5 States, namely, Maharashtra, Gujarat, Kerala, Mysore and West Bengal have full-time and adequately qualified Drugs Controllers with a well-organised administrative set-up. In most of the other States the controlling authority is the State Director of Health Services who functions as a Drugs Controller, in addition to his other multifarious duties as Director of Health Services. It has been observed that in States where there is a full-time Drug Controller, the standards of enforcement are more stringent than in States where the Director of Health Services functions as a Drugs Controller. It is an administrative fact that unless an organisation is headed by a well-qualified and knowledgeable officer on a full-time basis the administration cannot function effectively. Although the Drugs and Cosmetics Act and the Rules require that manufacturing and sale premises are inspected only at the time of granting or renewal of licences. This state of affairs is mainly due to the fact that in most states the total number of Drug Inspectors appointed are inadequate as compared to the number of licensed manufacturer and sale premises in the States. The Committee on Drug Control has recommended that there should be one full-time Drug Inspector for every 25 manufacturing premises and one full-time Drug Inspector for every 200 sale premises. On the basis of this yardstick, the total number of inspectors that should be in position in the country would number 575. Against this, the total number of Drug Inspectors appointed in the States are today 305.

It is proposed under this scheme to extend financial assistance to the States to enable them to reorganise their Drugs Control Administration so that the Administration is headed by a full-time competent officer assisted by adequate number of Drugs Inspectors.

While strengthening of the Inspectorate staff would help in combating the problem of sub-standard drugs, the problem of spurious drug has to be tackled on entirely a different footing. The manufacture of spurious drugs, by its very nature, is essentially a clandestine affair indulged in by unlicensed manufacturers or dealers. Antisocial elements generally engage themselves in the manufacture of spurious drugs and try to cash in on the reputation of established products. As these drugs are not manufactured by licensed manufacturers but manufactured clandestinely, the problem of spurious drugs becomes essentially a law and order problem just like other illegal activities such as counterfeiting of currency or smuggling of imported goods. The Drug Inspector does not normally have the necessary training that is required for tracking the manufacture and sale of spurious drugs which can be organised only with police assistance. The problem of suprious drugs can, therefore, be effectively tackled, by the joint efforts

of a Drug Control Organisation and the Police. In certain States such as Maharashtra and Gujarat where the Drug Control Administration is very well organised "Intelligence" Cells have been constituted in the Drug Control Organisation and Police Staff attached to these Cells.

Although State Governments have repeatedly been advised to constitute Special Squads for investigating offences relating to the manufacture and movement of spurious drugs, except in the States of Maharashtra and Gujarat no such squads have been constituted in any other State. Experience has shown that reports of movements of spurious drugs are more frequent in States where Drug Control has been lax. The object of this scheme is also to extend financial assistance to the States for setting up Anti-spurious Squads so that complaints regarding spurious drugs are speedily investigated and persons dealing in this activity apprehended.

II. *Agency for execution review and evalution :*

The State Government will be primarily responsible for executing these schemes. The Central Government would in addition to extending financial assistance, co-ordinate the activities of the Anti-Spurious Squads and also the activities of the Drug Control Administration

IV. *Control for Centrally sponsored scheme :*

It would be a Centrally Sponsored Scheme.

V. *Justification for its being taken up as a Central or Centrally sponsored scheme during the Fifth Plan :*

As already pointed out under (II) above, though the Drugs and Cosmetics Act has now been in force for nearly 25 years, the standards of enforcement are far from stisfactory. Barring Maharashtra, Gujarat, West Bengal, Mysore, Tamil Nadu and Kerala and to a limited extent Orissa, other States did not have any well-defined and properly phased schemes under the 4th Five-Year Plan for development of Drug Control. This lends room for the impression that either the States have not been able to appreciate the importance of this programme notwithstanding the repeated recommendations and exhortations of the Central Council of Health Ministers or they have not been able to accord the degree of priority that this vital sector of health activity deserves.

The Prime Minister and the Chairman of the Planning Commission had also written a letter to the Chief Ministers emphasising the importance of strengthening Drug Control with a view to eradicating spurious drugs. The Planning Commission made bulk allocations for the Health Sector of the State Plan Schemes and in many States the funds were mostly utilised for schemes other than Drugs and Food Control.

As for spurious drugs, experience shows that reports of their movement are more frequent from the States where Drug Control has been lax. The most disconcerting feature has been the lack of response on the part of several Sates to the information given to them about the positive clues of the names of parties dealing in spurious drugs. The Centre had to rest content watching the helpless state of affairs and could do very little without active police support from the States. A few cases of spurious drugs were investigated and proceeded against by the Central Drugs Inspector. Protracted legal proceedings necessitate repeated visits to States by the Drugs Inspector with no commensurate results.

Complaints have repeatedly been in the Press as well as in Parliament about Government's inability to eradicate manufacture and sale of spurious drugs. Our experience over the past 25 years shows that if this matter is left solely to the States, this sorry state of affairs is likely to continue. Although the State Governments realise the need for streamlining the Drug Control Administration and for establishing Anti-Spurious squads, they have not been able to take necessary action mainly because of lack of financial resources. The Task Force appointed by the Planning Commission has also recommended that Central Assistance should be provided to the States for reorganising the Drug Control Administrations in the States and for establishing Anti-Spurious Squads.

VI. *Details of Advance Action already taken for introduction of the scheme in the 5th Plan (Pilot studies, surveys, etc. completed experimental scheme already in operation and so on).*

The Task Force appointed by the Planning Commission has, made a detailed study of the subject and has recommended among other things, that finnacial assistance should be given to the States for strengthening the Drug Control Administration.

VII. *Broad details of the scheme to be implemented in the 5th Plan :*

The financial assistance would have to be granted to the States on two counts :

(i) For reorganising the Drug Control Administration by appointment of a full-time competent Drugs Controller with adequate number of qualified inspectors, and providing transport facilities.

(ii) Establishing Anti Spurious Squads with adequate facilities for quick investigation of the movements of spurious drugs.

So far as the reorganisation of the Drug Control Administration is concerned, it may be stated that an effective Drug Control Administration should have a Drugs Controller at the top, assisted by an Assistant Drugs Controller at headquarters and adequate number of Drugs Inspectors. Each zone should be incharge of an Assistant Drugs Controller with adequate number of Drugs Inspectors. The number of Drugs Inspectors that should be stationed at headquarters and in the zones would depend upon the number of manufacturing and sale premises located in the States. For the purpose of this scheme, we have adopted a yardstick of one Drugs Inspector for 25 manufacturing premises and one Drugs Inspector for 200 sale premises. On the basis of guidelines indicated above, the Administrative set up that would be required has been worked out in respect of each State and the relevant information is given at Appendix I. In addition to assisting the States for increasing the Inspectorate Staff, it is also proposed under this scheme to provide transport facilities to the Drug Control Administration by way of one mobile van for each zone in the States and one mobile van for the use of the headquarters. Under this scheme, assistance is also proposed to be given to the States for purchase of technical books required by the Drug Control Staff.

The Central Assistance that would be required to be extended to the States to enable them to bring up the Drug Control Administration to the desired level has been worked out in respect of each State and this information is given at Appendix II. *For the purpose of this scheme, we have proposed financial assistance only for the additional staff that would be required to be recruited in the States to bring the Administration to uniform level throughout the country.* It is realised that this pattern of assistance would adversely affect States which have well-organised Drug Control Administration and where the number of inspectors appointed are adequate in that the share of central assistance for them would be less. However, the object of this scheme is primarily to bring up States which have not given sufficient importance to Drug Control Administration and where the Drug Control Administration has been lax.

It may be relevant to mention that drug is a commodity which moves across State borders and as such unless the Drug Control enforcement is uniform and effective throughout the country, no State would be free from the menace of sub-standard or spurious drugs irrespective of the fact that any particular state may have an efficient drug control administration.

While strengthening of the Drug Control Administration by appointment of a fully qualified Drugs Controller and adequate number of Drugs Inspectors would enable the States to combat effectively the problem of sub-standard drugs, the problem of spurious drugs as pointed earlier, has to be combated on a different footing. Manufacture of spurious drugs is essentially an under cover activity indulged in mostly by unlicensed parties. Tackling such an unlawful activity would require the help of Police and "Watchers" in plain clothes who should move in leading wholesale markets in the States, or in areas where spurious drugs are reported to be moving and monitor "leading" information. The Police staff and Watchers should be under the control of Senior Drugs Inspectors who have had comprehensive training in legal procedures for carrying out raids, searches, seizures, institution of prosecutions and for conducting such cases. The Squads constituted for tracking down spurious drugs must be equipped to be mobile and therefore be provided with fast transport and ancillary equipment such as facilities for transmitting wireless messages etc. There should be close liaison between Senior Police Officers at the district levels and the officers commanding the Anti-Spurious Drugs Squads. Incentives should be given to 'informers' who provide clues to the hideouts of drugs and the connecting links in the trade. Rewards may also have to be given to those who manage to effect substantial hauls of spurious drugs. All these would indicate that a parallel police force has to be run direct by the Drug Control authorities or by their working in concert with the Senior Police Officers. In many States such as U.P., Madhya Pradesh, Bihar and Rajasthan, more than one Squad would have to be organised and in some cases as many as four, to operate in different parts of the States. It is estimated that about 25 Squads may be required to be organised in the States as under :—

Name of the State	No. of squads to be organised
1. Punjab	2
2. Haryana	1
3. Delhi	1
4. U.P.	4
5. Bihar	2
6. West Bengal	2
7. Rajasthan	2
8. Madhya Pradesh	3
9. Assam	1
10. Orissa	1
11. Andhra Pradesh	3
12. Tamil Nadu	1
13. Mysore	1
14. Kerala	1
	25
Central Cell—1 Squad for each zone×4	4
TOTAL	29

These squads may, in many cases, be required to cross inter-state territories in their pursuit of offenders. The Centre, on its own, may find it difficult to organise a police force for this purpose and make it operate in all the States. Each Squad, with its ramification of watchers and informers may cost about Rs. 2.00 lakhs (Appendix-C).

There should be a central Co-ordinating Cell at the Centre for this purpose complete with its complement of watchers and other legal staff. There are four zonal offices under the Central Drugs Standard Control Organisation at the centre. Considering that one Squad should be stationed in each zone, it will be necessary to provide for 4 Anti-spurious squads at the centre. Thus the net work of 25 Squads in states and 4 Squads at the Centre would comprise 29 Squads in all. Considering that each Squad should have 2 Drug Inspectors, 2 Police Officers, 1 field Assistant, 1 Driver and 3 Watchers, the cost for 29 squads on staff equipment and other charges would work out of Rs. 1.65 lakhs during 5th Plan period.

VIII. *Pattern of assistance indicating in respect of liabilities of Centre and States and other institutions for recurring and non-recurring expenditure .*

The cost involved in reorganising the Drug Control Administration in the States which would be of a recurring nature, will be met 100% by the Centre. The cost involved in providing travel facilities to the Drugs Inspector such as mobile vans etc., would be of a non-recurring nature and would also be met 100% by the Centre.

IX. *Outlay envisaged for the 5th Plan and Year-wise Phasing :*

(a) *Reorganisation of Drugs Control Administration in States :—*

Year	Staff	Equip-ment	Cons-truction	Other items	Total in lakh
1974-75	20.05	12.25	..	1.10	33.40
1975-76	26.38	10.150	..	1.10	37.98
1976-77	32.72	7.00	..	1.10	40.82
1977-78	39.05	3.00	..	1.10	43.65
1978-79	45.38	2.80	..	1.10	49.28
Total for 5 years	163.58	36.05	..	5.50	205.13

(b) *Setting up of Anti-Spurious Squads*

Year	Staff	Equip-ment	Cons-truction	Other items	Total
1974-75	13.87	17.40	..	5.60	36.87
1975-76	14.31	17.40	..	6.00	37.31
1976-77	14.76	8.70	..	6.00	29.46
1977-78	15.49	8.70	..	6.00	30.19
1978-79	15.94	8.70	..	6.00	30.64
					164.37 Lakh *i.e.* 165 lakh

X. *Physical targets envisaged and yearwise Phasing :*

The main objective of this Scheme is to assist the State Governments financially in streamlining their Drug Control Administration so as to make it effective in tackling the problem of sub-standard and spurious drugs. The implementation of this scheme would be done primarily by the State Governments and as such the laying down of specific targets would have to be considered by the States.

XI. *Any other details, remarks etc.*

1. ANDHRA PRADESH

Existing set up	Proposed set up	Additional staff req.	Estimated Expenditure during 5th Plan		
				No. of Posts	Emoluments in 5 yrs. (including incr.)
I. *Personnel*					Rs.
1. Dy. Drugs Controller-1	1. Drugs controller-1 (1300-1600)	1. Drugs Controller-1 (1300-1600)	I. 1. Drugs Controller (1300-1600)	1	1,02,090
2. Asstt. Drugs Controller-3	2. Dy. Drugs Controller one	2. Asstt. Drugs Controller-3 Rs. (700-1250)	2. Asstt. Drugs Controller Rs. (700-1250)	3	1,94,58
3. Drugs Inspectors-22	3. Asstt. Drugs Controller-6 4. Drugs Insps. (i) Manufacture-9 (ii) Sales-62	3. Drugs Inspectors-59	3. Drugs Inspectors Rs. (550-900)	59	23,59,764
				Total	26,56,434
II. *District* : 20	Zones-5		II. Equipment : Six vans @ 35,000	6 × 35 000	2,10,000
III. *Premises* :	*Equipment* :				
1. Manufacturing premises : 232	Six Mobile Vans @ Rs. 35,000 per van		III. Books, Journals & Periodicals	5000 × 5	25,000
					28,91,434
2. Sales premises: 12,323	*Books, Journals & Periodicals @ Rs. 5000 per yr.*		Total Central Assistance involved.		

2. ASSAM

Existing set up	Proposed set up	Additional staff req.	Estimated expenditure during 5th Plan		
				No. of posts	*Emoluments in 5 yrs.*
					Rs.
I. *Personnel*					
1. Asstt. Drugs Controller-1	1. Drugs Controller one 1300-1600	1. Drugs Controller-1 (1300-1600)	1. Drugs Controller-1300-1600	1	1,02,090
2. Drugs Inspector-5	2. Asstt. Drugs Controllers-3 (700-1250) 3. Drugs Inspectors:— (i) Manf.-1 (ii) Sales-2	2. Asstt. Drugs Controller-2 (700-1250) 3. Nil	2. Asstt. Drugs Controller 700-1250.	2	1,29,720
II *District*-11	Zones-2	II. *Equipment* M. Vans 3 × 35000	II. *Equipment* : M. Vans	3x35,000-	1,05,000
III. *Premises* : (i) Manufacturing—14 (ii) Sales Premises 252		III. Books, Periodicals & Journals Rs. 5000x5	III. Books periodicals & Journals	—	25,000
				Total	3,61,810
			Total Central Assistance involved :		3,61,810

3. BIHAR

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure for 5th Plan period		
			Posts	No.	Emoluments for 5 yrs. Rs.
I. Drugs Inspectors-4	1. Drugs Controller-1 (1300-1600)	1. Drugs Controller-1	1. Drugs Controller (1300-1600)	1	1,02,090
	2. Asstt. Drugs Controller-5 (700-1250)	2. Asstt. Drugs Controller-5	2. Asstt. Drugs Controller (700-1250)	5	3,24,300
	3. Inspectors :		3. Drugs Inspectors	29	11,60,000
	(i) Manf.—3		(350-900)		15,86,390
	(ii) Sales—30				
II. *District* - 17	Zones-4	II. *Equipment* : 5 Vans × 35,000	II. *Equipment*		1,75,000
III. *Premises* : (i) Manufacturing-72 (ii) Sales-6100		III. Books Periodicals & Journals. Rs. 25,000	III. Books Periodicals & Journals		25,000
					17,86,390
			Total Central Assistance involved		17,86,390

4. GUJARAT

Existing set up	Proposed set up	Additional staff	Estimated Expenditure for 5th Plan Period (Rs.)
1	2	3	4
I. *Personnel*	*Personnel*	The existing set up of the State Drugs Control	I. *Personnel* . . . . . Nil.
1. Director, D.C.A. Gujarat-1	---	Department in Gujarat is adequate to exercise	
2. Dy. Director Admn.-1 3. Asstt. Directors-5		a stringent control over the quality of drugs	
4. Drugs Inspectors-35		manufactured & marketed in the State.	
5. Law Officer-1			
II. *Districts* : 19	Zones . 5	II. *Equipment* Six Vans x 35,000	II. Equipment 6x35, 000 . . . 2,10,000
III. *Premises* : (i) Manufacturing-170 (ii) Sales—3288	—	III. Books ,Periodicals and Journals.	III. Books, Periodicals & Journals 25,000 25,000
			2,35,000
			Total Central Assistance . . . 2,35,000

5. KERALA

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure during the 5th Plan Period.		
				No. of Posts	*Emoluments* (Rs.)
I. *Personnel*	I. *Personnel* :		I. *Personnel*		
1. Drugs Controller-1	1. Drugs Controller -1	1. Asstt. Drugs Controller-3 Rs.700-1250	Asstt. Drugs Controller-3 700-1250	3	1,94,580
2. Asstt. Drugs Controller-1	2. Asstt. Drugs Controller-4	3. Drugs Inspectors-1	Drugs Inspector	1	40,000
3. Drugs Inspectors-11	3. Drugs Inspectors-12 Manuf.-2 Sales-10 } 12				

				Rs.
II. *Districts*-10	II. Zones -3	II. *Equipment* Rs. 1,40,000	II. *Equipment* . . . (Purchase of mobile vans)	1,40,000
III. *Premises :*	III. Equipment Vans : 4x	III. Books, Periodicals &	III. Books, Periodicals &	
1. Manufacturing-67	35,000	Journals 25,000	Journals	25,000
2. Sales 2031				
				3,99,580
			Total Central Assistance :	3,99,580

6. MADHYA PRADESH

Existing set up	Proposed set up	Additional staff	Estimated Expenditure for Fifth Plan period.		
				No. of Posts	Emoluments.
					(Rs.)
I. *Personnel :*	*Personnel*		I. *Personnel*		
1. Drugs Controller-1	1. Drugs Controller-1	1. Asstt. Drugs Controller-12	1. Asstt. Drugs Controllers (700-1250)	12	7,78,320
2. Drugs Inspectors-16	2. Asstt. Drugs Controller-12	2. Drugs Inspectors-11	2. Drugs Inspectors (350-900)	11	4,40,000
	3. Drugs Inspectors : (i) Manf. 7 (ii) Sales 20 = 27				12,18,320
II. Districts 43	Zones : 11	II. *Equipment* 12 Mobile Vans x 35,000	II. *Equipment* 12 Mobile vans × 35,000		4,20,000
III. *Premises*	*Equipment* 12 Mobile vans X	III. Books, Periodicals & Journals 25,000	III. Books, Periodicals & Journals		25,000
1. Manufacturing 169	35,000				
2. Sales 4029					
					16,63,320
			Total Central Assistance involved :		16,63,320

7. MAHARASHTRA STATE

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure during 5th Plan period		
				No. of Posts	Emoluments
1	2	3	4	5	6
					Rs.
I. *Personnel :*	I. *Personnel*		I. *Personnel*		
1. Commissioner 1	1. Commissioner 1			34	1,36,000
2. Joint Director 1	2. Joint Director 1	Drugs Inspectors 34	Drugs Inspectors 3		
3. Asstt. Dir. 9	3. Asstt. Dir.9	(350-900)	(350-900)		
4. Drugs Inspectors 70	4. Drugs Inspectors 104 (i) Mfr. =36 (ii) Sales —68 = 104				
5. Tech. Officer-2	5. Tech. Officer-2				
6. Law Officer-1	6. Law Officer-1				
7. Pharmaceutical Chemist-1	7. Pharmaceutical Chemist-1				
8. Analytical Chemist-2	8. Analytical Chemist-2				
9. Lab. Asstt.-1	9. Lab Asstt.-1				
II. *District* 26	*Zones :* 7	*Equipment* II. 8 Mobile Vans X 35,000	II. 8 Mobile Vans x 35,000		2,80,000
III. *Premises*	II. *Equipment* 8 Mobile vans × 35,000	III. Books, Periodicals & Journals Rs. 25,000	III. Books, Periodicals & Journals		25,000

1. Manufacturing-888 2. Sales-13,586	II. Books, Periodicals & Journals 25,000	4,41,000
	Total Central Assistance involved :	4,41,000

8. MYSORE STATE

Existing set up	Proposed set up	Additional staff	Estimated Expenditure during 5th Plan Period		
				No. of Posts	Emoluments
I. *Personnel :*	I. *Personnel :*	I. *Personnel*	I. *Personnel*		
1. Drugs Controller-1	1. Drugs Controller-1	1. Asstt. Drugs Controlers (700-1250)-3	1. Asstt. Drugs Controllers (700-1250)	3	1,94,580
2. Dy. Drugs Controller-1	2. Dy. Drugs Controller-1	2. Drugs Inspectors-3	2. Drugs Inspectors	3	1,20,000
3. Asstt. Drugs Controller-3	3. Asstt. Drugs Controllers-6				3.14,580
4. Drugs Inspectors-22	4. Drugs Inspectors : (i) Mfg.- 3 (ii) Sales- 22 25				
II. *District :* 20	II. Zones : 5 ——	II. *Equipment* 6M. Vans × 35,000	II. Equipment 6×35,000		2,10,000
III. *Premises*	III. *Equipment* 6 Mobile Vans × 35,000	III. Books, Periodicals & Journals 25,000	III. Books, Periodicals & Journals		25.000
1. Manufacturing-65					
2. Sales-4,448	IV. Books, Periodicals & Journals 25,000				5,49,580
			Total Central Assistance involved :		5.49.580

9. ORISSA

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure for the 5th Plan Period		
1	2	3	4	5	6
I. *Personnel*	I. *Personnel*	I. *Personnel*	I. *Personnel*	No. of Posts	Emoluments for 5 years.
1. Joint Drugs Controller-1	1. Drugs Controller-1	1. Drugs Controller-1 1300-1600	1. Drugs Controller 1300-1600	1	1,02,090
2. Drugs Inspectors-7	2. Joint Drugs Controller-1	2. Asstt. Drugs Controller-4 (700-1250)	2. Asstt. Drugs Controller (700-1250)	4	2,59,440
	3. Asstt. Drugs Controllers-4	3. Drugs Inspectros-1 (350-800)	3. Drugs Inspectors (350-900)	1	40,000
	4. Drugs Inspectors : (i) Mfr.- 2 (ii) Sales- 6 8				4,01,530
II. District : 13	II. Zones : 3 ——	II. Equipment Rs. 1,40,000	II. Equipment 4 Mobile vans		1,40,000
III. *Premises :*	III. *Equipment* 4 M. Vans×35,000	III. Books & Journals 25,000	III. Books, Periodicals & Journals		25,000
					5,66,530
1. Manufacturing-49 2. Sales-1,123	IV. Books, Periodicals and Journals Rs. 25,000				
			Total Central Assistance :		5,66,530

10. PUNJAB

Existing set up	Proposed set up	Additional staff Required	Estimated Expenditure during 5th Plan Period.		
				No. of Posts.	*Emoluments* Rs.
I. *Personnel*	I. *Personnel*		I. *Personnel*		
1. Drugs Inspectors-12	1. Drugs Controller-1	1. Drugs Controller-1 (1300-1600)	1. Drugs Controller. (1300-1600)	1	1,02,090
	2. Asstt. Drugs Controller-6	2. Asstt. Drugs Controller-6 (700-1250)	2. Asstt. Drugs Controller. (700-1250)	6	3,89,160
	3. Drugs Inspectors :— i. Mfr.; 3 ii. Sales : 12 — 15	3. Drugs Inspector-3 (350-990)	3. Drugs Inspectors (350-900)	3	1,20,000
					6,11,250
II. *Districts:* 20	Zones : 5 II. *Equipment* 6 mobile vans x35,000	II. *Equipment* 6 Mobile Vans 2,10,000	II. *Equipment* 6 Mobile vans x35,000		2,10,000
III. *Premises:*					
1. Manufacturing : 63 2. Sales : 2410	III. Books, Periodicals & Journals 25,000	III. Books & Journals 25,000	III. Books, Periodicals & Journals		25,000
					8,46,250
			Total Central Assistance involved :		8,46,250

11. RAJASTHAN

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure during 5th Plan		
I. Personnel	*I. Personnel*	*I. Personnel*	*I. Personnel*	*No. of Posts.*	*Emoluments* Rs.
1. Drugs Inspectors-6	1. Drugs Controller-1	1. Drugs Controller-1 (1300-1600)	1. Drugs Controller. (1300-1600)	1	1,02,090
	2. Asstt. Drugs Controller-7	2. Asstt. Drugs Controller-7	2. Asstt. Drugs Controller-7	7	4,54,020
	3. Drugs Inspectors :— i. Manufacture-2 ii. Sales : 16 — 18	3. Drugs Inspectors-12 (350-900)	3. Drugs Inspectors-12 (350-900)	12	4,80,000
					10,36,110
II. Districts : 23	II. Zones : 6	II. *Equipment* 7 Mobile vans 2,45,000	II. *Equipment* 7 Mobile Vans x35,000		2,45,000
III. *Premises :* 1. Manufacturing 50 2. Sales : 3176	III. *Equipment* 7 Mobile vans x35,000	III. Books & Journals : 25,000	III. Books & Journals		25,000
					13,06,110
	IV. Books, Periodicals & Journals 25,000		*Total Central Assistance Involved :*		13,06,110

12. UTTAR PRADESH

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure during 5th Plan		
I. Personnel	*I. Personnel*	*I. Personnel*	*I. Personnel*	*No. of Posts.*	*Emoluments* Rs.
1. Asstt. Drugs Controller-1	1. Drugs Controller-1	1. Drugs Controller-1	1. Drugs Controller-1 (1300-1600)	1	1,02,090
2. Drugs Inspectors-15	2. Asstt. Drugs Controller-14	2. Asstt. Drugs Controller-13	2. Asstt. Drugs Controller (700-1250)	13	8,43,180
	3. Drugs Inspectors :— i. Manuf. 14 ii. Sales : 80 — 94	3. Drugs Inspectors-79	3. Drugs Inspectors-79 (350-900)	79	31,60,000
					41,05,270

II. Districts :54	Zones : 13	II. *Equipment* 14 × 35,000 =4,90,000	*II. Equipment* 14 Mobile Vans	
III. *Premises* 1. Manufacturing : 349 2. Sales : 36,090	III. Books, Periodicals & Journals 25,000	III Books & Journals 25,000	III. Books, Periodicals & Journals	75,000
				Rs. 46,20,270
			Total Central Assistance Involved :	Rs. 46,20,270

13. WEST BENGAL

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure during 5th Plan.		
				No. of Posts.	*Emoluments* Rs.
I *Personnel* 1. Director, D.C.A., W. Bengal-1.	I. *Personnel* 1. Director, D.C.A.-1.	I. *Personnel* 1. Asstt. Directors-(700-1250)-5	I. *Personnel* 1. Asstt. Directors. (700-1250)	5	3,24,360
2. Asstt. Directors-2	2. Asstt. Directors-7	2. Drugs Inspectors-28, (350-900)	2. Drugs Inspectors (350-900)	28	11,90,000
3. Drugs Inspectors-23	3. Drugs Inspectors :— i. Mfr. : 20 ii. Sales 31 51				
4. Administrative Officer-1	4. Administrative Officer-1				
5. Law Officer-1	5. Law Officer-1				
II. Districts : 16	Zones : 4	II. *Equipment* 5 Mobile Vans 1,75,000	II. *Equipment* 5 Mobile Vans		1,75,000
III. *Premises* 1. Manufacturing : 508 2. Sales : 6,379	III. *Equipment* 5 Mobile Vans × 35,000	III. Books, Periodicasl & Journals 25,000	III. Books, Periodicals & Journals		25,000
					Rs. 16,44,300
			Total Central Assistance Involved :		Rs. 16,44,300

14. DELHI

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure for 5 years		
				No. of Posts.	Emoluments Rs.
I. *Personnel* 1. Asstt. Drugs Controller-2	I. *Personnel* 1. Drugs Controller-1	I. *Personnel* 1. Drugs Controller-1 (1300-1600)	I. *Personnel* 1. Drugs Controller. (1300-1600)	1	1,02,090
2. Drugs Inspectors-8	2. Asstt. Drugs Controller-2 3. Drugs Inspectors :— i. Manf. 4 ii. Sales 19 23	2. Drugs Inspectors-15 (350-900)	2. Drugs Inspectors :— (350-900)	15	6,00,000
					7,02,090
II. *District* : 1	Zones : 1	II. *Equipments* 2 Mobile Vans 70,000	II. Equipment 2 Mobile Vans		70,000
III. *Premises*	III. *Equipment* 2 Mobile vans × 35,000	III. Books & Journals 25,000	III. Books & Journals		25,000
					Rs. 7,97,090
I. Manufacturing-91					
2. Sales-3,806	IV. Books & Journals : 25,000				
			Total Central Assistance Involved :		Rs. 7,97,090

15. HIMACHAL PRADESH

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure during 5th Plan period	No. of Posts.	Emoluments Rs.
I. Personnel	*I. Personnel*	*I. Personnel*	*I. Personnel*		
1. Drugs Inspectors-2	1. Durgs Controller-1	1. Drugs Controller-1	1. Drugs Controller-1 (1300-1600)	1	1,02,090
	2. Asstt. Drugs Controller-2	2. Asstt. Drugs Controller-2	2. Assistance Drugs controller-2 (700-1250)	2	1,29,720
	3. Drugs Inspectors :— i. Manf. 1 ii. Sales 3 — 4	3. Drugs Inspectors-2	3. Drugs Inspectors-2 (350-900)	2	80,000
					3,11,810
II. Districts : 6	II. Zones : 1	*II. Equipment* 2 Mobile Vans 70,000	*II. Equipment* 2 Mobile vans		70,000
III Premises :	*III. Equipment* 2 Mobile vans	III. Books, Perodicals & Journals 25,000	III. Books & Journals		25,000
1. Manufacturing : 6	35,000				4,16,810
2. Sales-231	IV. Books, Periodicals & Journals Rs. 25,000		*Total Central Assistance Involved* :		4,16,810

16. HARYANA

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure during 5th Plan Period	No. of Posts.	Emoluments Rs.
I. Personnel	*I. Personnel*	*I. Personnel*	*I. Personnel*		
1. Asstt. Drugs Controller-1	1. Drugs Controller-1	1. Drugs Controller-1	1. Drugs Controller (1300-1600)	1	1,02,090
2. Drugs Inspectors-6	2. Asstt. Drugs Controller-2	2. Asstt. Drugs Controller-1	2. Asstt. Drugs Controller-1	1	64,840
	3. Drugs Inspectors :— i. Manf. 2 ii. Sales 5 — 7	3. Drugs Inspectors-1	3. Drugs Inspectors-1	1	40,000
					2,06,930
II. District 6	II. Zones - 1	*II. Equipment* 2 Mobile vans ×35,000	*II. Equipment* 2 Mobile Vans		70,000
III. Premises :	*III. Equipment*	III. Books & Journals :	III. Books & Journals :		25,000
1. Manufacturing-67	2 Mobile vans ×35,000	25,000			
					3,01,930
2. Sales-1031	IV. Books & Journals : 25,000		*Total Central Assistance Involved* :		3,01,930

17. PONDICHERRY

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure during 5th Plan	No. of posts	Emoluments Rs.
I. Personnel	*I. Personnel*	*I. Personnel*	*I. Personnel*		
1. Drugs Inspector-1	1. Drugs Controller-1	1. Drugs Controller-1	1. Drugs Controller. (1300-1600)	1	1,02,900
	2. Asstt. Drugs Controller-2	2. Asstt. Drugs Controller-2	2. Asstt. Drugs Controller.	2	1,29,720
	3. Drugs Inspectors : i. Manf. 1 ii. Sales : 3 — 4	3. Drugs Inspectors-3	3. Drugs Inspectors.	3	1,20,000
					3,52,620

II. Territory-	II. Zones: 1	II. Equipment 2 Mobile vans	II. Equipment 2 mobile vans	Rs. 70,000
III. Premises	*III. Equipment*	III. Books & Journals-	III. Books & Journals	25,000
1. Manufacturing-22	2 Mobile vans 35,000	Rs 25,000		4,47,620
2. Sales-300	IV. Books & Journals 25,000		TOTAL FINANCIAL ASSISTANCE INVOLVED :	4,47,620

18. CHANDIGARH

Existing set up	Proposed set up	Additional staff required	Estimated emoluments for 5 years of 5th Plan Period		
I. Personnel	*I. Personnel*	*I. Personnel*	*I. Personnel*	No. of Posts.	Emoluments Rs.
1. Drugs Inspectors-1	1. Drugs Controller-1	1. Drugs Controller-1	1. Drugs Controller. (1300-1600)	1	1,02,090
	2. Asstt. Drugs Controller-1	2. Asstt. Drugs Controller-1	2. Asstt. Drugs Controller (700-1250)	1	64,860
	3. Drugs Inspector-2	3. Drugs Inspectors-1	3. Drugs Inspectors (350-900)	1	40,000
					2,06,950
II. Territory : 1	Zone -1	*II. Equipment* 1 Mobile van 35,000	*II. Equipment* 1 Mobile Van		35,000
III. Premises	*III. Equipment* 1 Mobile van : 35,000	III. Books & Journals 25,000	III. Books & Journals		25,000
1. Manufacturing : 63					2,66,950
2. Sales :—	Books & Journals 25,000		TOTAL CENTRAL ASSISTANCE INVOLVED :		2,66,950

19. TAMIL NADU

Existing set up	Proposed set up	Additional staff required	Estimated expenditure during 5 yrs. of 5th Plan Period.		
I. Personnel	*I. Personnel*	*I. Personnel*	*I. Personnel*	No. of Posts	Emoluments. Rs.
1. Deputy Drugs Controller-1	1. Drugs Controller-1	1. Drugs Controller-1	1. Drugs Controller-(1300-1600)	1	1,02,090
2. Asstt. Drugs Controller-1	2. Dy. Drugs Controller-1	2. Asstt. Drugs Controller-2	2. Asstt. Drugs Controller	3	1,94,580
3. Drugs Inspectors-60	3. Asstt. Drugs Controller-4 4. Drugs Inspectors : i. Manf. 11 ii. Sales 61 72	3. Drugs Inspectors-3	3. Drugs Inspectors.	3	1,20,000
					4,16,670
II. District: 13	II. Zones : 3	*II. Equipment* 4 Mobile vans x 35,000	*II. Equipment* 4 Mobile Vans		1,40,000
III. Premises :	*III. Equipment* 4 Mobile Vans x 35,000	*III.* Books & Journals Rs.25,000	*III.* Books & Journal		25,000
					5,81,670
1. Manufacturing : 275	*IV.* Books, Periodicals &		TOTAL CENTRAL ASSISTANCE		
2. Sales 12291	Journals Rs.25,000		INVOLVED :		5,81,670

20. GOA, DAMAN & DIU

Existing set up	Propsed set up	Additional staff required.	Estimated Expenditure for 5 years. of 5th Plan Period	
I. Personnel	*Personnel*			Rs.
1. Drugs Controller-1	1. Drugs Controller-1	Nil	Staff : Nil	
2. Asstt. Drugs Controller-5	2. Asstt. Drugs Controller-cum-Drugs Inspector-5		Equipment :	70,000
			Books & Journals :	25,000
				95,000
				or 1,00,000
Territory :3	II. Zone : 1	Nil		
Premises :	*III. Equipment* 2 Mobile vans	*III. Equipment* 70,000	TOTAL CENTRAL ASSISTANCE REQUIRED :	1,00,000
1. Manufacturing 14	x 35,000			
2. Sales-75				
	IV. Books & Journals 25,000	IV. Books & Journals Rs. 25,000.		

21. MANIPUR

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure for 5 yrs. of 5th Plan		
I. Personnel		*Personnal*	*Personnel*	No. of Post	Emoluments Rs.
1. Drugs Inspector-1	1. Asstt. Drugs Controller-1	1. Asstt. Drugs Controller-1 (700-1250)	1. Asstt. Drugs Controller (700-1250)	1	64,860
	2. Drugs Inspector-1				
2. Territory-1	*Equipment* 1 Mobile van x 35,000	*Equipment* 1 Mobile van 35,000	2. *Equipment* 1 Mobile van		35,000
3. *Premises* :	Books & Journals 25,000	Books & Journals, 25,000	3. Books & Journals		25,000
1. Manufacturing					
2. Sales-142					1,24,860
			TOTAL CENTRAL ASSISTANCE :		1,24,860

22. TRIPURA

Existing set up	Proposed set up	Additional staff required	Estimated Expenditure for 5 yrs. of Plan Period.		
I. Personnel	*I. Personnel*		*I. Personnel*	No. of Posts.	Emoluments Rs.
There is no exclusive staff for Drugs Control in the Territory.	1. Asstt. Drugs Controller-1	Same as in Column-II	1. Asstt. Drugs Controller (700-1250)	1	64,860
	2. Drugs Inspector-1		2. Drugs Inspector. (350-900)	1	40,000
					1,04,860
II. Territory-1	*II. Equipment* 1 Mobile van x 35,000		*II. Equipment* 1 Mobile van		35,000
III. Premises	III. Books & Journals 25,000		III. Books & Journals		25,000
					1,64,860
1. Manufacturing-5			TOTAL CENTRAL ASSISTANCE		
2. Sales-49			INVOLVED		1,64,860

SUMMARY : Strengthenging of Drugs Control and Enforcement Wing in States

Sl. No.	Name of the State/Territory	Additional Establishment proposed to be provided	Total Central Assistance involved for shouldering expenditure @ 100% for 5 years of 5th Plan period
1	2	3	4
			Rs.
1.	*Andhra Pradesh*	*Staff* 1. Drugs Controller–one 2. Assitt Drug Controller–3 3. Drugs Inspectors–59 *Equipment* 4. Mobile Vans–6 5. Books and Periodicals–25,000	28,91,434
2.	*Assam*	*Staff* 1. Drugs Controller–1 2. Asstt. Drugs Controller–2 *Equipment* 3. Mobile Vans–3 4. Books & Periodicals–25,000	3,61,810
3.	*Bihar*	*Staff* 1 Drugs Controller–1 2. Asstt. Drugs Controller–5 3. Drugs Inspector–29 *Equipment* 4. Mobile Vans–5 5. Books & Journals –25,000	17,86,390
4.	*Gujarat*	*Staff*—Nil *Equipment* 1. Mobile Vans–6 2. Books & Journals–25,000	2 ,35,000
5.	*Kerala*	*Staff* 1. Asstt. Drugs Controller–3 2. Drugs Inspector–1 *Equipment* 3. Mobile Vans–4 4. Books & Journals—25 000	3,99,58
6.	*Madhya Pradesh*	*Staff* 1. Asstt. Drugs Controller–12 2. Drugs Inspectors-11 *Equipment* 3. Mobile Van–12 4. Books & Journals—25,000	16,63,32
7.	*Maharashtra State*	*Staff* 1. Drugs Inspectors–34 *Equipment* 2. Mobile Van–8 3. Books & Journals–25,000	4,41,000
8.	*Mysore State*	*Staff* 1. Asstt. Drugs Controller–3 2. Drugs Inspectors–3 *Equipment* 3. Mobile Vans–6 4. Books & Journals–25.000	5,49,58
9.	*Orissa*	*Staff* 1. Drugs Controller–1 2. Asstt. Drugs Controller–4 3. Drugs Inspector–1 *Equipment* 4. Mobile Vans–4 Books and Journals–25,000	5,66,53

1	2	3	4
			Rs.
10.	*Punjab*	*Staff* 1. Drugs Controller–1 2. Asstt. Drugs Controller–6 3. Drugs Inspetors–6 *Equipment* 4. Mobile Vans–6 5. Books & Journals–25,000	3,46,250
11.	*Rajasthan*	*Staff* 1. Drugs Controller–1 2. Asstt. Drugs Controller–7 3. Drugs Inspectors–12 *Equipment* 4. Mobile Vans–7 5. Books & Journals–25,000	13,06,110
12.	*Uttar Pradesh*	*Staff* 1. Drugs Controller–1 2. Asstt. Drugs Controller–13 3. Drugs Inspectors–79 *Equipment* 4. Mobile Vans–14 5. Books & Journals–25,000	46,20,280
13.	*West Bengal*	*Staff* 1. Asstt. Director–5 2. Drugs Inspectors–28 *Equipment* 3. Mobile Vans–5 4. Books & Journals–25,000	16,44,300
14.	*Delhi*	*Staff* 1. Drugs Controller–1 2. Drugs Inspectors–15 *Equipment* 3. Mobile Vans–2 4. Books & Journals–25,000	7,97,090
15.	*Himachal Pradesh*	*Staff* 1. Drugs Controller–1 2. Asstt. Drugs Controller–2 3. Drugs Inspectors–2 *Equipment* 4. Mobile Vans–2 5. Books & Journals–25,000	4,16,810
16.	*Haryana*	*Staff* 1. Drugs Controller–1 2. Asstt. Drugs Controller–1 3. Drugs Inspectors–1 *Equipment* 4. Mobile Van–2 5. Books & Journals–25,000	3,01,930
17.	*Pondicherry*	*Staff* 1. Drugs Controller–1 2. Asstt. Drugs Controller–2 3. Drugs Inspectors–3 *Equipment* 4. Mobile Vans–2 5. Books & Journals–25,000	4,47,620
18.	*Chandigarh*	*Staff* 1. Drugs Controller–1 2. Asstt. Drugs Controller–1 3. Drugs Inspector–1 *Equipment* 4. Mobile Van–1 5. Books & Journals–25,000	2,66,950
19.	*Tamil Nadu*	*Staff* 1. Drugs Controller–1 2. Asstt. Drugs Controller–3 3. Drugs Inspectors–3 *Equipment* 4. Mobile Vans–4 5. Books & Jorunals–25,000	5,81,670
20.	*Goa, Daman & Diu*	*Staff*—Nil *Equipment* 1. Mobile Vans–2 2. Books & Journals–25,000	1,00,000

1	2	3	4
21.	*Manipur*	*Staff* 1. Asstt. Drugs Controller 1 *Equipment* 2. Mobile Van-1 3. Books & Journals-25,000	
22.	*Tripura*	*Staff* 1. Asstt. Drugs Controller 1 2. Drugs Inspector-1 *Equipment* 3. Mobile Van-1 4. Books & Journals-25,000	
		GRAND TOTAL	250,13,374

I. Total Additional Staff for 5th Five Year Plan :

(1) Drugs Controller :	13
(2) Asstt. Drugs Controllers :	74
(3) Drugs Inspectors :	286
II Mobile Vans :	103
III. Books & Periodicals :	5.50 Lakh.

Appendix—C

EMOLUMENTS OF EACH SQUAD

Staff	No.	Emoluments 1974–75	Emoluments 1975–76	Emoluments 1976–77	Emoluments 1977–78	Emoluments 1978–79	Total
1	2	3	4	5	6	7	8	9
1. Drugs Inspectors (350-900) . . .	2	15,400	15,900	16,400	17,900	18,400	84,000
2. Police Officer (325-575) . . .	2	14,655	15,155	15,655	16,155	16,655	78,275
3. Field Asstt. (150-300)	1	4,322	4,466	4,610	4,754	4,900	23,052
4. Watchers (110-180)	3	9,131	9,395	9,619	9,863	10,107	38,905
5. Driver (150-300)	1	4,322	4,466	4,610	4,754	4,900	23,052
		47,830	49,362	50,894	53,426	54,962	2,56,474
Cost of 29 Squads :		Ist Yr.	IInd Year	3rd Yr.	4th Yr.	5th Yr.	
		13.87	14.31	14.76	15.49	15.94	74.37 lakh or say 75 lakhs

Cost per Squad : 75:29-2.60 lakhs

ANNEXURE—IV

A STATEMENT OF PROPOSED AMENDMENTS TO THE DRUGS AND COSMETICS ACT

(Chapter IX—Para 41—App. I)

Sl.No.	Section of the Act	Existing provision in the Drugs and Cosmetics Act, 1940	Proposed amendment
(A)	(B)	(C)	(D)
1.	Section 3(b) definition of the term "drug"	"drug" includes :— (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of disesase in human beings or animals; (ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by Notification in the Official Gazette;	After caluse (ii) the following shall be added : (iii) All substances intended for use as components of a drug including empty gelatin capsules. (iv) Such devices intended for internal or external use in the diagonisis, treatment, or mitigation of disease or disorder in human beings or animals as may be specified from time to time by the Central Government by notification in the Official Gazette in consultation with the Board.
2.	Section 3(f)	(f) manufacture in relation to any drung or cosmetic includes any process or part of a process formaking, altering, ornamenting finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale and distribution but does not include the compounding or dispensing of any drug or cosmetic in the ordinary course of retail business; and to manufacture' shall be construed accordingly;	Delete the words "with a view to its sale and distribution."
3.	Section5—The Drugs Technical Advisory Board	5. The drugs Technical Advisory Board. (1) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act. (2) The Board shall consist of the following members, namely;	In sub-section (2) after clause (xvi) the following shall be added : "(XVII) two persons to be nominated by the Central Government representing consumer's interests.
4.	Section 9—Misbranded cosmetics	Misbanded cosmetics— For the purpose of this Chapter, a cosmetic shall be deemed to be misbranded— (f) if its label or container bears the name of an individual or company purporting to be the manufacturer or producer of the cosmetic which individual or company is fictitious or does not exist, or	In clause (f) after the word "container" the following words shall be introduces : "or anything accompanying the cosmetics".
5.	Section 9 B Adulterated drugs	9B. Adulterated drugs—For the purposes, of this chapter, a drug shall be deemed to be adulterated.	After clause (b) the following clause shall be added: "(bb) if it contains any harmful or toxic material which renders it injurious to health.
6.	Section 10	10. Prohibition of import of certain drugs & cosmetics—From such date as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import— (a) any drug or cosmetic which is not of standard quality;	After (a) the following shall be added : (aa) any drug which is not generally recognised among experts as safe or efficacious for use under conditions recommended or suggested on the label thereof unless it is approved by such authorities and in a manner as may be prescribed."

(A)	(B)	(C)	(D)
7.	Section 10	10. Prohibition of import of certain drugs and cosmetics—From such date as may be fixed by the Central Government by Notification in the Official Gazette in this behalf, no person shall import— (a) any drug or cosmetic which is not standard quality; (d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of ingredients contained in it, in a manner readily intelligible to the members of the medical profession.	For sub-section (d) the following shall be substituted: "(d) Any patent or proprietary medicine unless there is displayed in the prescribed manner on the label of the container thereof the true formula or list of ingredients together with quantities thereof".
8.	Section 10	Explanation—The formula or list of ingredients mentioned in clause (d) shall be deemed to be true and sufficient compliance with that sub-clause if without disclosing a full and detailed recipe of the ingredients, it indicates correctly all potent or poisonous substances contained therein together with an approximate statement of the composition of the medicine.	For the existing Explanation the following shall be substituted :— "Explanation—The formula or list of ingredients mentioned in clause (d) shall be deemed to be true and sufficient compliance with that sub-clause if it indicated correctly all the active ingredients contained therein together with the quantities thereof.
9.	Section 12-Power of Central Government to make Rules.	12. Power of Central Government to make Rules— (1)The Central Government may, after consultation with the Board and after previous publication by notification in the official Gazette, make Rules for the purpose of giving effect to the provisions of this Chapter;	In sub-section (1), after the words "after consultation with the Board" the following words shall be inserted : "or on the recommendation of the Board".
10.	Section 12—Power of Central Government to make Rules.	12. Power of Central Government to make (1) ..... (2) Without prejudice to the generality of the foregoing power, such Rules may— (a) ..... (b) .... (c) prescribe the conditions subject to which small quantities of drugs the import of which is otherwise prohibited under this Chapter, may be imported for the purpose of examining, test or analysis or for personal use;	Rules—In sub-section (2), after clause (c) the following shall be added : "(cc) prescribe under clause (aa) of Section 10, the authority who will approve the drugs specified in it, the information to be called for in this connection and the manner in which such drugs should be investigated before approval is granted."
11.	Section 13 Offences	13. Offences—(1) Whoever contravenes any of the provisions of this Chapter or of any Rule made thereunder shall, in addition to any penalty to which he may be liable under the provisions of Section 11, be punishable with imprisonment which may extend to one year, or with fine which may extend to five hundred rupees or with both. (2) Whoever, having been convicted under sub-section (1), is again convicted under that sub-section shall, in addition to any penalty as aforesaid be punishable with imprisonment which may extend to two years or with fine which may extend to one thousand rupees, or with both.	For the existing Section 13, the following shall be substituted :— (1) Whoever imports (a) any drug deemed to be misbranded under clause (a), clause (b), clause (c), clause (d), clause (f), and clause (g) of Section or adulterated under Section 9B or any cosmetic contravening clause (ee) Section 10 shall be punishable with imprisonment which may extend to three years or with fine which may extend to rupees one thousand or with both. (b) Any drug other than a drug or cosmetic referred to in clause (a) in contravention of Section 10 or any rule thereunder shall be punishable with imprisonment which may extend to one year or with fine which may extend to five hundred rupees or with both. (2) Whoever having been convicted under sub-section (1) is again convicted under that sub-section shall, in addition to any penalty aforesaid be punishable with imprisonment which may extend to five years or with fine which may extend two thousand rupees or with both.

(A)	(B)	(C)	(D)
12. Section 17B	Adulterated drugs.	17B. Adulterated drugs—For the purpose of this Chapter a drug shall be deemed to be adulterated—	After clause (b), the following clause shall be added :— "(bb) if it contains any harmful or toxic material which renders it injurious to health".
13. Section 18	Prohibition of manufacture and sale of certain drugs and cosmetics.	18 Prohibition of manufacture and sale of certain drugs and cosmetics—From such date as may be fixed by the State Government by notification in the official Gazettee in this behalf, no person shall himself or by any other person on his behalf :— (a) manufacture for sale or sell, or stock or exhibit for sale, or distribute— (i) any drug or cosmetic which is not of standard quality; (ii) any misbranded drug or misbranded cosmetic; (iii) any adulterated drug; (iv) any patent or proprietary medicine unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of ingredients contained in it in a manner readily intelligible to the members of the medical profession. (v) any drug which by means of any statement, design or device accompanying it or by any other means purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed; (vi) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended; (vii) any drug or cosmetic in contravention of any of the provisions of this Chapter or any Rule made thereunder : (b) sell, or stock or exhibit for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any Rule made thereunder ; (c) manufacture for sale, or sell, or stock or exhibit for sale, or distribute any drug or cosmetic, except under and in accordance with the conditions of, a licence issued for such purpose under this Chapter; Provided that nothing in this Section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis. Provided further that the Central Government may, after consultation with the Board by notification in the official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale, sale or distribution of any drug or class of drugs not being of standard quality Explanation—The Formula or list of ingredients mentioned in sub-clause (iii) of clause (a) shall be deemed to be true and a sufficient compliance with that sub-clause if whithout disclosing a full	For Section 18, the following shall be substituted :— "18. *Prohibition of manufacture and sale of certain drugs and cosmetics* :— From such date as may be fixed by the State Govenrment by notification in the official Gazette in this behalf, no person shall himself or by any other person on his behalf :— (a) manufacture, or sell, or stock or exhibit for sale or offer for sale or distribute :— (i) any drug or cosmetic which is not of standard quality; (ii) any misbranded drug or misbranded cosmetic; (iii) any adulterated drug; (iv) any patent or proprietary medicine unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of ingredients contained in it together with the quantitiesthereof; (v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the direction indicated or recommended. (vi) Any drug which is not generally recognised by experts as safe or efficacious for use under the conditions recommended or suggested in the label thereof unless it is approved by such authority and in such manner as may be prescribed. (vii) any drug which by means of any statement, design or device accompanying it or by any other means purports or claims to prevent cure or mitigate any such disease or ailment or to have any such other effect as may be prescribed ; (viii) any cosmetic containing any ingredient which may render it unsafe and harmful under the directions indicated; (ix) any drug or cosmetic in contravention of any of the provisions of this Chapter or any Rules made thereunder; (b) Sell or stock or exhibit for sale, offer for sale or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any Rules made thereunder; (c) manufacture, or sell, or stock or exhibit for sale, or distribute any drug or cosmetic except, under and in accordance with the conditions of licence issued for such purpose under this Chapter. Provided that nothing in this Section shall apply to the manufacture, subject to the prescribed conditions, of small quantities of any drugs for the purpose of examination test or analysis.

(A)	(B)	(C)	(D)
		and detailed recipe of the ingredients it indicates correctly all the potent or poisonous substances contained therein together with an approximate statement of the composition of the medicine.	Provided further that the Central Government may, after consultation with the Board, by notification in the official Gazette, permit subject to any conditions specified in the notification, the manufacture, sale or distribution of any drug or class of drugs not being of standard quality. Explanation : The formula or list of ingredients mentioned in sub-clause (iv) of clause (a) shall be deemed to be true and a sufficient compliance with the sub-clause if, it indicates correctly all the active ingredients contained therein together with the quantities thereof."
14. Section 19(3) Pleas		19. Pleas.— (3) A person, not being the manufacturer of a drug or cosmetic or his agent for distribution thereof, shall not be liable for a contravention of Section 18 if he proves—	Under Section 19(3) the words "duly licensed" shall be added after the word "person."
15. New Section 19A			After Section 19 the following shall be added :- "19A. *Burden of Proof:* When any drug or cosmetic is seized from any person in the reasonable belief the drug or cosmetic is misbranded or adulterated, the burden of proving that such drug or cosmetic is not misbranded or adulterated shall be on the person from whose possession such drug or cosmetic seized."
16. Section 22. *Powers of Inspectors*		22. *Powers of Inspectors.*— (1) Subject to the provision of Section 28 and of any rules made by the Central Government in this behalf an Inspector may, within the local limits of the area for which he is appointed; (a) inspect any premises wherein any drug or cosmetic is being manufactured and in the case of sera, vaccines and any other drugs or cosmetics prescribed in this behalf, the plant and process of manufacture and means employed for standrdizing and testing the drugs.	22. *Powers of Inspectors :* (1) ..... "(a) inspect any premises wherein (i) any drug or cosmetic is manufactured and the plant and process of manufacture and the means employed for standardizing and testing the drugs or cosmetics; and (ii) any drug or cosmetic is sold or stocked or exhibited for sale or offered for sale or distributed.
17. *Section* 22 Powers of Inspectors		22. *Powers of Inspectors.*— (i) Subject to the provision of Section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed (cc) examine any record, register document or any other material object found in any place mentioned in clause (c) and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the Rules made thereunder;	After—sub-clause (cc) the following sub-clauses shall be added :— (d) seize and detain for such time as may be necessary any articles by mean of or in relation to which he reasonably believes that any provision of this Act or Rules have been contravened. (e) stop and detain for such time as may be necessary any vehicle suspected to contain any drug or cosmetic which he has reason to believe contravenes any of the provisions of the Act or the Rules made thereunder ; (f) seize in any place or any person any drug or cosmetic in respect of which he has reason to believe an offence punishable under this Act or Rules made thereunder, has been committed and alongwith the drug or cosmetic, other articles or documents which he has reason to believe may furnish evidence of the commission of any offence punishable under this Act.

(1)	(B)	(C)	(D)
			(g) require the production of any register or other documents relating to manufacture or sale of such drug or cosmetic and take on the spot or otherwise, statements of any person which he may consider necessary for carrying out the purposes of the Act.
			Clause (d) shall be renumbered (h)
18. New Section 22A			After Section 22 of the Act, the following new Section shall be added :—
			"Section 22A:—*POWER to summon persons to give evidence and produce documents for enquiries under the Act.*
			(i) An Inspector shall have the power to summon any person whose attendance he considers necessary either to give evidence or to produce a document or any other thing in any enquiry or investigations which such Inspector is making for any of the purposes of this Act.
			(ii) The summons to produce documents or other things under sub-section (i) may be for the production of certain specified documents or things or for the production of all documents or things of a certain descritpion in the possession of or under the control of the persons concerned.
			(iii) All persons so summoned shall be bound to attend either in person or by an authorised agent as the Inspector may direct and all persons so summoned shall be bound to state the truth of any subject, respecting which he is examined or make statements and produce such documents and other things as may be required.
			(iv) Every such enquiry as aforesaid shall be deemed to be a judicial proceeding within the meaning of Section 193 and 228 of the Indian Penal Code.
19. New Section 25A			After Section 25, the following Section shall be added :—
			"25A—*Presumption in certain cases*
			(1) When it is proved that a package containing any drug or cosmetic bears the name and address purporting to be the name and address of the person by whom it was manufactured, the Court may presume in a prosecution for contravention of this Act, or Rules that the drug or cosmetic was manufactured or sold as the case may be, by the person whose name and address appear on the label thereof.
			(2) In a prosecution for contravention of this Act, or Rules, it is sufficient proof of the offence to establish that it was commited by an employee or agent of the accused.
			(3) In trials under this Chapter it may be presumed unless and until the contrary is proved that the accused has committed an offence under this Chapter in respect of

(A)	(B)	(C)	(D)
			any drug or cosmetic if he fails to account satisfactorily for the possession of any apparatus of device designed for the manufacture of such drug or cosmetic or any material which has undergone any process towards the manufacture of any drug or cosmetic or of any raw material for such drug or cosmetic or of any packing or lebelling materials.
20. Section 27 Penalty for manufacture, sale etc., of drugs in contravention of this Chapter.		27. Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter—Whoever himself or by any other person on his behalf manufactures for sale, sells, stocks or exhibits for sale or distributes— (a) any drug— (i) deemed to be misbranded under clause (a), clause (b), clause (c), clause (d), clause (f), or clause (g) of Section 17 or adulterated under section 17B; or (ii) without a valid licence as required under clause (c) of Section 18, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to ten years and shall also be liable to fine.	For the existing Section 27, the following may be substitued :— (i) Whoever himself or by any other person on his behalf manufactures, sells, stocks or exhibits for sale or offers for sale or distributes— (a) any drug— (i) deemed to be misbranded under clause (a), Clause (b), clause (c), clause (d), clause (f) or clause (g) of Section 17 or adulterated under section 17B; or (ii) manufactures a drug without a valid licence as required under clause (c) of the seciion 18 shall be punishable with imporisonment for life and shall also be liable to fine:
		Provided that the Court may for any special reasons to be recorded in writing, impose a sentence of imprisonment of less than one year;	Provided that the court may for any special reasons to be recorded in writing impose a sentence of imprisonment which shall not be less than five years.
		(b) any drug other than a drug referred to in clause (a) in contravention of any of the provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to three years, or with fine, or with both :	(b) any drug other than a drug referred to in clause (a) in contravention of any of the provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to three years, or with fine or with both. Provided that where the drug has caused grievous personal injury the punishment shall be imprisonment for life.
21. Section 27A Penalty for manufacture, sale, etc. of cosmetics in contravention of this Chapter.		27A. Penalty for manufacture, sale, etc. of cosmetics in contravention of this Chapter—Whoever himself or by any other person on his behalf manufactures for sale, sells, stocks or exhibits for sale, or distributes any cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to five hundred rupees, or with both.	For the words "one year" the words "three years" shall be substituted.
22. New Section 27B . . .			After Section 27-A, a new section 27-B, may be added: "27-B—whoever himself or by any other person on his behalf maintains any record or submits any information which is false or misleading in any particular material under this Chapter or any rule made thereunder shall be punishable with imprisonment, which may extend to three years or with fine or with both.
23. Section 28		Penalty for non-disclosure of the name of the manufacturer etc.—Whoever contravenes the provisions of section 18-A shall be punishable with imprisonment for a term which	For the existing Section 28 the following may be substituted: "28—Penalty for non-disclosure of the name of the manufacturer, etc.

(A)	(B)	(C)	(D)
		may extend to one year, or with fine which may extend to five hundred rupees, or with both.	(i) Whoever contravenes the provisions of Section 18-A and Section 24 shall be punishable with imprisonment for a term which may extend to three years or with fine which may extend up to five hundred rupees or with both.
24. Section 30 Penalty for subsequent offences.		30. Penalty for subsequent offences—(1) Whoever, having been convicted of an offence— (a) under clause (a) of Section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to ten years and shall also be liable to fine: Provided that the Court may, for any special reasons to be recorded in writing, impose a sentence of less than two years;	For the existing Section 30, the following shall be substituted: "30. Penalty for subsequent offences: (i) whoever, having been convicted of any offence— (a) under clause (a) of Section 27, is again convicted of an offence under that clause, shall be punishable with death. While this is the recommendation of the Committee of Drugs Controllers, Citizens Central Council has recommended life imprisonment for repeated offences: Provided that the Court may, for any special reasons to be recorded in writing, impose a sentence of imprisonment for a term which shall not be less than ten years.
25. Section 30 Penalty for subsequent offences.		(1A) Whoever, having been convicted of an offence under section 27-A is again convicted under that section shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to one thousand rupees, or with both.	In clause 1-A of Section 30, the words "two years" shall be substituted by the words "six years".
26. Section 32 Cognizance of offences		32. Cognisance of offences (1) No prosecution under this Chapter shall be instituted except by an Inspector.	Under Section 32, for sub-section (1) the following shall be substituted: (1) "No prosecution under this Chapter or the Rules made thereunder shall be instituted except by an Inspector with the consent of the authority specified under sub-section 4 of Section 21".
27. Section 32 Cognizance of offences.		32. Cognizance of offences (1) No prosecution under this Chapter shall be instituted except by an Inspector.	After sub-section 1 of Section 32, the following proviso shall be added:— "Provided that in respect of the offence under Section 27(a), any police officer not below the rank of an Inspector of Police may also institute prosecution".
28. Section 32-A power of Court to implead the manufacturer etc.		32-A. Power of Court to Implead the manufacturer etc.—Where at any time during the trial of any offence under this Chapter alleged to have been committed by any person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, the Court is satisfied, on the evidence adduced before it, that such manufacturer or agent is also concerned in that offence, then the Court may, notwithstanding anything contained in sub-section (1) of section 351 of the Code of Criminal Procedure, 1898, proceed against him as though a prosecution had been instituted against him under section 32.	In section 32-A, the words "within seven days of its so being satisfied" may be added between the words "Code of Criminal Procedure, 1898" and "proceed against....."
29. Section 33 Power of Central Government to make Rules.		33. Power of Central Government to make Rules (1) The Central Government may after consultation with the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter.	In sub-section (1) after the words "after consultation with the Board" the following words shall be inserted:— "or on the recommendation of the Board".

(A)	(B)	(C)	(D)
30.	Section 33(2) Power of Central Government to make Rules.	(2) Without prejudice to the generality of the foregoing power, such rules may— (e) prescribed the forms of licences for the manufacture for sale, for the sale and for the distribution of drugs or any specified drug or class of drugs or of cosmetics or any specified cosmetic or class of cosmetics the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor.	Clause (e) of sub-section (2) of section 33 may be substituted by the following:— (e) Prescribe the various forms of licence for manufacture, for the sale and for the distribution of drugs or any specified drug or class of drugs or of cosmetics or any specified cosmetic or class of cosmetics, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the qualifications of the authority and the fees payable thereof including the fee for inspection of manufacturing premises;"
31.	Section 33(2) Power of Central Government to make rules.	(2) Without prejudice to the generality of the foregoing power, such rules may— (n) prescribe the powers and duties of Inspectors and specify the drugs or classes of drugs or cosmetics or classes of cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed.	Clause (n) of sub-section (2) of Section 33 may be substituted by the following:— "(n) prescribe the powers and duties of Inspectors and specify drugs or class of drugs or cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed, the qualifications of the authority specified in sub-section (4) of Section 21.
32.	Section 34	34(1) Where an offence under this Act has been committed by a company every person who at the time the offence was committed, was incharge of, and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly: Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence. (2) Notwithstanding anything contained in sub-section (1) where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly. Explanation—For the purpose of this Section— (a) 'company' means a body corporate, and includes a firm or other association of individuals; and (b) 'director' in relation to a firm means a partner in the firm.	After explanation the following explanation shall be added:— *Explanation* 2 Where a person, being the Chairman or Managing Director of a Company has, on behalf of the company, signed an application for licence under this Act, any contravention of the conditions of that licence shall, so long as such person holds an office in the company, be conclusively presumed to have been committed with his consent or connivance. *Explanation* 3 Where an application for licence under this Act is signed by an officer of a company other than the Chairman or Managing Director, it shall, for the purposes of this section, be deemed to have been signed also by the Chairman and the Managing Director of the Company.
33.	New Section 34-B .		After Section 34-A, the following shall be introduced as Section 34-B namely— 34-B. *Prohibition of import manufacture, sale, etc. of drugs or cosmetics etc., for reasons of public safety.*

(A)	(B)	(C)	(D)
34. Section 35(1)		*Publication of offender's name*— (1) If any person is convicted of an offence under this Act, it shall be lawful for the court before which the conviction takes place to cause the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the court may direct.	Sub-Section (1) of Section 35 shall be substituted by the following:— "35(1) if any person is convictee of an offence under this Act, the Court before which the conviction takes place shall, on an application made to it, cause the offender name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the court may direct.
35. New Section 37-A . . .			After Section 37, the following Section shall be added as Section 37-A:— "37-*A*—*Penalty for vexatious search or seizure*— Any Inspector exercising powers under this Act, or under the Rules made thereunder who vexatiously or without any reasonable ground of suspicion— (a) searches any premises where drugs or cosmetics or components thereof are manufactured, sold, stocked or distributed; or (b) seizes any stocks of any drug, cosmetic or component thereof, or (1) Notwithstanding the fact that any provisions contained herein before it shall be lawful for any authority, conferred with powers in this behalf under this Act, by the Central or State Government to prohibit import, manufacture, sale or distribution of any drug or cosmetic or component thereof, and order recall of the issues already made thereof, if he has reason to believe that the use of such drug or cosmetic or the component thereof is likely to involve such risk to human being or animal as to render it expedient or necessary to take immediate action". (2) the authority may, in such cases, by an order in writing or notification in the Official Gazette, prohibit, import, manufacture, sale or distribution of any drug or cosmetic or component thereof for such period not exceeding sixty days as may be specified in the order or notification, pending investigation in the matter in consultation with the Board. (3) if as a result of investigation or on receipt of opinion of the Board, the authority is satisfied that the use of the drug or cosmetic or component thereof is or is not likely to cause any such risk, he may pass such order as he deems fit. (c) commits any other act, to injure any person without having reason to believe that such act is necessary for the execution of his duty— shall be guilty of an offence under this Act, and shall be punishable for such an offence with fine which may extend to one thousand rupees.

(A)	(B)	(C)	(D)
36.	Section 38 Rules to be laid before Parliament.	38. Rules to be laid before Parliament— Every rule made under this Act shall be laid down as soon as may be after it is made before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if before the expiry of the session in which it is so laid or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.	Section 38 may be substituted by the following:— "Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days *which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both House* agree in making any modification to the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the Validity of anything previously done under that rule."

ANNEXURE V

NOTE REGARDING THE PROCEDURE ADOPTED FOR PURCHASE OF DRUGS FOR GOVERNMENT HOSPITALS AND SEMI-GOVERNMENT INSTITUTIONS IN MAHARASHTRA STATE

[CHAPTER IX PARA 45—App. I]

The Drugs for Government hospitals, and Semi-Government Institutions in the Maharashtra State are being purchased by inviting tenders by the Commissioner of Industries and Central Stores purchasing Officer of the State of Maharashtra.

The Government of Maharashtra have constituted a Committee consisting of the following members to advise the Central Stores purchasing Officer with regard to the items of drugs and medicines to be purchased :—

Members

1. Director of Haffkine Institute. . . . . Chairman.
2. Commissioner, Food and Drug Administration (Maharashtra State) . . . Member.
3. Jt. Director of Medical Education and Research (Maharashtra State) . . . Member.
4. Professor of Medicines, Grant Medical College, Bombay. . . . . Member.
5. Professor of Surgery, Grant Medical College, Bombay . . . . . Member.
6. Professor of Obstetrics and Gynaecology, Grant Medical College, Bombay . . Member.
7. Dy. Director of Health Services (HQ), Maharashtra State . . . . . Member.
8. Professor of Pharmacology, Grant Medical College, Bombay . . . . Convenor.

This Committee after making deliberations recommends to the Central Stores Purchasing Officer the items of drugs and medicines which are required to be used in the Government Hospitals and Semi-Government Institutions for purchase by tender system.

The Central Stores Purchasing Officer on receipt of the recommendations of this Committee invites tenders for the items. One of the foremost conditions in submitting the tender is that the tenderer should submit *Performance and No-conviction certificate* issued by Commissioner, Food and Drug Administration, Maharashtra State, along with his tender. No tender is taken into consideration in absence of these certificates.

In obtaining these certificates tenderer has to approach the Food and Drug Administration, Maharashtra State and apply for the same together with the information in the enclosed proforma at Appendix 'A'. These applications are scrutinized by the Officers of this Administration who make the necessary recommendations to the Commissioner, Food and Drug Administration, Maharashtra State, in the proforma enclosed as Appendix 'B'. The performance certificate is then either issued or refused depending upon the merits of each case. Similarly, non-conviction certificates are being issued to the applicants if their firm is not convicted for the last five years. The proformae of these certificates issued by this Administration are enclosed as Appendix 'C' and 'D'

Government of Maharashtra has also constituted a Drugs Selection Committee consisting of the following members :—

1. Commissioner of Industries (Maharashtra State).
2. Commissioner of Food and Drug Administration (M.S.),
3. Professor of Pharmacology, Grant Medical College, Bombay, representing the Medical Department.

The tenders so invited are being opened by Central Stores Purchasing Officer in presence of the representatives of the tenderers and then quotations are tabulated by the Central Stores Purchasing Officer. These tabulated quotations are finally checked and scrutinised by the aforesaid drugs Selection Committee. This Committee then makes the recommendations regarding the drugs and the manufacturer from whom these should be purchased by the Central Stores Purchasing Officer. While making their recommendation the Committee gives 'preference to the basic and original manufacturer of the drugs so as to ensure uninterrupted supply of the drugs to the institutions. This policy is adopted in case of life saving drugs and drugs which are consumed comparatively in large quantities. While scrutinizing and selecting these drugs this Committee also checks the samples of these drugs visually so as to make sure that the drug to be supplied is of acceptable quality.

The recommendations so made are then forwarded to Central Stores Purchasing Officer, who in turn fix the rate contract with the manufacturers for supply of drugs to the Government Hospitals and Semi-Government institutions.

Regular samples are drawn by Food and Drug Administration from the institutions to check their quality during the tender period. Experience has shown that sub-standard drugs are not supplied to Government or Semi-Government institutions.

A copy of the forms also enclosed at Appendix 'E'. (Not enclosed)

APPENDIX 'A'

Information to be supplied by the Applicant for issue of Certificate in respect of performance Certificate.

(1) Items quoted in the Tender.

(2) When first permitted by this Directorate to manufacture these items. (Quote No. and date of the letter)

(3) How many batches of these items have been and quantity manufactured during the last two years, state also the quantities of each batch size.

(4) Whether any samples of these products have any time been reported to be not of standard quality by any Government Analyst, if so, give details.

(5) Whether permission to manufacture these products was ever withdrawn or suspended by this Directorate. If so, give reasons and when such permission was withdrawn or suspended.

(6) Whether these products were accepted on any tender previously. If so, give details regarding when, it was accepted, quantity supplied, whether supplied regularly and whether there was any complaint.

(7) If the items to be supplied are thermolabile substances, state whether stability study is carried out.

(8) Whether the production in any of the departments was stopped by this Directorate during the last two years. If so, give details and reasons.

(9) Whether any of licences were suspended partly or wholly during the last five years. If so, give details.

(10) Whether you are manufacturing drugs quoted at your own premises or under a loan licence.

(11) Whether your firm has got own testing arrangments or whether tests are performed by an approved laboratory ?

(12) Whether you are manfacturer of the basic drug for which you have quoted.

(13) Whether any of the product previously accepted on Rate Contract were reported to be not of standard quality ? If so, give details.

I declare that the information given above is true and I am aware that any certificate issued on the basis of the above information is liable to be withdrawn if any particular given in the information are not true.

APPENDIX 'B'

Report regarding issue of perfomance/reliability and *bona fide* Certificates to firms for Rate Contract. E.S.I.S. and Govt. enders.

Note :

Our report should be based on the observations and General workings of the man facturers during the last 12 months. You may visit the plant if you feel this would help in giving the information. You are required to submit your report within 15 days of the receipt.

M/s.

1. Whether raw materials used in the manufacture are tested for Pharmacopoeial tests . . . Yes No.
2. Whether all therapeutically active ingredients present in the finished products are tested for quality, purity and strength (Excluding those which are not normally possible). Yes No.
3. Whether control samples of the finished products are retained . . . . Yes No.
4. Whether good manufacturing practices are followed as intimated in circulars issued earlier . . Yes No.
5. Whether licences are suspended during the last 12 months . . . . Yes No.
6. Whether stability studies are adequately conducted on the products which deteriorate on storage . Yes No.
7. Whether the production of any categories of drugs was suspended or stopped. If so, which categories. Yes No.
8. **If any samples of any categories of drug manufactured by the firm are reported to be not of standard quality do you think that this is the result of a laxity in quality control and/or failure to adopt good manufacturing practice and technique. If no products are drawn for test please state so. (Base your answer on the products tested and general observation during the last 12 months).**
9. Whether product development studies are carried out (Excluding stability studies). . . . . Yes No.

In my opinion the firm can/cannot be relied upon to supply quality drugs to Maharashtra State, Hopsitals or Employees State Insurance Scheme and any other tender.

APPENDIX 'C'

No. A/CERT/ /of 72.
Food and Drugs Administration,
Maharashtra State,
Griha Nirman Bhavan, Bandra (E)
Bombay-51.

CERTIFICATE

This is to certify that M/s... . ... have not been convicted in this State for adulteration or for manufacturing selling drugs below standards laid down in the Drugs and Consmetics Act, 1940, during last five years.

( )
for Commissioner.
Food and Drugs Administration.

APPENDIX 'D'

No. A/CERT/ /of 73,
Food and Drug Administration,
Maharashtra State,
Griha Nirman Bhavan. Bandra (E)
Bombay-51-AS.

PERFORMANCE CERTIFICATE

This is to certify that up to the time of wiriting this certificate the performance of M/s. .... in complying with the provisions of Drugs and Cosmetics Act, 1940 and the Rules thereunder is generally satisfactory.

This Certificate is given in accordance with condition of Tender of the.. . . .. and is given on the express condition that it will not be quoted or used for any other purpose except for the purpose of the said condition for the said tender.

( )
for Commissioner.
Food and Drug Administration.

CHAPTER—IX

ANNEXURE 'VI'

(Para. 45—App. I)

A MANUAL ON THE WORKING OF HOSPITAL STORES

Introduction :—1. The activities of the Hospital Pharmacy where drugs are processed by the hospital for the use of patients and the hospital stores where the drugs are stored, checked and issued contribute a great deal to the overall quality of medical service rendered by hospitals. The importance of these two institutions in an hospital has been rightly emphasized by the Union Health Minister in a letter addressed to State Health Ministers (Appendix I). The role, the State Drugs Control Authorities can play in toning up the functions of a Hospital Pharmacy and hospital stores were discussed at a meeting of the Drug Standard Control Officers from the Centre and the States and it was agreed that the conditions under which drugs formulations are processed by hospitals for the use of their patients, the functioning of stores etc. needed close surveillance with a view to ensuring that patients in hospitals receive drugs of quality.

2. The following recommendations were made at the meeting :—

(a) If drugs are manufactured for use of patients by hospitals in hospital pharmacies, the conditions of manufacture should be stringently controlled in the same manner as private manufacturer/manufacturers of similar items are controlled.

(b) Facilities for sterilisation services in hospitals should be frequently inspected by the Central and State Drugs Inspectors.

(c) The manner in which drugs are ordered, stored and issued by the hospitals should also be subjected to frequent checks so as to ensure :—

(i) that purchases are made in phased instalments to obviate financial loss to hospitals;

(ii) that drugs which require special storage conditions are stored properly; and

(iii) that drugs which bear a date of expiry are issued or turned over by arrangement with manufacturers in such a manner that hospitals are not saddled with any time expired stocks.

(d) The responsibility for ensuring "good manufacturing practices" including sterlisation facilities in hospitals and management of hospital stores should be fixed on specific members of the staff in hospitals who should also be made to maintain the necessary registers and records.

(e) In hospitals with 200 beds and above, a Chief Pharmacist who should be at least a graduate in pharmacy should be appointed and given gazetted status with an appropriate status with an appropriate salary scale. The Chief Pharmacist should have a thorough background knowledge of drugs, their substitute, storage conditions etc., and should be able to assist the hospital administration in maintaining the quality of drugs supplied to patients.

The Committee also recommended that similar facilities should be made available in smaller hospitals.

The General impression is that medical stores where drugs are stored for issue to the wards, patients etc. do not function satisfactorily. The object of this manual is to lay down guide-line or organising the medical stores in a hospital with particular reference to the location, personnel, conditions of storage of drugs, manner of distribution of drugs etc. Necessary modifications to suit any particular institution may be carried out by the Medical Superintendent wherever considered necessary, so long as the basic objectives are fulfilled.

3. Under the provisions of Drugs and Cosmetics Act & Rules a medical store run by a hospital is exempted from the requirements of taking a sales licence under the Act, subject to the following conditions :—

(i) the dispensing and supply of drugs shall be carried out by or under the supervision of a qualified person;

(ii) the premises where drugs are supplied or stocked under drugs shall be open to inspection by an Inspector appointed under drugs & Cosmetics Act who can, if necessary, take samples for test; and

(iii) the drugs shall be stored under proper storage conditions.

A drug Inspector is thus fully authorised to inspect the premises of medical stores of an hospital and ensure compliance with the conditions mentioned above

Location : 4.1 The medical stores should preferably be located in the basement of ground floor in a multi-storeyed building well removed from the autoclaves, heating apparatus, laundry etc. It should be well lighted and ventilated. All measures should be taken to maintain the place dust-free, neat and tidy.

4.2 The area provided for the stores should be such as to prevent undue congestion and disorderly storage of drugs.

Personnel :—4.3 The Staffing pattern of the stores will depend on its function. Thus the staff of the Medical Stores in a hospital which has manufacturing Pharmacy will vary from that of an ordinary stores. In the former case the following staff pattern is recommended.

4.4 A Chief Pharmacist, possessing adequate education qualifications, preferably a post-graduate degree in Pharmacy and having adequate practical experience (about 3 years) should be in overall charge of the following sections in the Hospital :

(i) Medical Stores.

(ii) Dispensary.

(iii) Hospital Pharmacy (Transfusion Solutions) and Central Sterlisation.

(iv) Quality Control.

He must also have a thorough background knowledge of drugs, their substitutes, storage conditions, drug market, and manufacture and testing of Transfusion Solutions etc. Considering the workload, the duties, responsibilities etc. to be shouldered by him the Chief Pharmacist should be treated on par with the senior cadre officers in the Hospitals and offered a salary scale of Rs. 700-1200 so that he may command respect not only from the staff members working under him but also from the medical staff in the hospital. This salary scale will also attract suitable candidates having the requisite qualifications and experience from the industry.

4.5 In case of hospitals maintaining hospital stores only a Chief Pharmacist possessing adequate educational qualifications say a graduate degree in Pharmacy and having adequate practical experience (about 3 years) should be in overall charge of the following Sections in the Hospitals;

(a) Medical Stores

(b) Dispensary

(c) Quality Control.

He must also have a thorough background knowledge of drugs their substitutes, storage conditions, drug market etc. The Chief Pharmacist in this case may be offered a salary scale of Rs. 400.950.

4.6 The chief Pharmacist should be associated with a Hospital Committee which should be entrusted with the responsibility for making purchases of medical stores either on rate contract or direct from the manufacturers. The Committee should consist of Heads of the department of Medicine and Pharmacology. The Chief Pharmacist should be the convener of the same and should furnish to the Committee competitive prices of products of identical composition. As far as possible, the products purchases should confirm to the requirements given in the latest edition of the National Formulary of India. Only those firms which in the opinion of the State Drugs Control Authorities adopt Good Manufacturing Practices and against whom there are no complaints for quality of drugs or other eithical practices should be enlisted for local purchases.

4.7 The Chief Pharmacist should be directly under the administrative control of the Medical Superintendent of the Hospital and all the different Section Heads of the Stores, Hospital Pharmacy (mentioned under 4.4 or 4.5 above) should function under his supervision & control.

Supervision

5. The medical Stores of a hospital should be under the suprvision of a person who is a registered pharmacist and has adequate experience in operating a Drug Store. He should be assisted by suitable number of other registered pharmacists.

Facilities for storage of drugs :

6.1 Storage of General drugs : The section should be well equipped with storage facilities i.e.,

(a) raised wooden platforms for storage of drugs and gunny bags, and

(b) steel racks, shelves etc., for storage of general drugs.

Storage of Narcotic drugs :

6.2 All narcotic drugs, barbiturates and other habit forming drugs should be stored in separate almirahs and the key for these almirahs should be kept with the supervisor mentioned at 5 above.

The stocks of these drugs should be physically verified by the Chief Pharmacist (mentioned in 4.4 or 4.5) at least once a month and signed by him.

Storage of drugs at low temperature :

6.3 Special attention should be given to storage of certain categories of drugs which are required to be kept at low temperature for retaining their potency. Some of these drugs shoud be stored between 2 to 10°C and others between 15 to 20°C.

Cold Storage :

6.4 Drugs which are required to be stored between 2 to 10°C will include (a) Sera (b) Vaccine (c) Galandular preparations and other thermolabile products. It is not possible to give an exhaustive list of these drugs which require cold storage but an illustrative list is given at Appendix -II. A list of such drugs indicating the brand names in the brackets should be exhibited prominently in the stores. Several products with brand names will fall within the purview of this list. Storage conditions are invariably shown on the outer packings of such drugs and these should be checked and compared by Supervisor mentioned in 5 above.

6.5 For storage of drugs covered by 6.4 it would be advisable to have separate room or a portion maintained at this temperature range. A recording thermometer should be provided and the temperature should be noted at least twice a day by the supervisor mentioned at 5 above & singed by him. In case such room is not available adequate number of refrigerators should be provided for the purpose. The maintenance of these refrigerators in working order is the responsiblity of the Supervisor mentioned at 5 above.

6.6 Drugs such as Insulin, certain Vaccines etc. should not be allowed to freeze. Care should be taken to see that such drugs are not kept in the freezing compartment of the refrigerators. The Chief Pharmacist referred at 4.4 or 4.5 should personally check and ensure that such drugs are not kept outside the refrigerators. A list of such drugs should be exhibited in the stores.

Storage at cool temperature (15° to 20° C)

6.7 Drugs such as antibiotics, Vitamins, hormones, Liver, preparations etc. are required to be stored at a cool temperature. An illustrative list is given at Appendix III. Storage conditions are invariably shown on the outer packing of drugs and these should be checked and compared by the Supervisor mentioned in 5 above. Air-Conditioned storage accommodation should be provided for the purpose and a record of the maximum and minimum temperature by a recording thermometer should be maintained, checked and signed by the supervisor referred at 5 above at least twice a day. The space of this room should be adequate considering the maximum stock of drugs likely to be purchased by the hospital during any time of the year.

6.8 The Chief Pharmacist referred at 4.4 and 4.5 should ensure that no drug falling in this category is stocked away from this room. An inspection register for recording the observations of the Chief Pharmacist during the check should be maintained.

Storage of drugs with life-period :

7.1 It is advisable to store such drugs in a separate area in the Medical Stores to facilitate regular checking of these drugs with respect to their 'dates of expiry' of potency. Such products with expiry dates should be arranged on the racks or the shelves in the medical stores in such a manner that drugs having a shorter life period are kept in the front while those with a comparatively longer life-period are stored in the rear. A card system should be adopted for indicating the upto date stock position of such dated products together with their 'dates of expiry'. In addition to this, a separate 'Date Expiry Register' for such products should also be maintained for ready reference by the stores in charge. Both the cards as well as the Expiry Date Register should be reviewed regularly at least once a *fortnight* by the Chief Pharmacist referred to at 4.4 or 4.5 above to ensure proper distribution of such drugs in the various wards.

7.2 Stocks of drugs nearing their dates of expiry should also be physically inspected by the Chief Pharmacist referred to at 4.4 or 4.5 and examined for any visible signs of deterioration of the content of such drugs, for example, change of colour of the products or change in the physical conditions, such as caking of pencillin or tetracyline in

vials. In the event of any such deteriorated goods, the Chief Pharmacist referred at 4.4 or 4.5 should indicate the action taken in respect of the goods in the register which should be dated and signed by him and he should personally ensure that action as suggested is actually taken in the matter.

7.3 If scrutiny of the stocks reveals that certain drugs will be crossing the dates of expiry within a period of 3 months or so and if the Chief Pharmacist referred at 4.4 or 4.5 feels that the balance stocks of such drugs cannot normally be consumed by the hospital within that period, then steps should be taken by the Chief Pharmacist for replacement of the stock from the manufacturer, or in alternative he may consider the feasibility of offering such stocks to other Govt. Hospitals in consultation with the Medical Superintendent of the Hospital. To avoid such contingencies it would be better if the requirements of the drugs are assessed by the Chief Pharmacist on a realistic basis and orders placed in such a manner as to ensure phased delivery to the Hospital.

Pending final action from the manufacturers the stocks of drugs which become data-expired, should be removed to a separate area specially earmarked for the purpose with the notice in red **"DATE EXPIRED DRUGS—NOT TO BE ISSUED"** in bold letters.

Complaint Register :

8.1 A complaint Register should be maintained by the Chief Pharmacist wherein all the complaints regarding adverse reactions of any drug on patients from different wards should be incorporated and the details of action taken on such complaints both by the Hospital authorities as well as the Drugs Control authorities may be indicated against each. Whenever any complaint (such as side reactions) regarding drug of any batch is reported further issue of the batch should be suspended forthwith till such time as the cause for the side reactions is identified. Side reactions which are frequently encountered with the treatment of penicillin and the instructions as to the line of action to be followed in such cases are indicated in a letter issued by the Director General of Health Services, New Delhi (copy enclosed Appendix -IV). Such complaint Register may be maintained in the following proforma:—

(1) Sl. No. (2) Date of Complaint (3) Ward No. from which complaint received (4) Name of the Drug (5) Manufacturer's name (6) Batch Number (7) Nature of the complaint (8) Action taken by the Hospitals/Drugs Control Authorities (9) Final remarks (10) Whether the drug from the batch had been issued to other patients and whether any untoward reaction has been reported.

8.2 If drugs stored by the hospitals have deteriorated before the date/expiry, such cases should also be entered in the Complaint Register.

Receipt of Drugs :

9.1 There should be a system in the Stores Section whereby the supply of all the drugs received in the Medical Stores from the manufacturers are **properly checked** by a person **specially designated** for the purpose preferably the same person responsible for reviewing the stocks of date expiry drugs for their description, quantity batch numbers and date of expiry, if any, as mentioned in the order from delivery challans/invoices to avoid any subsequent confusion about the nature of drugs received.

9.2 Random samples should be checked visually to make sure that the products confirm to the tendered specifications particularly with the products having Date of Expiry and the products do not show any visible sign of deterioration such as change of colour, caking up etc.

If any such deterioration is observed the matter should be reported immediately to the Medical Superintendent and the local Drugs Inspector and stock should not be used until the Drugs Inspector's permission is received. The manufacturer should also be apprised of the position.

9.3 After the examination, the above officer should give his "No. objection" to accept the supply in writing on the Hospital copies of the respective delivery challans/invoices etc. by putting his signature and date.

Distribution of Drugs to the Wards :

10.1 Drugs as far as possible should be supplied to the wards in the original packings of the manufacturer. If, however, it is not possible to do so they should at least be supplied in clean containers which will preserve the integrity and the properties of the original drugs. It should be appropriately labelled with the name of the drug and the quantity.

It is advisable that proper precautions are taken in disposing of the 'original' empty containers of drugs so as to prevent their misuse by unscruplulous persons. The containers should be destroyed in the presence of a responsible officer and a written statement must be signed and maintained.

10.2 The Chief Pharmacist should visit wards to check that drugs requiring special storage conditions such as cold storage are properly stored and stocks of drugs which are not normally required are not kept in the wards.

General

11.1 In case of failure of the electric supply or airconditioning Unit the necessary authorities should be immediately contacted and telephone number of such authorities should be readily available on the desk of the Chief Pharmacist. Failure of the electric supply or airconditioning Unit for a longer period should be at once reported to the Medical Superintendent. The Chief Pharmacist should be empowered with the authority for repair of air-conditioning Units, by the Medical Superintendent.

Import of Drugs :

12.1 Drugs can be imported from abroad upto Rs. 1000/- C.I.F. value (This is exclusive of postal and air-charges), at a time for the use of the hospital. The benefit of this provision can be made use of by the hospital stores in case of newer life-saving drugs. A list of such newer life-saving drugs which can be imported is enclosed at Appendix V. These drugs are exempted from the custom duty by the Ministry of Finance Notification No. 9/21/70-Customs V dated 22-6-1971.

APPENDIX-I

Copy of D.O. No. F. 3-13/70-D dated the 17th June, 1971 sent to all State/Union Territories, Health Ministers by the Deputy Minister for Health and Family Planning.

Dear.....

At a recent meeting of the Drugs Standard Control Officers from the Centre and the States, the question of excercising stringent control over the quality of drugs used by the hospitals was considered. It was felt that the conditions under which the drugs formulations are processed by hospitals for the use of their patients, the functioning of Hospital stores and the operation of sterile service in hospitals needed close surveillance and a number of measures were suggested which are contained in the attached note.

May I therefore suggest that the Superintendents of Hospitals in your State be advised to avail themselves of the assistance of the State Drugs Control authorities in organising Hospitals Stores, Hospital Pharmacy and dispensing and sterile service establishments on the lines recommended by the Drug Control authorities. In particular the hospital authority should invite more frequent inspection of their hospitals by the officers/Inspectors of the State and Central Government and extend to them all assistance. Mutual co-operation between Drugs Control authorities and hospital authorities would contribute a great deal towards improvements of hospital services in the country.

I shall be glad to know in due course the action taken in the matter.

Yours sincerely,
Sd/- A. K. KISKU

APPENDIX—II

Illustrative list of Drugs Requiring storage at cold temperature (2°C to 10°C) but which are not to be frozen. This is not an exhaustive list and the Pharmacists should check the labels on the Drugs to know about the proper storage.

(1) Sera in general.
(2) Vaccines in general.
(3) Whole human blood.
(4) Concentrated Human Red Blood corpuscles—4°C to 6°C.
(5) Normal H man plasma.
(6) Frozen plasma—at a temperature not above—18°C (Minus—18°C).
(7) Thrombin (Bovine orgin).
(8) Thromboplastin.
(9) Cobra Venom in Solution.
(10) Viper Venom in Solution.
(11) Posterior Pituitary Injection.
(12) Oxytocin Injection.
(13) Vassopressin Injection.
(14) Corticotropin Gelatin Injection.
(15) Corticotrin Zinc Oxide Injection.
(16) Cholistin Sulphamethate Injection.
(17) Suxemethonium Chloride Injection.
(18) Insulin Preparations.
(19) Human Gamma Globulin Injection.
(20) Normal Liquid Human Serum Albumin.
(21) Schick Test Toxin.

Appendix III

Illustrative List of Drugs Requiring storage at a Cool Temperature (15C to 25 C). This is not an exhaustive list and the Pharmacists should check the labels on the Drugs to know about the proper storage.

Antibiotics :

1. Crystalline Pencillin Preparations.
2. Potassium Phenoxymethyl Penicillin preparations.
3. Benzethine Pencillin preparations.
4. Cloxicillin preparations.
5. Methicillin preparations.
6. Ampicillin preparations.
7. Streptomycin Sulphate & Chloride preparations.
8. Dihydrostreptomycin sulphate and Chloride preparations.
9. Chloramphenicol & its salts preparations.
10. Tetracycline, Oxytetracycline. Chlortetracycline and demythyl chloretetracycline preparations.
11. Bacitracin & Zinc Bacitracin preparations.
12. Cephaloridino preparations.
13. Neomycin preparations.
14. Neobiocin preparations.
15. Nystatin preparations.
16. Viomycin preparations.
17. Cycloserin preparations.

Arsenicals :

18. Neoarasphenamine Injection.
19. Sulpharasphenamine Injection.
20. Tryprsamide Injection

Blood Preparations :

21. Dried Plasma—below 20°C.
22. Human Fibrim Foan—below 20°C.
23. Human Fibrinogen—below 20° C.
24. Human Serum dried—below 20° C.
25. Human Thombin—below 20° C.

Hormone Preparations

26. Corticotropin.
27. Betamethasone Sodium Phosphate Injectio
28. Chorionic Gonadotropin
29. Prednisolene Sodium Phosphate Injection.
30. Thyried Tablets.
31. Oxytocin Tablets.

Vitamin Preparations :

32. Preparations containing Vitamin A.
33. Preparation containing Vitamin B1
34. Preparation containing Vitamin B2

1 M of P&C/75—32.

35. Preparation containing Vitamin B6
36. Preparation containing Vitamin C
37. Preparation containing Vitamin D.
38. Vitamin B-Complex Elixir & Injection.
39. Vitamin K Injection.
40. Vitamin KI preparations.

Others :

41. Dextran Injection.
42. Dextran Sulphate Injection.
43. Destrose Injection.
44. Dextrose & Sodium Injection.
45. Frogenevine Maleate Injection.
46. Heparin Injection.
47. Hyaluronidase Injection.
48. Chlorambucin preparations.
49. Chlorahexidine.
50. Choline Theophyllinate preparationes.
51. Dihydrotachysterol.
52. Dimercaprol Injection.
53. Iodone Injection.
54. Glyceryl Trinitrate tablets.
55. Domiphane Bromide.
56. Nitrofurantoin tablets.
57. Pentaenithratol tablets.
58. Phenetzine tablets.
59. Prophyliodine Injection.
60. Tetrachloranhylene Capsules.
61. Trichlorethylene.
62. Vinyl Ether.
63. Anesthetic Ether.
64. Paradehyde.
65. Halothane.
66. Pancreatin.
67. Penicillamine Hydrochloride Capsules
68. Liver Injection Grude.
69. Protein Hydrolysate Inj.
70. Ergot Liquid Extract

APPENDIX -IV

Prevention and Treatment of Penicillin Reactions

An Expert Committee of the World Health Organisation recommended in 1959 that individual and public health measures should be taken to prevent or treat penicillin reactions (WHO Expert Committee on Veneral Infections and Treponematoses, 1960); particular reference was made to anaphylactic reactions. These measures for prevention and treatment are still valid, and are summarized below with appropriate modification according to recent experience and knowledge (Guthe et al. 1958; Epstein 1966; Brandrisee et al. 1964: Calnan, 1964: Danbold, 1960; King & Nicol, 1964: American Public Health Association, 1960; A. perdrup, personal communication).

Prevention of penicillin reactions at the patient level:

1. Always have emergency kit for treatment of allergic reactions readily available.

2. Always have an exact past history of the patient's previous content with penicillin, previous penicillin reactions, and allergic diatheses. In infants less than 3 months old, inquire about penicillin allergy in the mother.

3. No penicillin treatment should be given to patients with a previous history of reactions; indications for administration of penicillin are severly restricted in patients with an allergic diatheses (e. g., bronchial asthma).

4. If possible ,refer patients with suspected penicillin allergy (preferably within 3 months of the alleged reaction) to a specialist trained in mordern Amunological techniques (skin testing with penicillin and penicillin derivatives serological tests) in order to provide the patient with an objective diagnosis and a permanent record.

5. Always tell the patient that he is going to receive penicillin treatment.

6. No penicillin should be employed for external treatment or on mucous membranes, particularly not on macerated or eczematized skin. especially likely to cause sensitization. Other antibiotics, not likely to be given systemically later, can be employed for local treatment (e. g., neomycin, bacitracin, gramicidin). Due to cross sensitivity of the semisynthetic penicillins all have the 6-aminopenicillanic acid nuclues reactions, although less frequent, may also be expected to occur eventually with cephalosperin.

7. Avoid the use of penicillinase-resistant penicillins (meticillin, closacillin, nafcillin, ancillin and quinacillin) which should be reserved for infections caused by penicillanase -producing staphylococci.

8. Ensure the through washing and adequate sterilization of all purpose syringes which have been used in penicillin treatments, when using them to inject other drugs. If possible, use disposable syringes and needles.

9. If possible, retain all patients for half -an-hour in the clinic after an injection of penicillin (most anaphylactic reactions occur shortly after Injection).

Most investigators hold the view that antihistamines have an insignificant effect both in the propylaxis and in the treatment of immediate reactions (Calnan, 1964; Scipel et al. as also is the case with prophylactic ephedrine and the ephylline (Horkheimer & Stresseman, 1960). They are, on the other hand, recommended in late penicillin reactions (Willcox, 1964). The "antinflammatery" effect of corticosteriods, however, should be used also in the treatment of penicillin anaphylaxis after the emergency drugs have been administered (Calanan, 1964 ;Will-eox, 1964). However, corticosteriods should not be trusted for prophylactic purposes except in cases where penicillin treatment is absolutely indicated despite the potential risk of the patient being penicillin -sensitive (Calnan, 1964).

Pencillinase has been found to be rapidly effective in breaking down circulating benzylpenicillin .at least as measures by the circulating blood (Greaves, 1961) but its effect on already formed antibody-antigen complexes is not known (Westerman et al. 1966) and is likely to be minimal. Experence has shown, though, that it may be of some use in treatment of anaphylatic reactions if given very soon after symptoms have been observed (Wasterman et. al., 1966) Greaves, 1961; Trinca and Keen, 1960; Backer, 1960). In late reactions, particularly, the breaking -down effect on circulating penicillin and tissue penicillin may prevent further proteing-binding and formation of antigenic conjugates. However, penicillinase itself has in turn been reported to induce anti-penicillinase antibodies (Weiss. Grepea, 1959) and to provoke senitivity reactions (Becker, 1960) mostly of minor significane but also in some few cases of analpylactie character (Gaputi, 1959, Hyman 1959; Reisch, 1959 Thomes, 1959) a fact which calls for caution (Becker, 1960).

Desensitization can be achieved by the use of graded doses (Reiseman et. al. 1962) but the procedure is not without considerable danger and should be reserved for patients who are and when there is no effective alternative antibiotics (Valery et. al. 1960).

Life Saving Drugs :

1. Amylobarbitone Sodium Injection.
2. Phentoin Sodium Injection (Dilantin).
3. Isoprenaline Injection.
4. Edrephonium Chlorise Injection (Tensilon).
5. Amino Caproic Acid Injection (Amicar).
6. Trasylol Injection.
7. Diazepam Injection.
8. Streptokinase Injection.
9. Polymyxin B Sulphate Injection.
10. Colistin Sulphate Tablets & Injection.
11. Colistin Sulphomethate Injection.
12. Methicillin Sodium Injection.
13. Gloxacillin Sodium Injection & Capsules.
14. Getamicin Sulphate Injection (Garamycin).
15. Carbemicillin Injection (Pyopen)
16. Trimetheprin /Sulphamethazazole Tablets (Septrin).
17. Elyorouracil Injection.
18. Methotrexate Injection and Tablets.
19. Lincomycin Hydrochloride Injection & Capsules.
20. Thiotepa Injection.
21. Actinomycin D Injection.
22. Tinblastino Sulphate Injection.
23. Tincristine Sulphate Injection.
24. Mitomycin C Injection.
25. Dopa and its Capsules.
26. Rifamycin Capsules.
27. Chorionic Gondadotrophin Injection (Antintrons).
28. Allopurinol Tablets (Zytone).
29. Blecomycin Injections.

CHAPTER X

Measures for providing essential drugs and common household remedies to the general public, especially in rural areas.

The Committee on Drugs and Pharmaceuticals Industry was constituted by the Ministry of Petroleum & Chemicals by the Resolution dated the 8th February, 1974 to examine the various aspects of the drug industry. One of the terms of reference was "to recommend measures for providing essential drugs and common household remedies to the general public especially in rural areas."

2. The Committee during the course of their discussions, particularly on the availability of essential medicines in larger quantities, felt that although the question of substitution of brand names of the medicines marketed by the Industry by generic names was not a specific term of reference for this Committee, the subject follows clearly from the other terms of references, such as reduction/rationalisation of prices of formulations for the consumers, making the essential drugs available to the general public, attainment of leadership role by the public sector, promoting the growth of the Indian sector etc. Besides, the question was also directly linked with many important facets of the industry such as drug patents, irrational practice of medicines, excessive use of ingredients in multi-drug formulations, proliferation of such preparations and baneful influence on the medical profession etc. of medicines marketed under brand names Keeping the above aspects in view, the Committee decided that this question should also be looked into by the Committee. The Committee also felt that the views of eminent medical personnel from the different parts of the country should be obtained in this regard. Accordingly, a panel was set up with the following members:—

1. Dr. Ranen Sen, Member of Parliament.
2. Shri P.S. Ramachandran, Drugs Controller (India) DGHS, New Delhi.
3. Dr. B. Shah, Deputy Director General (DGTD), New Delhi.
4. Dr. A.B. Chowdhury, M.B., Ph. D., F.A.M.S. F.N.A., Director, Calcutta School of Tropical Medicine, Chitteranjan Avenue, Calcutta-12.
5. Dr. B. Ray Chaudhury, M.D., (Cal.) F.R.C.P., Ph.D (Edin.), Associate Professor of Medicine, Institute of Post Graduate Medical Education and Research, 22-Lower Circular Road, Calcutta-17.

(This report was submitted to the Govt. on 21st Feb., 1975.)

6. Dr. K.L. Wig, M.B.B.S. (Pun.) F.R.C.P. (London) M.R.C.S. (England) D.T.M. & H. (London) F.A.M.S-79, Sundar Nagar, New Delhi.
7. Dr. S. Padmavati, Director, Principal, Maulana Azad Medical College, New Delhi.
8. Dr. K.G. Nair, MD (Bombay) Ph. D. (Chicago) F.A.C.C. (U.S.A.) F.I.C.A. (U.S.A.). Director-Professor of Medicine, Head Deptt. of Cardiology and Radio-Isotope Unit KEM Hospital and Seth G.S. Medical College, Bombay.
9. Dr. B.J. Vakil, Hony. Professor Gastroenterology, Grant Medical College, Hospital, Bombay.
10. Dr. K.V. Thiruvengadam, B.Sc. MD, F.A.M.S. Professor of Medicine and Vice Principal, Stanley Medical College, Physician, Government Stanley Hospital, Madras.
11. Dr. B.B. Gaitonde, M.D. M.S.C. (Med)., F.A.Sc. Director, Haffkine Institute, Bombay. ... . Convenor.

Dr. P.R. Gupta, Adviser (Drugs) in the Ministry of Petroleum & Chemicals was also associated with this Panel.

3. The terms of reference for this Panel were as follows :—

(i) To recommend measures for providing essential drugs and common household remedies to the general public especially in the rural areas, and

(ii) Whether it would be in the national interest to substitute brand names by generic names and if so, the manner and extent to which it should be done.

4. Dr. K.L. Wig, regretted his inability to work on this Panel, because of his preoccupation with other assignments. Dr. B. Shah also informed his inability to join this Panel as he was proceeding on leave.

5. The Panel met in Bombay on 8th and 9th June, 1974 at the Haffkine Institute, and submitted its report on the 29th June, 1974 to the Chairman of the Committee. A copy of the Panel's report is attached (Annexure I).

6. The Committee on Drugs and Pharmaceuticals Industry at its meetings on 25th July, 1974 and 21st and 22nd January, 1975 considered the Report of the Medical Panel and adopted the same with some modifications.

Supply of essential drugs & Common House Hold Remedies.

7. Keeping in view the essentiality of the medicines their need and the availability of the concerned bulk drugs/active ingredients, the Committee, after due consideration, drew up a revised list (Annexure II) of medicines, which in its opinion are extensively used in medical practice, both in urban and rural areas. In order to make these essential drugs available at a reasonably low price throughout the country, the Committee recommends the following measures :—

(i) Production of the drugs/medicines as identified in Annexure II, should be given top priority for the manufacture of the relevant bulk drugs/active ingredients.

(ii) The Ministry of Petroleum & Chemicals should take all such measures, which will increase the production of these drugs expeditiously. Special assistance, priority for power supply, other incentive schemes etc. may be given to entrepreneurs, preferably Indian, who come forward to undertake production of these essential drugs. In short, if there are any impediments, these should be immediately looked into and removed.

(iii) In case of some drugs, the technical know-how is already available, but there is a production short-fall. More entrepreneurs should be encouraged to take to production of such drugs. In case of those drugs, for which technical know-how is not available in the country, special incentives maybe given to National Laboratories to develop the know-how on a time-bound basis. If necessary, the foreign technical know-how may also be obtained immediately.

(iv) *Distribution* : To make these drugs available in rural areas, the distribution system must be rationalised and decentralised, in regard to household remedies and commonly used medicines which do not require the prescription of doctors. For this, assistance should be sought from the postal department. Indian Oil Company Depots, kerosene depots. Co-operative Societies should be encouraged for the distribution of drug in rural areas. Packing details should be looked into. Tablets should be supplied in strip packings. Liquid preparations should be supplied in bottles fitted with pilfer proof closures. Export of the bulk drugs required for the production of medicines mentioned at (Annexure II), as well as their formulations should be so regulated that there is no shortage of these essential drugs in the country at any time.

(v) *Dispensing* : At present, there are a number of difficulties, especially in small towns and rural areas, to establish pharmacies for dispensing of drugs. One of the major difficulties is the non-availability of trained pharmacists. According to the Drugs Act, those who possess a Diploma in Pharmacy can only be lincensed as dispensers. The Diploma Course is quite lengthy and the remuneration paid to the dispenser is not attractive. It was considered that a short-term need oriented course, after matriculation, may be instituted for young people, who could take up the job of distribution of these medicines in the rural areas and other remoter parts of the country. The Committee recommends that steps should be taken to revise the present syllabus of training of the pharmacists. The Pharmacy Council should be approached to tailor the course to suit the needs of the country. An intensive, need-oriented course of a short duration should be instituted for training of dispensers, who then could be licensed to establish pharmacies and drug stores in smaller towns and rural areas.

(vi) Primary Health Centres should be given adequate financial assistance for purchase of drugs. So that rural population also gets the same quality of drugs in adequate amounts as in urban areas.

Substitution of brand names of drugs by generic names :—

8. The question of substitution of brand names by generic names was extensively discussed. All facets of the problem, such as Indianisation of brand names, impact on drug prices, bio-availability, quality of drugs, enforcement of drug control, multiple ingredient preparations, export of drugs, labelling difficulties, impact on small-scale industry, patent rights, distribution system, acceptance by the medical profession, role of distributors and pharmacists, effect on the growth of pharmaceutical industry, difficulties and inconvenience in the use of tongue twisting generic names

etc., were discussed in detail. The Committee also met the representatives of various organisations such as Indian Medical Association (IMA), Organisation of Pharmaceutical Producers of India (OPPI), Indian Drug Manufacturers Association (IDMA), All India Manufacturer's Organisation (AIMO), members of the Development Council for Drugs and Pharmaceuticals etc., to elicit opinion on this very important question of far reaching significance. The Committee also considered the memoranda submitted by various State Governments, Public Sector and others including small scale sector undertakings and different associations mentioned above.

9. The Committee had before it the report of the medical panel recommending the abolition of brand names in a phased manner starting with specific drugs identified by the panel.

10. Throughout the world, and in our country as well, a medical student receives his training on drugs under generic names. In fact, in all text books of therapeutics as well as pharmacology, drugs are mentioned by generic names always. In the interest of rational practice of medicine, therefore, it is in the fitness of things that medical practitioners should continue to use prescribe a drug under generic name, so that they are fully conscious of the type of therapy prescribed for their patients. More often, the practising physician is likely to be unaware of the active ingredients of a drug prescribed under brand name. Two branded products containing the same or similar active ingredients may be prescribed to patients resulting in overdosage and consequent toxicity/damage to the patient's health.

11. Further, many brand names are phonetically similar creating confusion, which can be seen from the following examples:—

Cornil and Corlin.; Codogin and Codopin ; Delazone and Deltazyne ; Diaginol and Dianabol ; Dicazine and Dicarzen; Etadryl and Metagyl ; Methicol, Methiscol, Methiolin, Methionine etc.

12. To bring about uniformity in names, the W.H.O. issues periodically a list of non-proprietary names with the recommendation that these be adopted by national organizations. The intention here is to prevent confusion and chaos in the field of prescribing medicines. It is also necessary to point out that all national formularies including the Indian National Formulary, prepared by the most eminent leaders of medical profession in this country, list all drugs and formulations under generic names or pharmacopoeial names. Further a large number of very important and potent drugs such as insulin, sera, vaccines, antibiotics, digitalis glycosides are mostly marketed under generic names without any difficulty or disaster.

13. It has often been alleged that, the branded products containing the same ingredients differ to a very great extent in their prices, and the products bearing generic names are decidedly cheaper. Several examples have been cited such as Aspirin and Aspro, Paracetamol and Metacin etc. It is reasonable to accept that promotional efforts and expenses incurred by the manufacturers to establish their brand names are commensurate with higher prices. In fact, in the larger context this is not in the best interest either of the manufacturer or the patient. If the same money is spent on better standardization, quality control and Research and Development, the national gains will be substantial.

14. The drugs which are sold under brand names fall under two categories :—

(1) Those which contain a single ingredient,

(2) Those which contain multiple ingredients.

A larger number of single ingredient drugs are pharmacopoeial but are still being marketed under brand names. Since there is no control over the number of brand names that can be given to a single drug formulation, we have a state of confusion with respect to brand names. Thus, a single drug, such as aspirin, paracetamol or nikethamide, is being marketed separately in this country under several brand names. This is not in the best interest of either the medical profession or of the patient, who is often led to believe that one branded drug isd ifferent from the other and possess superior values. In effect, this is not the case and the patient is unwillingly made to pay higher prices for his treatment.

15. In the case of multi-ingredient preparations, the situation is still worse. Brand names have been responsible for putting up a large number of unnecessary and often irrational formulations in the market. In fact the organised sector has maintained dominance over the drug market principally through their branded products containing multiple ingredients. Many examples can be given to illustrate this point. This has resulted in excessive use of drugs particularly under the names 'tonics' containing vitamins in excessive quantities. Multiple drug combinations in amounts far in excess of what is required result in colossal national wastage of drugs. This could be substantially reduced if the brand names are eliminated. In this respect, it is to be emphasised that the entire British Health Service runs on the British National Formulary preparations, which are by and large, single ingredient drugs, rather than multiple ingredient preparations. The Food and Drug Administration of the United States (F.D.A.) appointed a Committee of Experts drawn from National Research Council (N.R.C.) and National Academy of

Sciences (N.A.S.) to evaluate the efficiency of over 3,000 preparations marketed in the United States. It was proved that a majority of these do not possess therapeutic efficiency and were directed to be either withdrawn or to provide further evidence of their effectiveness. There is thus a case for controlling multiple ingredient branded products marketed in this country, particularly by the organised sector, and promoted rigorously. This, in itself will serve to loosen the hold of the organised sector on the pharmaceutical industry to a great extent.

16. The medical profession has acquired the habit of prescribing branded products. This has unfortunately come out of tradition of several years and not by virtue of training in medical colleges. At no stage brand names are introduced in the medical curriculum. The brand names have a corrupting influence on the profession. A doctor more often patronises branded product and, unwittingly therefore, makes his patient pay more than necessary. This is a matter which the medical profession should think over very seriously.

17. A number of new drugs are being introduced in this country under brand names. This has a two-fold effect. A company with aggressive sales promotion establishes its new product under a brand name and reaps the benefits during the period the patent is valid.

After the patent period is over, having established the brand names, it continues to reap this harvest much to the disadvantage of other entrepreneurs. Thus, inspite of the modification of the Patents Act, the disadvantage to the Indian entrepreneur continues in a large measure. Many examples of this can be given. Chloramphenicol is marketed under the brand name of chloromycetin and nikethamide is marketed under the brand name of Coramine. In both these cases, the process patents have expired. However, the concerned pharmaceutical firms manufacturing these drugs continue to derive benefits by virtue of their established brand names.

18. It is often argued that the quality of a product is assured because of its brand name and substitution of brand name by generic name will result in lowering of standards. Maintenance of quality is the responsibility of the manufacturer and it does not go with the brand name. Scrutiny of the total number of substandard, misbranded and spurious products reported by various drug control organisations and the drug testing laboratory of the Government of India at Calcutta will reveal that there are more instances of branded products being misbranded or, therefore, spurious. There have been no instances where a product marketed under generic name has ever been reported to be spurious. Thus, branding of products promotes a tendency to prepare misbranded or spurious products.

19. Quality must be maintained and every effort must be made to see that all drugs introduced in the market conform to pharmacopoeial or prescribed standards. Very often, it is stated that the branded products of certain firms have standards higher than those prescribed by the pharmacopoeia. Pharmacopoeia standards are adequate enough to protect the interests of the patient. If higher standards are going to result in higher pricing, which is said to be the case with respect to some branded products marketed by a few firms in the organised sector, there is no advantage to be gained. However, as long as the quality control organisation is properly strengthened, there is no reason to fear that a substandard product will be marketed. It is, therefore, absolutely essential to achieve high standards of quality control throughout the length and breadth of the country, irrespective of whether the drugs are going to be marketed under generic or brand names.

20. It is often argued that bioavailability is an important factor in the efficiency of a drug. The W.H.O. Technical Series Report on bioavailability has highlighted differernt facets of this problem, particularly, the fact that as yet there are no established and accepted methods for evaluation of bioavailability of different brands of drugs. A drug manufactured by a firm, may differ from batch to batch in its bioavailability. Bioavailability is particularly important in the case of oral preparations and that too with respect to only a very few drugs. It cannot be denied, that in case of drugs like digoxin, phenytoin etc. bioavailability is important, but this has nothing to do with brand or generic names. The Drug Control authorities will have to exericse effective control over the standards of such drugs which will need bioavailability studies as per recommendations of the W.H.O., whether these drugs are introduced under generic or brand names.

21. In view of all the above considerations, it is clear that there is a strong case for substitution of brand names by generic names. In the considered opinion of the Committee it may not, however, be advisable to accomplish this change immediately. The medical profession has been traditionally used to prescribing drugs under brand names and a sudden shift may result in considerable confusion and difficulties for prescribing doctors. A sudden change may also affect the present distribution system. The manufacturers will also be faced with some difficulties with respect of labelling etc., if a sudden change is brought about. Steps will have to be taken to strengthen Drug Control organisations in various states in order to enable them to exercise very rigorous control over the quality of drugs.

22. The Committee, therefore, is of the view that this change over from brand names to generic names should brought about in a phased manner as recommended by the medical panel. In view of all the above considerations and taking into accounts and taking into account the intrioate facets of the problem, the following recommendations are being made.

(a) Brand names should be abolished in a phased manner.

(b) A beginning should be made for a change over to generic names starting with the drugs mentioned in Annexure III. Mostly these drugs are already being marketed under generic names and heir generic names are quite elegant.

(c) Drugs which are exported may be allowed to bear brand names.

(d) All supplies of single ingredient drugs and drugs included in Indian Pharmacopoeia for Central and State Government Institutions and local bodies should be tendered and supplies made under generic names. At present, drugs, though tendered under generic names, are supplied under brand names, and this should be discouraged.

(e) All drugs other than those listed in the Annexure III should bear labels displaying prominently the generic names. Brand names may be shown on lables in a less conspicuous manner.

(f) The Drug Controller should, while granting permissions, be requested not to give recognition to brand names of New drugs. new drugs should not be allowed to be marketed under brand names, when first introduced into this country.

(g) Multiple drugs combinations often containing drugs, particularly vitamins, in amounts far in excess of what is required are presently marketed in India. The majority of such combinations are irrational. There is a colossal national wastage of drugs because of such combinations. The Drug Control Administration should immediately go into the various drug combinations and take prompt measures to eliminate irrational drug combinations. No firm should be allowed to incorporate excessive quantities of any drug over and above what is required to go into the formulations for therapeutic and prophylactic purposes. Pharmacopoeial Committee should be requested to give new/generic names for multiple ingredient preparations. New types of multi-ingredient preparations should not be allowed to be marketed hereafter unless they are mentioned in the National Formulary or Pharmacopoeia and approved by the Drug Controller of India. If any amendment of the Drugs and Cosmetics Act and Rules is considered necessary for this purpose, this should be carried out.

(h) Non-proprietory names as recommended by W.H.O. from time to time should be adopted.

(i) Bioavailability studies are important in cases of a few drugs, although this factor has recently been overplayed not always on rational basis. Facilities should be created in different parts of the country, so that the industry, both large and small scale, can take advantage of such facilities to plan and conduct bioavailability and pharmacokinetic studies.

(j) In order to keep the medical profession, particularly the general practitioners, well-informed about New Drugs and also to popularise the generic names, it is essential to take steps immediately,

(i) To revise the Indian National Formulary and make it up-to-date.

(ii) To publish journals on the lines of Prescriber's Journals, U.K., Medical Letter, U.S.A., or Formulary Notes of Sri Lanka. Such publications will have to be under the control of an Editorial Board Comprising leaders of the medical profession in the country constituted by the Ministry of Health, Government of India.

23. The Committee is of the view that from legal point of view there should be no difficulty in abolishing the brand names. Abolishing of brand names will entail first the amendment of the Trade and Merchandise Marks Act, 1958 and subsequently the Drugs and Cosmetic Rules.

24. A periodic review of the impact of this step on the drug industry price and availablity of medicines is necessary etc. So as to take suitable corrective measures, if required.

25. Apart from emphasising the needs for ensuring more rigid and uniform quality control throughout the country, the Committee also recommends to the Government for early implementation of the recommendations made with regard to measures for providing essential drugs and common household remedies especially in the rural areas.

26. While making the above recommendations, the Committee would emphasise that the recommendations regarding the change over from brand names to generic names has to be implemented cautionally and on a phased manner ensuring simultaneously the necessity of enforcing quality control on drugs and in particular the concerned recommendations made in the Interim Report of the Committee on 'Quality Control' of drugs.

27. The Committee in concluding this report would like to place on record its deep and warm appreciation of the quick and excellent work done by the eminent doctors of the panel and in particular by Dr. B. B. Gaitonde, Director, Haffkine Institute, Bombay, who took special interest in this complex problem and finalised the Report in a very short time.

(Out of the 117 essential medicines, the items which in the opinion of the Committee could be concerned as household remedies are shown at Annexure IV).

SUMMARY OF RECOMMENDATIONS

Essential drugs and common household remedies-Supply thereof

In order to make the essential drugs as indentified by the Committee, available in large quantities and at a reasonably low price throughout the country, the Committee recommends following measures:—

Production:

(i) Production of those medicines should be expanded or taken up in adequate quantities giving top priority for the manufacture of the relevant bulk drugs/active ingredients.

[Chapter X—Para 7(i)]

(ii) The Ministry of Petroleum & Chemicals should take all such measures, which will increase the production of those drugs expeditiously. Special assistance, priority for power supply, other incentive schemes etc. may be given to entrepreneurs, preferably the National Sector, who come forward to undertake production of these essential drugs. In short, if there are any impediments, these should be immediately looked into and removed.

[Chapter X—Para 7(ii)]

Technology:

(iii) In cases of some drugs, the technical know-how is already available, but there is a production shortfall. More entrepreneurs should be encouraged to take up the production of such drugs. In case of these drugs for which technical know-how is not available in the country, special incentives may be given to national Laboratories to develop the know-how on a time-bound basis. If necessary, the foreign technical know-how may also be obtained immediately.

[Chapter X—Para 7(iii)]

Distribution:

(iv) To make these drugs available in rural areas, the distribution system must be rationalised and decentralised, in regard to household remedies and commonly used medicines which do not require the prescription of doctors. Assistance should also be sought from the postal department, Indian Oil Company Depots, kerosene depots. Cooperative Socties should be encouraged for the distribution of drugs in rural areas.

[Chapter X—Para 7(iv)]

Packing :

(v) Packaging details should be looked into. Tablets should be supplied in strip packings, liquid preparations should be in bottles fietted with pilfer proof closures.

[Chapter X—Para 7 (iv)]

Exports :

(vi) Export of the bulk drugs required for the production of medicines identified by the committee, as well as their formulations should be so regulated that there is no shortage of these essential drugs in the country at any time.

[Chapter X—Para 7 (iv)]

Dispensing :

(vii) At present, there are a number of difficulties, especially in small towns and rural areas, to establish pharmacies for dispensing of drugs. To obviate these problems, immediate steps should be taken to revise the present syllabus of training of the pharmacists. The Pharmacy Council should be approached to tailor the course to suit the needs of the country. An intensive, need-oriented course of a short duration after matriculation should be instituted for training of dispensers, who then could be licensed to establish pharmacies and drug stores for distribution of these medicines in smaller towns, rural areas and remote parts of the country.

[Chapter X—Para 7 (v)]

(viii) Primary Health Centres should be given adequate financial assistance for purchase of drugs, so that the rural population also gets the same quality drugs in adequate amounts as in urban areas.

[Chapter X—Para 7 (vi)]

2. Substitution of brand names by generic names :

(i) Brand names should be abolished in a phased manner.

[Chapter X—Para 22(a)]

(ii) A beginning should be made for a change-over to generic names starting with the drugs as identified by the Committee. These drugs are mostly being marketed under genric names and their generic names are quite elegant.

[Chapter X—Para 22(b)]

(iii) Drugs which are to be exported may be allowed to bear brand names.

[Chapter X—Para 22(c)]

(iv) All supplies of single ingredient drugs and drugs included in Indian Pharmacopoeia for Central and State Government Institutions and local bodies should be tendered and supplies made under generic names. At present, drugs, though tendered under generic names, are supplied under brand names, and this should be discouraged.

[Chapter X—Para 22(d)]

(v) All drugs other than these listed in the Annexure III should bear labels displying prominently the generic names. Brand names may be shown on labels in a less conspicious manner.

[Chapter X—Para 22(e)]

(vi) The drug Controlier should, while granting permissions, be requested not to give recognition to brand names of new drugs. New drugs should not be allowed to be marketed under brand names, when first introduced into this country.

[Chapter X—Para 22(f)]

(vii) Multiple drugs combinations often containing drugs, particularly vitamins, in amounts far in excess of what is required are presently marketed in India. The majority of such combinations are irrational. There is a colossal naticnal wastage of drugs because of such combinations. The Drug Control Adminis tration should immediately go into the various drug combinations and take prompt measures to eliminate irrational drug combinations. No firm should be allowed to incorporate excessive quantities of any drug over and above what it required to go into the formulations for therapeutic and prophylactic purposes. Pharmacopoeial Committee should be requested to give new/generic names for multiple-ingredient preparations. New types of multi-ingredient preparations should not be allowed to be markted hereafter unless they are mentioned in the National Formulary or Pharmacopoeia and approved by the Drugs Controller of India. If any amendment of the Drugs and Cosmetics Act and Rules is considered necessary, this should be carried out.

[Chapter X—Para 22(g)]

(viii) Non-proprietory names as recommended by W.H.O. from time to time should be adopted.

[Chapter X—Para 22(h)]

(ix) Bioavailability studies are important in cases of a few drugs, although this factor has recently been over-played not always on rational basis. Facilities should be created in different parts of the country, so that the industry, both large and small-scale, can take advantage of such facilities to plan and conduct bioavailability and pharmaco-kinetic studies.

[Chapter X—Para 22(i)]

(x) In order to keep the medical profession, particularly the general practitioners, well-informed about new drugs and also to popularise the generic names it is essential to take the following steps immediately :

(a) To revise the Indian National Formulary and make it up-to-date.

(b) To publish journals on the lines of the Prescriber's Journals, U.K., Medical Letter, U.S.A., or Formulary Notes of Sri Lanka. Such publications will have to be under the control of an Editorial Board comprising leaders of the medical profession in the country constituted by the Ministry of Health, Government of India.

[Chapter X—Para 22(i)]

3. Periodic Review :

A periodic review of the impact of this step on the drug industry, prices and availability of medicines is necessary so as to take suitable corrective measures, if required.

[Chapter X—Para 24]

4. Availability of Medicines :

Government should take steps for early implementation of the recommendations made above with regard to measures for providing essential drugs and common household remedies especially in the rural areas.

[Chapter X—Para 25]

5. Quality Control :

The Committee emphasises that the recommendation regarding the change over from brand names to generic names has to be implemented cautiously and on a phased basis ensuring. Simultaneously the necessity of enforcing quality control on drugs and in particular the concerned recommendations made in the Interim Reports of Committee on 'Quality Control of Drugs'.

[Chapter X—Para 26.]

ANNEXURE I

(Chapter X—Para 5)

Report of the Panel constituted by the Committee on Drugs and Pharmaceuticals, Ministry of Petroleum and Chemicals, Government of India, New Delhi

The Panel met on 8th and 9th June, 1974, at the Haffkine Institute Bombay. The following were present :

1. Dr. Ranen Sen
2. Dr. A. B. Chowdhury
3. Dr. S. Padmavati
4. Dr. B. Ray Chaudhari
5. Dr. K. V. Thiruvengadam
6. Shri P. S. Ramachandran
7. Dr. K. G. Nair
8. Dr. B. J. Vakil
9. Dr. P. R. Gupta
10. Dr. B. B. Gaitonde ..... Convener.

Shri M. K. Ranganekar attended by special invitation.

The Committee discussed in detail the following :

(1) Measures for providing essential drugs and common house-hold remedies, especially in rural areas.

(2) Whether it would in the national interest to substitute brand names by generic* names and, if so, the manner and the extent to which it should be done.

I. With regard to the first term of reference, it was felt that a list of essential drugs, particularly those, which are used extensively in medical practice in both urban and rural areas, will have to be prepared. Accordingly, the lists of the essential drugs prepared by the Committee on Essential Drugs, 1967, as well as those prepared by Prof. Padmavati and the Drugs Controller (India), were scrutinised and a new list (Appendix I) was prepared. In the opinion of the Committee, drugs mentioned in the attached list are extensively used and are essential for medical practice. In order to make these essential drugs available at a reasonably low price throughout the country, the Committee recommends the following measures :

(i) Production of these drugs should be stepped up immediately giving top priority for the manufacture of the relevant basic drugs.

(ii) The Ministry of Petroleum & Chemicals should take all such measures, which will increase the production of these drugs expeditiously. Special assistance, priority for power supply, other incentive schemes etc., may be given to entrepreneurs, preferably Indian, who come forward to undertake production of these essential drugs. In short, if there are any impediments, these should be immediately looked into and removed.

(iii) In case of some drugs, the technical know-how is already available, but there is a production short-fall. More entrepreneurs should be encouraged to take to production of such drugs. In case of those drugs for which technical know-how is not available in the country, special inoentives may be given to National Laboratories to develop the know-how on a time-bound basis. If necessary, the foreign technical know-how may also be obtained immediately.

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*The term "generic" denotes "non-proprietary"

Distribution :

(iv) To make these drugs available in rural areas, the distribution system must be rationalised and decentralised. For this, assistance should be sought from the postal department, Indian Oil Company Depots, Kerosene depots. Cooperative Societies should be encouraged for the distribution of drugs in rural area. Packaging details should be looked into. Tablets should be supplied in strip packings. Liquid preparations should be supplied in bottles fitted with pilfered proof closures. Exports of the basic drugs (Appendix I) as well as their formulations should be so regulated that there is no shortage of essential drugs in the country at any time.

Dispensing :

(v) At present, there are a number of difficulties, especially in small towns and rural areas, to establish pharmacies for dispensing of drugs. One of the major difficulties is non-availability of trained pharmacists. According to the Drug Act, those who possess a Diploma in Pharmacy can only be licensed as Dispensers. The diploma Course is quite lengthy and the remuneration paid to the dispenser is not attractive. The Panel recommends that steps should be taken to revise the present syllabus of training of the pharmacists. The Pharmacy Council should be approached to tailor the courses to suit the needs of the country. An intensive, need-oriented course of a short duration should be instituted for training of dispensers, who then could be licensed to establish pharmacies and drug stores in smaller towns and rural areas. Primary Health Centres should be given adequate financial assistance for purchase of drugs, so that rural population gets the same quality of drugs in adequate amounts as in urban areas.

II. Substitution of brand names of drugs by generic names

The question of generic names and brand names was extensively discussed. All facets of the problem, such as impact on drug prices bioavailability, quality, of drugs, enforcement of drug control, multiple ingredient preparations, export of drugs, labelling, difficulties, impact on small-scale industry, patent rights, distribution, system, acceptance by the medical profession, role of distributions and pharmacists, effect on the growth of pharmaceutical industry, difficulties and inconvenience in the use of tongue-twisting generic names etc., were discussed in detail. After taking into account all these very intricate problems, the Panel makes the following recommendations :

(a) Brand names should be abolished in a phased manner. This step is in the right direction both for rational practice of medicine and general national interest. Drugs which are exported may be allowed to bear brand names.

(b) A beginning should be made for a change over to generic names for the drugs, mentioned in Appendix II. These drugs are used very extensively and their generic names are as elegant as brand names. These drugs should, therefore, not be allowed to be marketed under brand names with immediate effect.

(c) The change over from brand names to generic names may result in the increase of spurious and substandard drugs. It is, therefore, strongly recommended that steps should be taken to ensure more rigid and uniform quality control throughout the country.

(d) All supplies of single ingredient drugs and drugs included in Indian Pharmacopoeia for Central and State Government Institutions and Local Bodies should be tendered and supplies made under generic names. At present, drugs, though tendered under generic names, are supplied under brand names, and this should be discouraged.

(e) All drugs other than those listed in Appendix II, should bear labels displaying prominently generic names. Brand names may be mentioned in brackets.

(f) The Drugs Controller (India) be requested not to give recognition to the brand names of new drugs when first introduced in this country.

(g) Multiple drug combinations often containing drugs, particularly vitamins, in amounts far in excess of what is required are presently marketed in India. The majority of such combinations are irrational. There is a colossal national wastage of drugs because of such combinations. The Panel, therefore, strongly recommends that the Drug Control Administration should immediately go into the various drug combinations and take prompt measures to eliminate irrational drug combinations. No firm should be allowed to import excessive quantities of any drug over and above what is required to go into the formulations for therapeutic and prophylactic purposes.

(h) The Indian Pharmacopoeia Committee be approached to devise simple, short and suitable non-proprietary names for drugs, which have not long and difficult generic names.

(i) Bio-availability studies are important in cases of a few drugs, although this factor has recently been over-played not always on rational basis. The Panel recommends that facilities should be created in different parts of the country, so that the industry, both large and small-scale, can take advantage of such facilities plan and conduct bioavailability and pharmacokinetic studies.

(j) In order to keep the medical profession, particularly the general practitioners, well-informed about New Drugs and also to popularise the generic names, it is essential to take steps immediately to :

(i) revise the Indian National Formulary,

(ii) to publish journals on the lines of the Prescriber's Journals, UK, Medical Letter, USA or Formulary Notes of Sri Lanka.

Such publications will have to be under the control of an Editorial Board comprising leaders of the medical profession in the country constituted by the Ministry of Health, Government of India.

Sd/- Dr. Ranen Sen

Sd/- Dr. A. B. Chowdhury

Sd/- Dr. S. Padmavati

Sd/- Dr. B. Ray Chaudhury

Sd/- Shri P. S. Ramachandran

Sd/- Dr. K. G. Nair and Dr. B. J. Vakil

Sd/- Dr. P. R. Gupta & Dr. B. B. Gaitonde

Sd/- Dr. K. V. Thiruvangadam.

APPENDIX I

Tablets and Capsules (Granules included)

1. Cap. Chloramphenicol 250 mg.
2. Cap. Tetracycline Hydrochloride 250 mg.
3. Tab. Iodochlorhydroxy Quinoline 0.5 gm.
4. Tab. Nitrofurantoin
5. Tab. Chlorpheniramine
6. Tab. Ferrous Sulphate
7. Tab. Folic Acid
8. Tab. Digoxine
9. Tab. Aspirin
10. Tab. Phenobarbitone
11. Tab. Chlorpromazine
12. Tab. Predinisolone
13. Tab. Hexa Vitamin (N.F.I.)
14. Tab. Vitamin B. Complex
15. Tab. Vitamin C
16. Tab. Sulphadimidine
17. Tab. Metronidazole
18. Tab. Hydrochlorothiazide
19. Tab. Reserpine
20. Tab. Glyceryltrinitrate
21. Tab. Analgin
22. Tab. Antacid (B.N.F.)
23. Tab. Piperazine (Syrup Piperazine)
24. Tab. Tetrachlorethylene
25. Tab. Tolbutamide
26. Tab. Thiacetazone & Isoniazid (each tablet to contain Thiacetazone 37.5 mg. BPC & Isoniazid 75 mg. IP)
27. PAS granules
28. Tab. I.N.H.
29. Tab. Dapsone (50 mg)
30. Tab. Chloroquine Sulphate 0.2 gm (or Tab. Chloroquine Phosphate 0.25 gm IP)
31. Tab. Primaquine Diphosphate (2.5 gm. of Primaquine base)
32. Tab. Diethylcarbamazine Citrate (50 mg)
33. Tab. Anti-asthmatic (containing ephedrine Hcl. 50 mg. Theophylline 65 mg. and Phenobarbitone 30 mg)
34. Tablets containing alkaloids of Ergot equivalent to 0.4 mg of total alkaloids ergotoxin.
35. Capsules of Vitamin A 6000 units and Calciferol 1000 Units.
36. Tab. Vitamin A
37. Tab. Vitamin D
38. Tab. Milk of Magnesia
39. Oral Contraceptive (approved by Family Planning Department).

Injections

1. Injection Penicillin
2. Inj. Streptomycin
3. Inj. Emetine Hydrochloride

4. Inj. Atropine
5. Inj. Adrenaline
6. Inj. Nor-Adrenaline
7. Inj. Dextrose Saline
8. Inj. Furosemide
9. Inj. Morphine Sulphate
10. Inj. Pethidine
11. Inj. Paraldehyde
12. Inj. Predinisolone
13. Inj. Anti-Tetanus Serum
14. Inj. Methyl Ergometrin
15. Inj. Chlorpheniramine Meleate
16. Inj. Fortified Benzyl Penicillin PP (Procaine Benzyl Penicillin 3,00,000 units. Benzyl Penicillin 1,00,000 uni
17. Inj. Aminophylline /0.5 gm/2ml)
18. Inj. Oxytocin (Oxytocin 5 i.u./ml)
19. Inj. Chlorpromazine
20. Antivenom Serum (Polyvalent)
21. Rehydration fluid (for treatment of cholera cases)
22. Glucose Ampoule (containing dextross 25%)
23. Distilled Water (25cc ampoule)
24. Inj. Phenobarbitone Sodium (200mg/ml)
25. Inj. Mepheteramine
26. Diphtheria-Pertussis-Tetanus Vaccine
27. Inj. Totanus Toxoid
28. Inj. Diphtheria Toxoid
29. Inj. Anti-Diphtheria Serum
30. Oral Polio Vaccine
31. Inj. Insulin Plain (40 units per ml)
32. Inj. Sodium Pentathol
33. Inj. Succinyl Choline
34. Inj. Xylocaine.

Miscellaneous (Syrup, Ointments, mixtures, eye drops, ear drops, etc.)

1. Sulphacetamide Eye Drops
2. Homatropine Eye Drops
3. Esserine sulfate eye drops
4. Benzyl Benzoate Emulsion
5. Acid Carbolic
6. Lysol
7. Tr. Iodine
8. Syrup Piperazine
9. Ext. Belladonna (Combination of Phenobarb & Belladonna)
10. Chloramphenical suspension (125 mg/ml)
11. Syrup Paracetamol (125 mg in 5 ml)
12. Tetracycline Hydrochloride Ointment 1% in sterile ointment base
13. Gripe Mixture for infants (5 ml contains Dill oil BPC 0.005 ml; sodium bicarbonate I.P.O. 0.005 gm dehydrated alcohol I.P. 0.0248 ml (Syrup & Preservative).
14. Syrup Noscapine
15. Whitefields Ointment Benzoic acid 6 g; salicylic acid 32g; alcohol 70% upto 100g)
16. Nitrofurazone ointment (0.2% in non-greasy ointment base)
17. Petroleum Jelly

18. Potassium, Permanganate 5g packets
19. Diethyl Ether (Anaesthetic)
20. Cetrimide Lotion
21. Iodine Solution (Claudium Solution) for sterilizing raw catgut, loops and loop introducers (Iodinel 1g, Pot Iodide 1.5 g, Distilled Water to produce 100 ml)
22. Plaster of Paris Bandages.
23. Adhesive Plaster
24. Ethyl Chloride (100 ml spray)
25. Boric Acid-Alcohol-Glycerol drops (Boric Acid 1.5% Glycerol 3.3% in alcohol 95%, 10 ml)
26. Bleaching Powder
27. Phenyle
28. Epsom Salt
29. Krushen's Salt. (Each gram contains Sod. Sulphate Exsic 20 mg., Sod. chloride 10 mg., Pot. chloride 10mg, Potassium Sulphate 55 mg., Citric Acid 45 mg., Magnesium sulphate excis).
30. Ointment containing : Resublimed Iodine 4%, Mehyl Salicylate 5%
31. Ointment containing : Oil Eucalyptus 8%, Oil clove 1%, Camphor 5%, Menthol 3%, Thymol 2%, Methyl Salicylate 5%.

APPENDIX II

1. Chloramphenicol
2. Tetracycline
3. Ferrous Sulphate
4. Aspirin
5. Chlorpromazine
6. Reserpine
7. Tolbutamide
8. Analgin
9. Piperazine
10. Crystalline Pencillin G
11. Streptomycin
12. INH Tablets
13. Tablets INH—Thiacetazone.

(All dosage forms of above drugs be marketed under generic names.)

ANNEXURE—II

Chapter X—Para 7)

Tablets and Capsules (Granules included)

Sl. No.	Name of the Product	Bulk drug involved
1	2	3
1.	Capsule Chloramphenicol—250 mg.	Chloramphenicol.
2.	Capsule Tetracycline Hydrochloride—250 mg.	Tetracycline. Hydrochloride
3.	Tablet Iodochlorhydroxy Quinoline—250 mg.	Iodochlorhydroxy Quinoline.
4.	Tab. Nitrofurantoin—50 mg.	Nitrofurantoin
5.	Tablet Chlorpheniramine—4 mg.	Chlorpheniramine
6.	Tablet Ferrous Sulphate—200 mg.	Ferrous Sulphate
7.	Tablet Folic Acid—5 mg.	Folic Acid
8.	Tablet Dixogin—0.25 mg.	Digoxin
9.	Tablet Aspirin—300 mg.	Acetyl Salicylic Acid
10.	Tablet phonobarbitone—30 mg., 60 mg.	Phenobarbitone
11.	Tablet Chlorpromazine—10 mg.	Chlorpromazine
12.	Tablet Prednisolone—5 mg.	Prednisolone
13.	Hexa Vitamin Capsules and Tablets. (Each tablet or Capsule contains) :	
	Vit. A—5000 I.U.	Vitamin A, calciferol—
	Vit. D—400 I.U.	—vitamin D2/Vit. D.3
	Vit. B1—2 mg.	Thiamine hydrochloride
	Vit. B2—3 mg.	(Vit. B1), Riboflaving
	Nicotinamide—20 mg.	(Vit. B2), Nicotinamide
	Vit. C—75 mg.	Ascorbic Acid (Vit. C)
14.	Tablet Vitamin B-complex, Prophylactic N.F.I. :	
	Vit. B.1—2 mg.	Vit. B.1 Vit. B.2.
	Vit. B.2—2 mg.	Vit. B.6—(Pyridoxine
	Vit. B.6—0.5 mg.	hydrochloride)
	Nicotinamide—25 mg.	Nicotinamide, Calcium—
	Calcium Pantothanate—1 mg.	Pant othenate, Yeast.
	Yeast—100 mg.	
15.	Tab. Vitamin B-Complex with Folic Acid and Vitamin-C, therapeutic N.F.I.	
	For therapeutic use :	
	Vitamin B-1—10 mg.	Vit. B1, Vit. B2, Vit. B6,
	Vitamin B-2—10 mg.	Cal. Pantothenate, Nia-cinamide Folic
	Vitamin B-6—2.5 mg.	Acid, Vitamin-C.
	Cal. Pantothenate—5 mg.	
	Niacinamide—100 mg.	
	Folic Acid —1.5 mg.	
	Vit. C—150 mg.	
16.	Tab. Vitamin C—50 mg., 100 mg. and 500 mg.	Ascorbic Acid
17.	Tab. Sulphadimidine—500 mg.	Sulphadimidine (Synonym)—Sulphametha-zine.
18.	Tablet Metronidazole—200 mg.	Metronidazole
19.	Tablet Hydrochlorthiazide —25 mg., 50 mg.	Hydrochlorthiazide.
20.	Tablet Reserpine—0.25 mg.	Reserpine
21.	Tablet Glyceryl Trinitrate—0.5 mg.	Glyceryltrinitrate
22.	Tablet Analgin—500 mg.	Analgin.

1	2	3
23.	Tablet Antacid Dried Al. hydroxide—120 mg. gel. Peppermint oil 0.003 ml. Mg. Trisilicate—250 mg.	Al. hydroxide Mag. Trisilicate, Peppermint oil.
24.	Tab. Piperazine citrate—300 mg.	Piperazine citrate.
25.	Cap. Tetrachloroethylene 1 cap. contain 1 ml. of the drug	Tetrachloroethylene
26.	Tablet Tolbutamide —500 mg.	Tolbutamide
27.	Tablet Thiacetazone (50 mg.) and Isoniazid (100 mg.)	Thiacetazone and INH
28.	PAS/Sodium PAS/Granules/Tablets—500 mg..	Para-amine salicylic acid/sodium para-aminosalicylate
29.	Tablet INH—100 mg. tab.	Isonicetinic Acid hydrazide
30.	Tablet Dapsone—100 mg. tab.	Dapsone
31.	Tab. Chloroquine Phosphate 250 mg. tablet	Chloroquine-Phosphate
32.	Tab. Primaquine phosphate 2.5 mg of base and 7.5 mg. of base	Primaquine phosphate
33.	Tab. Diethyl carbamazine citrate—50 mg tablet	Diethylcarbamazine citrate
34.	Tablet Anti-asthmatic : Ephedrine Hcl.—10 mg. Phenobarbitone—7.5 mg. Theophylline—125 mg.	Ephedrine Hcl. Phenobarbitone Theophylline
35.	Tablet Alkaloids of Ergot—150 mg.	Prepared Ergot
36.	Tablet of Vitamine A (6000 I.U.) and Vitamin D (1000 I.U.)	Vitamin A and Vitamin D
37.	Tablet Vitamin A 50,000 I.U.	Vitamin A
38.	Tablet Vitamin D 50,000 I.U.	Vitamin D (calciferol)
39.	Tablet Milk of Magnesia—300 mg.	Magnesium Hydroxide
40.	Tablet Paracetamol—500 mg.	Paracetamol
41.	Tablet Quinine Sulphate—0.3 mg..	Quinine Bisulphate
42.	Tablet Pathalyl Sulphathiazole—500 mg.	Phythalyl Sulphathiazole
43.	Oral Contraceptive :— (a) Norethisterone—1.0 mg Ethinyl Estradiol—30 mg. (b) Dl-norgestrel—0.5 mg Ethinyl Estradiol--30 mg.	Norethisterone Ethinyl Estradiol dl-norgestrel

Injections

1.	Inj. Pencillin : (a) Benzyl Penicillin Injection—5,00,000 units (b) Procaine Benzyl Penicillin Injection—2,50,000 units/ml. (c) Fortified Benzyl Penicillin Injection—Procaine Benzyl Penicillin—3,00,000 Units + Benzyl Penicillin 1,00,000 units/ml.	Penicillin G
2.	Inj. Streptomycin Sulfate—1 mg.	Streptomycin
3.	Inj. Emetine hydrochloride—60 mg. of Emetine hydro-chloride/ml.	Emetine Hcl.
4.	Inj. Atropine Sulphate—0.5 mg./ml	Atropine Sulphate
5.	Inj. Adrenaline Tartrate/Maleate Contains equivalent of adrenaline 1 in 1000	Adrenaline Tartrate Adrenaline Maleate
6.	Inj. Nor-Adrenaline Acid Tartrate 1mg./ml.	Noradrenaline Acid—Tartrate
7.	Inj. Dextrose Saline —5% w/v —10% w/v —25% w/v —50 % w/v	Dextrose
8.	Inj. Frusemide 20 mg. of Frusemide/2 ml. of water	Frusemide
9.	Inj. Morphine Sulphate—10 mg. ml.	Morphine Sulphate
10.	Inj. Pethidine Hydrochloride—50 mg./ml.	Pethidine Hydrochloride
11.	Inj. Paraldehyde	Paraldehyde
12.	Inj. Prednisolone Sodium Phosphate 20 mg./ml.	Prednisolone Sodium Phosphate
13.	Inj. Tetanus Antitoxin 1500 I.U., 10,000 I.U., 50,000 I.U..	Tetanus Antitoxin
14.	Inj. Methyl Ergometrine maleate 0.2 mg /ml.	Methyl Ergometrine Maleate.

1	2	3
15.	Inj. Chlorpheniramine Maleate 10 mg./ml.	Chlorpheniramine Maleate.
16.	Inj. Aminophylline 250 mg./10 ml. ampoule	Aminophylline
17.	Inj. Oxytocin 5 units/ml.	Oxytocin
18.	Inj. Chlorpromazine Hcl. 25 mg./ml.	Chlorpromazine Hcl.
19.	Antivenom Serum (Polyvalent Crotaline Antivenine)	
20.	Rehydration Fluid Dextrose in Sod. Chloride injection 25% w/v	Dextrose and Sod. Chloride
21.	Injection Glucose containing 5% w/v	Glucose
22.	Water for injection	—
23.	Inj. Phenobarbitone 200 mg./ml.	Phenobarbitone Sodium
24.	Inj. Mephenteramine Sulphate 15 mg./ml.	Mephenteramine Sulphate
25.	Diphtheria-Pertussis-Tetanus Vaccine I.P.	Diphtheria Toxoid Tetanus toxoid Pertussis-vaccine.
26.	Inj. Tetanus Toxoid I.P.	Tetanus Toxoid
27.	Inj. Diphtheria Toxoid I.P.	Diphtheria Toxoid
28.	Inj Diphtheria Antitoxin 10,000—20,000 Units	Diphtheria Antitoxin
29.	Oral Polio Vaccine	Aqueous suspension sutiable live-attenuated strains of Poliomyelitis virus-type I, II and III.
30.	Inj. Insulin Plain 20, 40 or 80 units/ml.	Insulin
31.	Inj. Thiopentone Sodium 500 mg. 1 gm.	Thiopentoll
32.	Inj. Succinyl Choline Chloride 50 mg./ml.	Succinyl Choline Chloride
33.	Inj. Lignocaine 0.5 %, 1% and 2%	Lignocaine Hydrochloride
34.	Inj. Vitamine B-Complex N.F.I. Each ml. Vit. BI —10 mg. Vit. B2 — 2 mg. Vit. B6 — 2 mg. Mitacinamide — 2 mg. Vit. B.12 —10 mg. Penthenol — 2 mg.	B1, B2, B6, Niacinamide, Cal Pantothenate, B12
35.	Inj. Thiamine Hydrochloride 5 mg. ml.	Vit. B1 (Thiamine hydrochloride)
36.	Inj. Cyanocobalamin 100 mcg and 500 mcg/mL	Cyanocobalamin
37.	Typhoid-paratyphoid A and B Vaccine I.P.	
38.	Cholera Vaccine Each ml. contains not less than 8,000 million of Vibric Cholerae.	
39.	Small Pox Vaccine (Freeze dried) (Vaccine Lymph)	
	Missellaneous	
1.	Sulphacetamide Eye drops 10%, 20%, 30%	Sulphacetamide Sodium
2.	Homatropine Eye drops :— Homatropine Hydrobremide 0.1 G Sodium Chloride 28.0 mg. Solution for Eye drops 5.0 ml.	Homatropine Hydrobromide
3.	Esserine Sulfate Eye drops Physostigmine Salicylate Physostigmine Salcylate 25.0 mg. Sodium Chloride 40.0 mg. Sodium Metabisulphite 2.0 mg. Solution for Eye Drops 5.0 ml.	Physostigmine Salicylate
4.	Benzyl Benzoate Emulsion 25%	Benzyl Benzoate.
5.	Acid Carbolic Lotion (25%)	Phenol
6.	Lysol : 50% Cresol V/V in a Saponaceous Solvent	

1	2	3
7.	Tr. Iodine Solution (Aqueous) Iodine —1.25 g. Potassium Iodine —2.5 g.	
7(a)	Tincture Iodine : Iodine —2.5 g. Potassium Iodine —1.5 g. Purified Water —2.5 ml. Alcohol —90% up to 25 ml.	Iodine
8.	Tr. Benzoin Benzoin Crushed —100 g. Alcohol —90% up to 1000 ml.	Benzoin
9.	Syrup Piperazine (500 mg. of Piperazine Citrate/5ml.)	Piperazine Citrate
10.	Extract Bellodonna I.P.	Belladonna Root Powder
11.	Chloramphenicol Suspension 125 mg./5ml.	Chloramphenicol Palmitate
12.	Syrup Paracetamol 125 mg./5ml.	Paracetamol
13.	Tetracycline Hydrocholride Eye Ointment 1% W/W Tetracycline	Tetracycline Hydrochloride
14.	Gripe mixture : Oil Anethi—0.0016 ml. Oil Anisi—0.0016 ml. Oil Caraway—0.0062 ml. Sod. Bicarbonate—290 mg. Alcohol 90%—3 ml. Distilled Water—30 ml.	Oil Anethik, Oil Anisi, Oil Caraway, Dod. Bicarbonate, 90% Alcohol, Distilled Water.
15.	Noscapine Linctus B.P.C. 15mg./5ml.	Noscapine
16.	Whitfields Ointment Benzoic Acid—60% Salicylic acid—3%	N Benzoic Acid Salicylic Acid
17.	Nitrofurazone Ointment Nitrofurazone—0.5%	Nitrofurazone
18.	Petroleum Jelly	
19.	Potassium Permanganate Solution : (0.1 per cent)	Potassium Permanganate
20.	Anesthetic Ether.	
21.	Cetrimide Lotion (1%)	Cetrimide.
22.	Plaster of Paris Bandage	Calcium Sulphate-hemihydrate
23.	Adhesive Plaster	Zinc Oxide
24.	Ethyl Chloride Spray	Ethylchloride
25.	Boroglycerine Eye Drops (1%)	Boric Acid Glycerine
26.	Bleaching Powder	Calciumhypochlorite
27.	Phenyl	Cresol Caustic Soda
28.	Epsom Slats	Magnesium Suplphate,
29.	Health Slats—0 Sod. Chloride—10% Sod. Sulphate—2% Pot. Chloride—1% Pot. Sulphate—5.5% Citric Acid—1.5 % Pot. Iodide—0.001% Mag. Sulphate to—100 %	Sod. Chloride, Sod. Sulphate Pot. Chloride, Pot. Sulphate, Citric Acid, Pot. Iodide, Mag. Sulphate

1	2	3
30.	Iodine Ointment :— Methyl Salicylate—5% Iodine— 5%	Iodine
31.	Sprain Ointment :- Methyl Salicylate Ointment : Methyl Salicylate—500 g. White Bees wax—200 g. Wool Fat—105 g. Menthol—100 g. Water—45 g. Cajuput Oil—25 g. Eucalyptol—25 g.	Methyl Salicylate White Bees Wax. Wool Fat, Menthol Cajeput Oil. Eucalyptol
32.	Cough Syrup	
33.	Ammoniated Mercury Ointment Ammoniated Mercury —5 g. Liquid Paraffin—3 g. White Ointment—92 g.	Ammoniated Mercruy. Liquid Paraffin— —White
34.	Pain Balm Clove Oil 1% Oil of Eucalyptus 8% Camphor 5%, Menthol 3% Thymol 2%, Methyl Salicylate 5%	

ANNEXURE III

[Chapter X—Para 22(b)]

1. Chloramphenicol and its esters such as palmitate, monostearoyl glycollate, succinate and stearate.
2. Tetracycline, Oxytertracycline, Chlortetracycline, Demethyl-chlor-tetracycliness, 5 Deoxy-Oxytetracycline.
3. Ferrous sulphate
4. Aspirin (Acetyl Salicylic acid)
5. Chlorpromazine
6. Roserpine
7. Tolbutamide
8. Analgin
9. Piperazine and all its salts such as adipate, citrate and phosphate.
10. Crystalline Penicillin G such as procaine, long-acting benzathine penicillin, including semisynthetic penicillins.
11. Streptomycin
12. INH
13. Combination of INH-Thiacetazone.

(All single ingredient dosage forms of the above drugs shall be marketed under generic names.)

ANNEXURE IV

(Chapter X—Para 27)

Household Remedies

Sl. No. Name of the Product

1. Tablet Iodochlorhydroxy Quinoline—250 mg.
2. Tablet Ferrous Sulphate—200 mg.
3. Tablet Aspirin 300 mg.
4. Hexa Vitamin Capsules and Tablets
   (Each tablet or Capsule contains) :
   Vit. A—5000 I.U.
   Vit. D—400 I.U.
   Vit. B1 2 mg.
   Vit. B2 3 mg.
   Nicotinamide—20 mg.
   Vit. C—75 mg.
5. Tablet Vitamin B-Complex, Prophylactic N.F.I.
   (Vit. B.1 —2 mg.
   Vit. B.2 —2 mg.
   Vit. B.6 —0.5 mg.
   Nicotinamida —25 mg.
   Calcium Pantothenate —1 mg.
   Yeast —100 mg.)

5.a. Tab. Vitamin B-Complex with Folic Acid and Vitamin C, therapeutic N.F. II.
   For therapeutic use :—
   Vitamin B-1 —10 mg.
   Vitamin B-2 —10 mg.
   Vitamin B-6 —2.5 mg.
   Cal. Pantothenate —5 mg.
   Niacinamide —100 mg.
   Folic Acid —1.5 mg.
   Vit. C —150 mg.

6. Tab. Vitamin C-50 mg.
   100 mg. and 500 mg.
7. Tab. Antacid
   Dried Al-hydroxide—120 mg.
   gel.
   Peppermintoil—0.003 ml.
   Mg. trisilicate—250 mg.
8. Tabl. Milk of Magnesia 300 mg.
9. Tab. Quinine Sulphate 0.3 g.
10. Sulphacetamide Eye Drops
    10%, 20%, 30%
11. Benzyl Benzoate Emulsion 25%
12. Acid Carbolic Lotion (25 %)
13. Lysol :—
    50% Cresol V/V in a Saponaceous Solvent
14. Tr. Iodine Solution (Aqueous)
    Iodine—1.25 g.
    Potassium Iodida —2.5 g.

14. a. Tinoture Iodine
    Iodine—2.5 g.
    Potassium Iodide—1.5 g.
    Purified Water—2.5 ml.
    Alcohol—90 % up to 25 ml.

15. T. Benzoin.
Benzoin Crushed—100 g.
Alcohol 100 ml.- 90%
upto 90 ml.

16. Gripe mixture
Oil Anethi—0.0016 ml.
Oil Anisi—0.0016 ml.
Oil Caraway —0.0062 ml.
Sod. Bioarbonate—290 mg.
Alcohol 90% —3ml.
Distilled Water—30 ml.

17. Nosoapine Linctus B.P.C. 15 mg./5ml.

18. Whitfields Citntment
Benzoic Acid—60 %
Salicylic Acid —3 %

19. Nitrofurazone Ointment Nitrofurazone—0.5 %

20. Potassium Permanganate
Solution—(O.1 per cent)

21. Cetrimide Lotion (1%)

22. Adhesive Plaster

23. Boroglycerine Eye-Drops (1%)

24. Bleaching Powder.

25. B Phenyl

26. Epsom Salts.

27. Health Salts.
Sod. Chloride—10%
Sod. Sulphate—2%
Pot. Chloride—1%
Pot. Sulphate—5.5 %
Citric Acid —1.5%
Pot. Iodide—0.001 %
Mag. Sulphate to—100 %

28. Iodine Ointment :—
Methyl Salicylate—5%
Iodine —5%

29. Sprain Ointment :—
Methyl Salicylate
Ointment :—
Methyl Salicylata—500 g.
White Beeswax—200 g.
Wool Fat—105 g.
Menthol—100g.
Water—45 g.
Gajuput Oil —25 g.
Euclyptol—25 g.

30. Cough Syrup

31. Pain Balm
Clove Oil 1%
Oil of Eucalyptus 3%
Camphor 5%, Menthol 3%
Thymol 2%, Methyl Salisylate 5%.

CHAPTER XI

CONCLUSION AND ACKNOWLEDGEMENT

In conclusion, we may state that it has been constant endeavour of Government to see that the majority of our people particularly in the rural areas and the weaker sections of the society get drugs and medicines at cheap and reasonable cost. The pharmaceutical industry in India, we are convinced, has a great potential, and given proper support, encouragement and guidance, it can meet the social needs and achieve the objectives set before it.

2. At the outset, we wish to place on record our gratitude to Shri D.K. Borroah and Shri Shah Nawaz Khan, the former Ministers in the Ministry of Petroleum and Chemicals, Dr. Karan Singh, Minister of Health and Family Planning, Shri K.D. Malaviya and Shri K.R. Ganesh, the present Ministers in the Ministry of Petroleum and Chemicals for the interest evinced by them and the encouragement and assistance we received from them.

3. We gratefully acknowledge with thanks the assistance and support received from the Government of India. We also wish to thank the State Governments of Maharashtra, Gujarat, Andhra Pradesh, Tamil Nadu and West Bengal for the assistance and hospitality rendered by them during our visits to the respective places, to study the status and problems of the industry. In particular, we convey our deep gratitude and acknowledgement of the interest shown by Shri Siddharta Shankar Roy, Chief Minister, West Bengal and Health Ministers of West Bengal, Maharashtra, Andhra Pradesh and Tamil Nadu. The Governments of Maharashtra and West Bengal were good enough to arrange for special trips for the members of the Committee to Pimpri and Durgapur Chemical Complex, respectively.

4. During our visits to various manufacturing units and the research and development institutions, we were greatly impressed by the enthusiasm of Indian scientists, research scholars and technologists. We had also occasion to discuss problems relating to the Pharmaceutical Industry with various manufacturers, their associations organizations, the Indian Medical Association, scientists and research scholars, many of them submitted detailed memoranda in reply to the questionnaire issued by the Committee. We would like to express our thanks to all those individuals and associations for their assistance and co-operation.

5. The question of substituting generic names for brand names was a complex one. We, therefore, sought the assistance of eminent doctors to advise the Committee on this vexed question, as well as on the identification of essential drugs. The Committee had the benefit of having in a very short time their report which formed the basis for our conclusions on these issues. We acknowledge with thanks the valuable assistance given by Dr. A.B. Chowdhury and Dr. B. Ray Chaudhury of Calcutta, Dr. S. Padmavati of New Delhi, Dr. K.G. Nair and Dr. B.J. Vakil of Bombay and Dr. K.V. Thiruvengadam of Madras.

6. We also thank the two public Sector Units, viz., the Indian Drugs and Pharmaceuticals Limited and the Hindustan Antibiotics Limited as well as the Drug Control Organization of various States we visited for the assistance rendered by them to the Committee.

7. During the short time that was available to us we have tried to analyse the problems of Pharmaceutical Industry, and have made recommendations which would enable the Public Sector to attain a commanding height in the Industry. We have also recommended steps to be taken to encourage Indian large and small scale sectors.

8. We have recommended in our report the establishment of a National Drug Authority which should be entrusted with the responsibility of planning, procuring and producing drugs, supplying of raw materials, obtaining technology from abroad, co-ordinating the work of various research and development institutions, and distributing essential drugs.

9. This and various other recommendations made by us, we believe, will go a long way in developing the Pharmaceutical Industry in India, through indigenous efforts. Strengthening of Drug Control Organization at the Centre and the States will ensure quality and standard of drug manufactured. Encouragement to and co-ordination of various R & D institutions will help the Industry to equip itself with modern technology and know-how. These recommendations when implemented, we hope, will in a large measure satisfy the social needs of the country. The fulfilment of these needs is imperative and we cherish the hope that Government will implement the recommendations made in this report expeditiously.

10. We cannot conclude without expressing our warm and sincere appreciation for the full co-operation and assistance received from the Ministry of Petroleum and Chemicals and Ministry of Health and Family Planning. We wish to place on record our high appreciation of the work done by Dr. P.R. Gupta, our Member Secretary for the assistance rendered during the tenure of the Committee, in addition to his normal duties, and in the preparation of this report. We also thank the officers and staff of the Committee including Dr. O.P. Madan of I.D.P.L., Shri V. Rajagopalan, Under Secretary and Shri O.P. Grover, Section Officer for the assistance rendered by them.

Abbreviations used

A.U.	Actual Users (refers to the manufacturers)
BICP	Bureau of Industrial Costs and Prices
CSIR	Council of Scientific and Industrial Research
CDRI	Central Drug Research Institute, Lucknow.
COB	Carrying on Business
DGTD	Directorate General of Technical Development
DPCO	Drugs (Prices Control) Order, 1970
E.I.	Established Import
FERA	Foreign Exchange Regulation Act, 1973
G.C.A.	General Currency Area
H.A.L.	Hindustan Antibiotics Ltd.
H.O.C.	Hindustan Organic Chemicals Ltd.
IDPL	Indian Drugs and Pharmaceuticals Ltd.
IPCL	Indian Petrochemical Corporation Ltd.
ICMR	Indian Council of Medical Research
ICAR	Indian Council of Agricultural Research
IIT	Indian Institute of Technology
IDR Act	Industries (Development & Regulation) Act, 1951
L.P.G.	Liquified Petroleum Gas
MRTP	Monopolies and Restrictive Trade Practices Act 1969
NCL	National Chemical Laboratory, Poona
N.C.S.T.	National Committee on Science and Technology
N.D.A.	National Drug Authority of India
"Organised" Sector	Units registered/licensed under the I (DR) Act, 1951, and borne on the books of DGTD
OCED	Organisation for Economic and Co-operative Development
R&D	Research and Development
RRL	Regional Research Laboratory
RPA	Rupee Payment Area
S.T.C.	State Trading Corporation of India

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