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PARLIAMENT OF INDIA
RAJYA SABHA

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DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

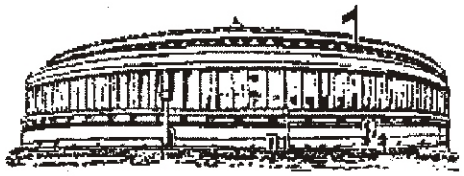
THIRTIETH REPORT

ON

THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2007

(PRESENTED TO THE RAJYA SABHA ON 21ST OCTOBER, 2008)
(LAID ON THE TABLE OF THE LOK SABHA ON 21ST OCTOBER, 2008)

RAJYA SABHA SECRETARIAT
NEW DELHI
OCTOBER, 2008/ASVINA, 1930 (SAKA)



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(2007-08)

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Shrimati Vandana Garg, Joint Secretary
Shri R.B. Gupta, Director
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@ Ceased to be Member *w.e.f.* 18th July, 2008.
* Nominated *w.e.f.* 18th February, 2008.
$ Ceased to be Member *w.e.f.* 3rd March, 2008.

COMPOSITION OF THE COMMITTEE
(2008-09)

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Shri Dinesh Singh, Assistant Director

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* Nominated *w.e.f.* 12th August, 2008.
# Nominated *w.e.f.* 20th August, 2008.

PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, after having been authorized by the Committee to present the Report on its behalf, present this Thirtieth Report of the Committee on the Drugs and Cosmetics (Amendment) Bill-2007*.

2. In pursuance of Rule 270 of the Rules of Procedure and Conduct of Business in the Council of States, relating to the Department-related Parliamentary Standing Committees, the Hon'ble Chairman, Rajya Sabha, referred** the Drugs and Cosmetics (Amendment) Bill, 2007 **(Annexure-I)**, as introduced in the Rajya Sabha on the 21st August 2007 and pending therein, to the Committee on the 23rd August 2007 for examination and report.

3. A Press Release inviting suggestions/comments from general public was issued in September, 2007. In response thereto, the Committee received 40 memoranda.

4. The Committee considered the Bill in its meetings held on the 9th and 31st October, 2007, 25th January, 7th and 27th May, 9th and 29th July and 12th August, 2008. The Committee visited Karnataka (Bangalore), Kerala (Thiruvanthapuram), Tamil Nadu (Chennai) and Andhra Pradesh (Hyderabad), from 7th to 14th January, 2008 **(Annexure-II — Study Note Phase I)**; Madhya Pradesh (Indore), Gujarat (Ahmedabad) Maharashtra (Mumbai) and Goa (panajim) from 12th to 19th February, 2008 **(Annexure-III—Study Note Phase II)**. These were the States with maximum (about 75%) concentration of the drugs manufacturing units.

5. The Committee held wide ranging discussions with all the stake-holders on various provisions of the Bill. Divergent views were expressed by the representatives of the associations of drug manufacturers, cosmetics industry, medical devices industry represented by CII and FICCI, pharmacists, experts, chemists, Drug Inspectors' associations, Drug Controllers' associations, State Governments etc., Besides, NGOs and Consumers' Fora highlighting concerns of the consumers also appeared before the Committee. The Committee also interacted with the Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, the Drug Controller General of India, representatives of Drug Technical Advisory Boards (DTABs) and Pharmacy Council of India and also heard Dr. R.A. Mashelkar, on whose report the Bill is modeled. The list of witnesses is given in **Annexure-IV and V.** The Committee sought clarifications from the above entities not only on the various viewpoints put forth before it on the Bill but also shared its apprehensions on the existing drug control scenario in the country.

6. The Committee, thereafter, took up clause-by-clause consideration of the Bill at its meeting held on the 12th August 2008. One or two members of the Committee expressed reservations on certain provisions of the Bill. At its meeting held on 20th August 2008, the Committee discussed and adopted the draft Report. However, Dr. R.C. Dome and Shri Pannian Ravindran put forth their ''Note of Dissent'' and stated that the same may be appended to the report.

7. The Committee has relied upon the following documents/information in finalizing its Report:

(i) Background Note on the Bill received from the Department of Health and Family Welfare;

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* Published in Gazette of India Extraordinary Part II Section-2, dated 21st August, 2007.

** Rajya Sabha Parliamentary Bulletin Part II, No. 44391, dated 24th August, 2007.

(ii) Presentation and clarification by the Secretary of the Department of Health and Family Welfare and Drug Controller General of India;

(iii) Memoranda received on the Bill from various associations, NGOs and experts;

(iv) Replies to the Questionnaires on the Bill; and

(v) Oral evidence on the Bill.

8. On behalf of the Committee, I would like to acknowledge with thanks the contributions made by those who deposed before the Committee and submitted their valuable suggestions on the subject matter of the Bill.

9. For facility of reference and convenience, observations and recommendations of the Committee have been printed in bold in the body of the Report.

AMAR SINGH
Chairman,
Department-related Parliamentary
Standing Committee on Health and Family Welfare.

NEW DELHI;
August 20*th,* 2008
Asvina 29, 1930 *(Saka)*

REPORT

The Drugs and Cosmetics Act 1940 is a consumer protection legislation which is mainly concerned with the standards and quality of drugs and regulates the import, manufacture, sale and distribution of drugs and cosmetics. During its more than half a century of being in force, the Act has undergone modifications at twelve occasions, the last being carried out in 1995. However, efforts made by Government through these amendment legislations to make the Drugs and Cosmetics Act adaptive to the fast charging scenario, both in the country and at the global level, have not proved to be very effective.

2. The Drugs and Cosmetics (Amendment) Bill 2007, **(hereinafter to be referred in the Report as 'Bill')** is the latest initiative of the Government which seeks to address the problems of the drugs regulatory system in the country. The Main features of the Bill are as follows:—

(a) substitution of the "Drugs Technical Advisory Board" as well as the "Drugs Technical Advisory Board for Ayurvedic, Siddha and Unani Drugs" by the "Central Drugs Authority";

(b) insertion of a new Chapter 1A in the Act with a view to providing for the constitution of the Central Drugs Authority and other connected or incidental matters thereto;

(c) insertion of a new Chapter 1B in the Act, providing for grant of permission for clinical trials, punishment for conducting clinical trial without permission, trial of offences, etc; and

(d) expansion of the compositions of the Drugs Consultative Committees.

The statement of Objects and Reasons appended to the Bill states as under:—

"The Central Government had constituted an Expert Committee under the chairmanship of *Dr. R.A. Mashelker, Director General of the Council of Scientific and Industrial Research in January 2003 to undertake a comprehensive examination of drug regulatory issues, including the problem of spurious drugs and to suggest measures to improve the drug administration in the country. The Committee, inter alia, recommended setting up of a Central Drugs Authority reporting directly to the Ministry of Health and Family Welfare and a system of centralised licensing. The Central Government considered the recommendations of the Committee and proposes to make amendments in the Act, in order to facilitate setting up of a Central Drugs Authority and introduction of Centralised licensing for manufacture of drugs in pursuance of the said recommendations."*

3. The Additional Secretary, Department of Health and Family Welfare, during the course of his evidence before the Committee on the 9th October, 2007, gave an idea about the remarkable achievement made by the Indian Pharmaceutical industry in the production of drugs and pharmaceuticals in the Indian market as well as export market in the last few decades. The country was rated as the fourth largest producer of drugs in the world. In addition to industry's growth, the service sector of pharmaceutical industry was also attracting global pharmaceutical industry. Not only this, India has become a favourite destination for drugs related research. Its capability was acknowledged by the fact that the largest number of USFDA approved sites outside the United States were in our country. The Committee was given to understand that this encouraging scenario was hampered by the weak and ineffective drug regulatory system in different States of the country. Although the Drugs and Cosmetics Act, 1940 has been in force for more than half a

century, the implementation of this Act had been less than satisfactory. The main reasons for the uneven levels of enforcement across the States, as cited by him are, non-uniformity in the interpretation of the provisions of law and their implementation, varying levels of competence of the regulatory officials and the lack of a comprehensive and effective Centralised regulatory system in the nature of a Central Drugs Authority, as available in most of the countries of the world. He explained that the problems in the drugs regulatory system in the country are further compounded by shortage of drug inspectors, inadequate and weak drugs control infrastructure at the State and Central levels, inadequate testing facilities, lack of specially trained cadres for specific regulatory areas, non-existence of data banks, non-availability of accurate information, etc. thereby resulting in a steady deterioration of the regulatory system. The existing weak and fragmented drugs regulatory system had failed to deal effectively with the changing scenario in the drugs sector.

4. Keeping in view the wide-ranging national concern about the quality and efficacy of drugs and pharmaceuticals and an urgent need for a world-class drugs regulatory system in the country, the Ministry of Health and Family Welfare constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelker, Director-General, CSIR in 2003 to suggest further measures to improve the control and management of drugs administration in the country. The Committee examined the broader issues by looking at the recommendations of earlier Committees (Hathi Committee Report of 1975, the Pharmaceutical Research and Development Committee Report of 1999) as well as relevant policies (Drugs Policy, 1986, Drugs Policy, 1994, Pharmaceutical Policy, 2002, Health Policy, 2002). The Committee also examined the drugs regulatory systems prevailing in large number of countries around the world. Part 'A' of the Mashelkar Committee Report submitted in November, 2003, contained recommendations related to amendments for improvement in the drugs regulatory infrastructure in the country including setting up of a Central Drugs Authority and a system of centralized licensing. The Committee was given to understand that the Drugs and Cosmetics (Amendment) Bill, 2007 has been brought forward pursuant to the aforesaid recommendations of the Mashelker Committee.

5. Due to the far-reacting implications of the Bill, the Committee decided to issue a Press Release seeking the views from all the stakeholders as well as public at large. In response, the Committee had received a large number of memoranda. After scrutinizing them, the Committee felt that for an in-depth examination of all conceivable aspects connected with the Bill, it was necessary to interact with all the stakeholders. The Committee, accordingly, visited Karnataka (Bangalore), Kerala (Thiruvanthapuram), Tamil Nadu (Chennai) and Andhra Pradesh (Hyderabad), from 7th to 14th January, 2008; Madhya Pradesh (Indore), Gujarat (Ahmedabad) Maharashtra (Mumbai) and Goa (Panajim) from 12th to 19th February, 2008. These were the States with maximum (about 75%) concentration of the drugs manufacturing units.

6. During these study visits, the Committee had the opportunity to interact with all the stake-holders directly, right from the representatives of the small and medium pharmaceutical companies, representatives of associations of drug manufacturers, cosmetics industry, medical devices industry, pharmacists, chemists, Drug Inspectors' associations, Drug Controllers' associations, NGOs and Consumers' fora and representatives of State Governments. Besides, the Committee also held a series of meetings in Delhi where quite a few witnesses representing different Government agencies involved in the implementation of the Act appeared before it. Finally, the Committee also heard Dr. R.A. Mashelker, whose Report has been projected as the very basis of the Bill. These interactions enabled the Committee to understand the complexities and problems prevailing in the existing regulatory system, and also the lack of co-ordination between the Central and the State Governments in the context of carrying out its various functions. The Committee also sought the views of the Department on the various issues/apprehensions raised by the stakeholders through detailed questionnaire as well as direct discussion with the Health Secretary and his team of officers. It would not be wrong to conclude that this exercise re-confirmed the Committee's

observations and recommendations contained in the Report. The Committee would like to emphasize that during this prolonged exercise, Committee's endeavor was to make an objective assessment of the Drugs and Cosmetics (Amendment) Bill 2007 and report thereon.

7. **The clauses where amendments have been suggested by the Committee are discussed in the succeeding paragraphs.**

8. **CLAUSE-2**

8.1 Section 3 of the Drugs and Cosmetics Act, 1940 deals with 'definitions'. Clause 2(i) seeks to insert the definition of the term 'clinical trial' as follows:—

> *"(aaii)* "clinical trial" means systematic study of any drug or cosmetic in human subjects to generate data for discovering or verifying its clinical, pharmacological (including pharmacodynamic and pharmacokinetic) or adverse effects with the objective of determining safety, efficacy or tolerance of the drug or the cosmetic;"

An objective analysis of the definition of 'clinical trial' indicates that allopathic drugs as well as Ayurvedic, Siddha and Unani (ASU) drugs, **medical devices and its associated products** and cosmetics will be brought under its purview.

8.2 During the course of its interactions with representatives of a number of Ayurvedic, Unani and Siddha (ASU) drug manufacturers' associations, emphatic objections were raised on the proposed inclusion of ASU drugs under the ambit of Clinical Trials. Main reason cited was that ASU medicines being not formulated on the lines of modern medicines, it required different approach for assessing their efficacy and utility. Their exclusion from the scope of clinical trial was, accordingly, advocated by them. The Committee had the opportunity to ascertain the views of representatives of ASU Drug Technical Advisory Board on various provisions of the Bill. On a specific query about clinical trial of ASU drugs being envisaged in the Bill, it was clarified to the Committee that clinical trial of ASU drugs needed to be based on different parameters and restricted only to new drugs. The Committee was given to understand that in the case of ASU drugs, clinical trial was only validation of the claims mentioned in the classical literature and pharmacopeias without any change being made in the ingredients and method of preparation. Clinical trials were also being carried out for the same formulation but for a different disease without changing the composition. It was, accordingly, suggested that definition of 'clinical trial' in the context of ASU drugs should be specifically in accordance with their traditional concepts and classical scriptures.

8.3 Representatives from the Cosmetic industry, who appeared before the Committee, stated that the definition of 'clinical trial' was too wide and not in line with the definition of 'Cosmetics' as given in the Act. It was pointed out that the impact of cosmetics on human body could not be equated with that of drugs since the physiological and therapeutic use of both were completely different. Agreeing to the fact that cosmetics and its related products also needed to be regulated, they were of the opinion that instead of clinical trial for cosmetics, the words **'dermatological safety studies'** may be substituted in the Bill for ascertaining their safety and efficacy.

8.4 The Committee had the opportunity to interact with a number of representatives from the medical devices industry also. With the inclusion of the term 'medical device' under the definition of the term 'drug', definition of the term 'clinical trial' was also applicable on the medical devices. It was, however, pointed out that medical devices differed significantly from drugs. Accordingly, the definition of clinical trial of medical devices needed to be in accordance with their components and utility and formulated in such a manner that it was" consistent with the international standards, *i.e.* the definition of Global Harmonization Task Force - the international body regulating medical devices.

8.5 In reply to a specific query regarding the appropriateness of clubbing the clinical trial of medical devices, a different class of product from drugs, under one umbrella definition of the terms

'clinical trial', the Ministry admitted that owing to the distinct nature and functions of medical devices, it would be appropriate to give a separate definition for their clinical trial.

8.6 **The Committee, after analysing the opinion of the stakeholders, is of the view that even though ASU drugs are formulated by methods different from that used for modern allopathic drugs, the chances of harm that a drug - either modern or ASU, may likely cause are similar and cannot be ruled out. The Committee would also like to point out that definition of 'drug' as given in the Act is applicable to both allopathic and ASU drugs. The Committee, therefore, opines that Ayurvedic, Unani and Siddha drugs should not be excluded from the scope of definition of clinical trial of drugs.**

8.7 **The Committee is inclined to agree with the contention of representatives of the cosmetics industry that physiological and therapeutic impact of drugs and cosmetics on human body is completely different. Therefore, there is a need to separate trials of cosmetics from drugs so far as the case of ascertaining their safety and efficacy is concerned. Such a study may be carried out on human volunteers under pre-defined test conditions as per standard industry protocol to ascertain the performance safety and efficacy of a cosmetic. The Committee's attention has also been drawn by ever-increasing number of cosmetic products including Ayurvedic and herbal products flooding the market-both domestic and international. Reports indicating harmful effects of some of such products on consumers also continue to be received. Main reason for such a situation is lack of any effective mechanism to check such products. The Committee, therefore, strongly feels that like clinical trial envisaged for drugs, similar provision should be there for regulating the dermatological safety studies for cosmetics. Necessary modification in the Bill may, accordingly, be made.**

8.8 **The Committee feels that the issue raised by the medical devices industry for having a separate definition of clinical trial for medical devices is very pertinent. It is convinced that owing to the distinct nature and functions of medical devices from that of the drugs, a separate definition of clinical trials for medical devices would be necessary. The Committee also takes note of the clarification given by the Ministry that medical devices are a separate and distinct category. Due to exigency, a few medical devices were being treated under the category of drugs. Now suitable amendment would be made to put these under the category of medical devices, to be defined separately in the Act. The Committee, accordingly, recommends that a separate definition of clinical trial for medical devices may be included in the Act. The Committee is also of the opinion that the definition of clinical trial for medical devices may be formulated in such a manner that it is consistent with the international standards which may read as follows:—**

> **"Any systematic investigation or study in or on human subjects, undertaken to assess the safety and/or performance of a medical device"**

8.9 Committee's attention was also drawn to another drawback in the definition of the term 'clinical trial' by a number of stakeholders. It was pointed out that the use of words 'any drug' in the definition implied that clinical trial of all types of drugs whether new or already in circulation could be conducted. The Committee also took note of the fact that already a definition of 'clinical trial' as given under rule 122 DAA of the Drugs and Cosmetics Rules, 1945, specifically mentions only 'new drug'. It was accordingly, suggested that the proposed definition of 'clinical trial' should relate only to new drugs. **The Committee is inclined to agree with the suggestion in view of the fact that all substances intended for use as components of a drug are included under the definition of 'drug' given in the Principal Act. Thus a product with a marketing authorization, when used or assembled in a different form, can be considered a new drug.**

8.10 The Committee would also like to point out that the term 'any drug' gives rise to apprehensions about chances of clinical trial of drugs in circulation taking place due to unhealthy competition among pharmaceutical companies. **Therefore, the Committee recommends that the words "any drug" in Clause 2 (i) (aaii) be replaced with the words "any new drug". The Committee also observes that with the definition of 'clinical trial' being included in the Act, there was no need of having the same in the Rules.**

8.11 Clause 2 (ii) of the Bill seeks to substitute the definition of 'medical device' as given in Section 3 (iv) of the Act by a more elaborate definition reproduced below:—

> "drug" includes
>
> *"(iv)* such medical device, medicated device, instrument, apparatus, appliance, material, software necessary for their application, intended for internal or external use in human beings or animals, whether used alone or in combination, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Central Drugs Authority, for the purpose of diagnosis, prevention, monitoring, treatment or mitigation of any disease or disorder; diagnosis, monitoring, treatment, alleviation of or compensation for, any injury or handicap; investigation, replacement or modification of anatomy or physiology; or control of conception, and which does not achieve its intended action primarily by any pharmacological or immunological or metabolical process, but is included in the pharmacopoeias mentioned in the Second Schedule;";

8.12 It was strongly advocated by the representatives of the medical devices industry appearing before the Committee that instead of including medical devices under the definition of drugs, they needed to be treated as an independent entity, as both were two different classes of products so far as their manufacturing, use and outcomes were concerned. It was also clarified that medical devices comprised three categories of products, *viz.* Implantable Devices, In-Vitro Diagnostic Products and Medical Electronic Products. Implantable Devices were implanted within the human body ranging from syringes/needles to coronary stents. In-Vitro Diagnostic Products covered entire range of equipments, devices etc. for diagnosis of all types of diseases such as Diabetes, Cancer, T.B. etc. Medical Electronic Products were used in any hospital set up. It was, accordingly, suggested that the Global Harmonization Task Force (GHTF) definition of 'medical devices' should be inserted, being more comprehensive, covering intended uses not covered in the proposed definition and 'encompassing the broad and diverse range of medical devices in use today and in foreseeable future.

8.13 Another problem area highlighted was the industry's experience with regulation of the few categories of medical devices presently covered under the Act, although limited but being far from satisfactory. While agreeing to the fact that medical devices and its related products have remained improperly regulated over the past few decades, it was also pointed out that with the development of new advanced technology and rapidly increasing product range every year, it would become extremely difficult to conform to and get regulated by the existing regulations/standards. Another point raised was that while imported Medical Devices were being registered, for indigenous Medical Devices the process was yet to be implemented, thus putting the local industry at disadvantage so far as their export was concerned. An additional menace faced by the Medical Device industry was device re-use beyond the recommended usage cycles. Presently, there was no provision looking into the regulation of this crucial aspect. It was, accordingly, suggested that a separate chapter for Medical Devices offering a 'comprehensive legal framework' needed to be included in the Act.

8.14 **The Committee finds logic in the view aired by the medical devices industry that the current system is inadequate in regulating certification, quality assurance and post marketing surveillance of both imported and locally made medical devices. Given the fact**

that use of medical devices in healthcare is increasing day by day and also the fact that the industry was at a growing stage, proper regulation is required to meet safety and efficacy norms as also to meet global standards and competitiveness of the medical devices products. The Committee also observes that the Mashelker Committee, in its Report, had dwelt at length on the issue of regulation of medical devices in the country. It was emphasized therein that the medical devices should be specifically defined and relevant rules and guidelines framed for their proper regulation. The other two major recommendations of the Committee were (i) the setting up of a specific Medical Devices Division for proper management of approval, certification and quality of medical devices and an appropriate regulatory mechanism for certification, quality assurance and post-marketing surveillance of both imported and indigenous medical devices. The Committee is however, surprised to note that the only action proposed in the Bill was substitution of existing definition of medical device by a more detailed definition. Another disturbing feature was continuance of medical devices under drugs. The Committee also feels that mere inclusion of medical devices in the pharmacopeias mentioned in the Second Schedule of the Act along with drugs will not serve the purpose.

8.15 **On being asked about the appropriateness of making separate provisions for the regulation, surveillance and monitoring of medical devices, the Ministry had replied in the affirmative. It was assured that keeping in view the distinct nature and functions of medical devices, the same would be defined separately with specific provisions for their regulation, surveillance and monitoring. The Committee, therefore,' recommends that suitable modifications may be made in the Act with a separate chapter covering all the related aspects of regulation of medical devices. The Committee also strongly feels that a dedicated division as recommended by the Mashelkar Committee may be set up to deal with regulation, licensing, surveillance and monitoring of uniform implementation of the laws on medical devices in the country. The Committee also recommends that a comparative analysis of the GHTF definition of Medical devices and the proposed definition in the Bill may be made and should be followed by necessary modifications in the definition of 'medical device.**

8.16 Committee's attention was drawn towards another draft Medical Devices Regulation Bill floated in the public domain by the Department of Science and Technology. On being specifically asked about the implications of this development on the proposed legislation before the Committee, the Ministry clarified that as the present Bill included medical devices, the replication of it by the Department of Science and Technology appeared to be uncalled for. Views of the Ministry have already been conveyed to the Cabinet Secretariat. **The Committee fails to understand the circumstances leading to such an initiative by the Department of Science and Technology with the nodal Ministry obviously being taken unaware. The Committee can only hope that this issue is resolved at the earliest.**

9. **CLAUSE-3**

9.1 **Clause 3** of the Bill proposes to introduce a new Chapter lA in the Act, relating to **CENTRAL DRUGS AUTHORITY. Section 5** under the new Chapter lA provides for constitution of a Central Drugs Authority. Relevant provisions read as follows:—

> "5. (*1*) The Central Government shall, by notification in the Official Gazette, constitute an Authority to be known as the Central Drugs Authority of India.
>
> (3) The Central Drugs Authority shall consist of a Chairperson and not more than five but at the least three, Members to be appointed by the Central Government by notification in the Official Gazette.

5A. The Chairperson and Members of the Central Drugs Authority shall be appointed by the Central Government from amongst persons who have special knowledge of, and at the least fifteen years' professional experience in pharmaceutical industry, research or teaching, or public administration, finance or law:

Provided that a person who is, or has been, in the service of Government shall not be appointed as a Chairperson or Member unless such person has held the post of Secretary and Additional Secretary to the Government of India or any equivalent post in the Central Government or a State Government or a public sector undertaking."

9.2 Statement of Objects and Reasons to the Bill mentions that the proposed constitution of Central Drugs Authority is based on the specific recommendation made by the Mashelker Committee in this regard. Status note submitted by the Ministry and subsequent interactions of the Committee with its representatives gave the genesis of this proposal. It was informed that the Drugs and Cosmetics Act, 1940 had been in force for more than half a century but the implementation of the Act has been less than satisfactory. The main reasons for this were uneven levels of enforcement across the States, non-uniformity in the interpretation of the provisions of law and their implementation, varying levels of competence of the regulatory officials and the lack of a comprehensive and effective centralized regulatory system in the nature of a Central Drugs Authority, as was available in many countries in the world. It was also explained that inspite of the Central Government's repeated efforts to strengthen the State Drug Control Organizations and Central Drug Standard Control Organisation—through various schemes, like the Capacity Building Project implemented with the help of the World Bank, during the last four decades, the situation in many States has remained disheartening. The CDSCO had also been functioning with the limitation of being a branch of the Central Government.

9.3 Against this background, an Expert Committee under the chairmanship of Dr. R.A. Mashelker was constituted by the Government in 2003. The Committee examined the broader issues by looking at the recommendations of earlier Committees (Hathi Committee Report of 1975, the Pharmaceutical Research and Development Committee Report of 1999) as well as Drugs Policy, 1986, Drugs Policy, 1994, Pharmaceutical Policy, 2002 and Health Policy, 2002. The Committee also interacted with all the stakeholders. It was recommended by the Committee that the most appropriate solution would be a strong, well equipped and professionally managed Central Drugs Authority reporting directly to the Ministry. The existing organisation for drugs regulation in the country at the central level, *i.e.* Central Drugs Standard and Control Organization (CDSCO) would be restructured into a Central Drugs Authority which apart from the traditional functions of CDSCO would address the new emerging fields pertaining to biotechnology products, medical devices, diagnostics, new drugs and clinical trials etc.

9.4 During its extensive interactions with different stakeholders, representing the entire spectrum of the pharmaceutical industry as well as the State authorities and central bodies, one view which was emphatically impressed upon constantly was that it would not be desirable to create a Central Drugs Authority, a small body having a wider mandate but lacking in representation of technically qualified/experienced experts. It was also pointed out that the position was further proposed to be made complicated and impractical by doing away with the two Drug Technical Advisory Boards representing technical expertise from allopathic and ASU drug sector.

9.5 While the existing Drug Technical Advisory Boards (DTABs) are highly technical bodies comprising of experts from various fields, the Central Drugs Authority would comprise of a Chairperson and three to five members to be nominated by the Government from amongst eminent persons having special knowledge of, and at least 15 years' professional experience in pharmaceutical industry, research or teaching or public administration, finance or law. The proposed CDA was not considered to be a progressive reform-based step but actually a set-back

with the absence of required technical expertise from different fields. It was also felt that the proposed CDA would simply create a resting ground for retired bureaucrats with technical experts having minimal chances of becoming its members. It was, accordingly, advocated by some stakeholders that CDA, if established, should be a more broad-based organisation having representation of State Drug Control Organizations, pharmaceutical industry and professional and Consumer associations etc.

9.6 **Committee's attention was also drawn, both during its study visits and meetings at Delhi, with all the witnesses representing different categories of stakeholders — be it small and big pharma industry associations, various State Governments, Drugs Controllers/ Inspectors/Associations/ bodies/associations from ASU sector — that recommendation of the Mashelker Committee was for a strong, well-equipped and professionally managed CDSCO, to be given the status of Central Drugs Administration and not creation of a Central Drugs Authority.**

After making a comparative analysis of Mashelker Committee recommendations and the different provisions of the Bill, the Committee was surprised to note that the contention of various witnesses was justified. The Committee would like to point out the following specific recommendation made by the Mashelker Committee.

> ***"The existing infrastructure at the Centre and States was not adequate to perform the assigned functions efficiently and speedily. Creating another authority such as a National Drug Authority (NDA) will not solve the problem at hand. It was essential to strengthen the existing organisations to enable them to undertake all the functions envisaged for NDA. A strong, well equipped, empowered, independent and professionally managed CDSCO, which could be given the status of Central Drug Administration (CDA), reporting directly to Ministry of Health would be the most appropriate solution."***

9.7 Feeling somewhat surprised by these conflicting reports, the Committee took up this matter with the Secretary, Ministry of Health and Family Welfare in its meeting held on the 29th July, 2008. Admitting some important departures in the Bill from the Mashelkar Committee recommendations, Secretary apprised the Committee that this deviation was reflected in the proposed legislation only after discussion by the then Health Secretary with Dr. Mashelkar, as given in the file notings. Realizing the complexity of the issue the Committee ascertained the views of Dr. Mashelkar also in its meeting held on the 12th August, 2008. The Committee was given to understand that in the light of considerable time gap between the Mashelkar Committee Report given in November, 2003 and proposed Bill coming up in 2007, ground realities have somewhat changed. A Central Drugs Authority in place of a restructured CDSCO has now become a viable option.

9.8 **The Committee observes that the Mashelkar Committee was an Expert Committee constituted by the Government in 2003 to examine all the aspects relating to quality control of drugs and their regulatory mechanism. The Committee also notes that the aforesaid conclusive recommendation made by the Mashelkar Committee has been arrived at after very intensive consultations with all the stakeholders. Not only this, in the Questionnaire sent to all the State Drug Controllers by the Mashelkar Committee, one of the questions asked was if CDSCO was to be strengthened, then would there be still a need for a National Drug Authority. In response, 19 out of 31 States (with 4 no comments) stated that there was a definite need to strengthen the Central Administration and if CDSCO could perform the statutory functions efficiently, there was certainly no need of NDA. The Committee also takes note of the fact that out of the 19 States which responded, five were Andhra Pradesh, Goa, Gujarat, Maharashtra and Tamil Nadu which belonged to the seven States having more than 75 per cent drug manufacturing units in the country.**

9.9 **In order to have first-hand information at the ground level, the Committee had undertaken study visits of all the States having 75 per cent of drug manufacturing units in the country. The only exception was West Bengal. This exercise of the Committee was supplemented by extensive discussions in a series of meetings held at Delhi and also feedback received in response to the press release. It would not be wrong to conclude that Committee's experience has also matched with the Mashelker Committee's findings. In view of the above assessment, the Committee is not inclined to accept the reasoning offered by the Secretary, Ministry of Health and Family Welfare for making such a major departure from the recommendations made by an Expert Committee.**

9.10 **The Committee would also like to draw attention to the following statement made in the Pharmaceutical Policy, 2002:—**

> ***"The Ministry of Health and Family Welfare would set up a world class Central Drugs Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective network of drugs standards enforcements administrations in the States with the CDSCO as a nodal centre, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals."***

9.11 **The Committee fails to understand as to why, instead of implementing the recommendations of the Mashelkar Committee for strengthening, modernizing, restructuring and reforming the existing Central Drugs Standard Control Organisation (CDSCO) into a world class system, the Government has entered into a rigmarole of setting up a new Authority. Central Drugs Authority, a small body primarily having members with administrative background taking the place of the two Drug Technical Advisory Boards having technical expertise from allopathic and ASU drug sector, is simply not acceptable to the Committee. The Committee, accordingly, recommends the setting up of a "Central Drug Administration" as an independent body under the Ministry of Health and Family Welfare with its headquarters at Delhi, with its Zonal and Sub-Zonal offices at State level, by strengthening, modernizing and restructuring the CDSCO.**

9.12 The Ministry, while informing the Committee on the manner in which it planned to restructure the CDA , elaborated that in the proposed CDA , the CDSCO with its Headquarters, Zonal Offices, Sub-Zonal Offices, Port Offices, Laboratories and Training Centre, would be absorbed into it. Thereafter, the CDA would become functional with 10 Divisions at the Headquarters. In addition to new Zonal Offices and Sub-Zonal Offices, new Laboratories would be created and some of the existing Sub-Zonal Offices would be up-graded to Zonal Offices and the Laboratories would be strengthened, restructured and reoriented. The proposed CDA would have ten distinct divisions to handle all the areas. These ten divisions would be:—

(1) Division for Regulatory Affairs, Enforcement, Legal and Consumer Affairs,

(2) Division for New Drugs and Clinical Trials,

(3) Division for Biological and Biotechnology Products,

(4) Division for Pharmacovigilance/Drugs Safety,

(5) Division for Medical Devices and Diagnostics,

(6) Division for Imports,

(7) Division for Organisational Services and Finance,

(8) Division for Quality Control Affairs,

(9) Division for Indian System of Medicine and Homoeopathy,

(10) Division for Training and International Cooperation.

9.13 **The Committee observes that broadly speaking, the proposed set up under the Central Drugs Authority is based on the set-up of Central Drug Administration proposed by the Mashelkar Committee. Ten Divisions are proposed under both the set-ups, the only difference being a separate division of Indian System of Medicine and Homoeopathy under the Ministry set-up. Another major difference between the two set-ups is that the Central Drugs Authority would be replacing the two drugs Technical Advisory Boards and performing their functions and also advising the Drug Controller General (I), who will be the Member-Secretary of CDA on all matters relating to drugs and cosmetics. Since the Committee is not in favour of creation of a separate "Central Drugs Authority", and has recommended the restructuring of CDSCO as "Central Drug Administration" - an independent body under the Ministry of Health and Family Welfare, the Central Drug Administration as suggested by the Mashelker Committee may be brought into effect as early as possible.**

9.14 **Representatives of the organisations from AYUSH-sector strongly advocated the need for having an Additional Drug Controller (AYUSH), keeping in view the ever increasing acceptance of AYUSH drugs. The Committee is inclined to agree with this viewpoint. The Committee finds that the Ministry, while elaborating the proposed plan of expansion of the offices and the necessary expansion in the number of senior-level officers and supporting staff that would be required for its efficient functioning under the CDA, has stated that the post of Drug Controller General (India) would be raised from the present level of the grade of Joint Secretary to Government of India to that of the grade of Additional Secretary to Government of India.**

It was also proposed to revive one post of Additional Drugs Controller (AYUSH) to assist DCG (I) in the quality control and regulation of ASU products, and along with it, one more post of Additional Drugs Controller (India) was proposed to be created for assisting DCG (I) in all other matters.

9.15 **The Committee observes that in view of the wider mandate of a "Central Drug Administration" necessary expansion in the number of senior-level officers and supporting staff would be required for its efficient functioning. The Committee has been informed that an elaborate plan of expansion has been approved and being brought into shape. A special drive to fill up all the vacant posts in the CDSCO and the Drug Labs was already underway. 62 new posts of Drug Inspectors and 10 posts of Technical officers have already been created for strengthening of CDSCO and mitigating the problem of shortage of Drug Inspectors to some extent. The Committee observes this as a welcome measure.**

9.16 **Under new chapter lA, Section 5B speaks of the term of office of Chairperson and Members, of Central Drugs Authority; Section 5C relates to salaries, allowances, pensions and other conditions of service of Members, Section 5 D is regarding vacancies, etc. not to invalidate proceedings and Section 5 E refers to staff of the Central Drugs Authority.**

In view of the Committee's disagreement with the Ministry's proposal for creating a separate Central Drugs Authority, Sections 5B, 5C, 5D, and 5E mentioned above stand void.

9.17 Section 5F under new chapter 1A deals with the Powers and Functions of Central Drugs Authority.

Sub-clause (1) of Clause states as under:—

> "5F. (1) The Central Drugs Authority may issue licences under clause (c) of section 10, clause (c) of section 18 and clause (c) of section 33EEC, and collect fees therefor."

9.18 The Committee notes that the Drugs and Cosmetics Act, 1940, is a central legislation and is implemented by the Central and State Governments together. Under the Act, the following are the responsibilities of the Central Government—

1. Clearance (Market approval) of new drugs;
2. Laying down of standards;
3. Control over import of drugs and cosmetics;
4. Enactment of legislation; and
5. Licensing under the Central Licensing Approving Authority (CLAA) schemes.

The responsibilities of State Government are as follows:-

1. Licensing of manufacture of drugs;
2. Licensing for sale of drugs; and
3. Post Marketing Surveillance.

9.19 The Ministry has informed that one of the major problems faced in enforcement of the rules and regulations under the Drugs and Cosmetics Act was the non-uniformity of licensing process among the Centre and States. In spite of repeated pleas made by the National Human Rights Commission, Hathi Committee, Estimates Committee (7th Lok Sabha) for the Central Government to assume the responsibility for granting manufacturing licenses, the same could not be implemented for one reason or the other. Therefore, the Bill proposes to streamline the licensing activity by shifting the drug manufacturing license issuing power from the States to the Centre. States will be, thus, responsible only for granting licenses for stock, distribution and sale of drugs and to carry out Post Marketing Surveillance on the quality of drugs moving in the market. The Ministry stated that it will give the needed focus and uniformity to the work of licensing and manufacturing on the one hand, while allowing the States to pay greater attention to the distribution aspect, which appears currently somewhat neglected. The regulatory system, therefore, would become more effective. It was also stated that the bringing in of a Central Drugs Authority with licensing functions will also help in the creation of data banks, especially with respect to manufacture and licensing of drugs.

9.20 During the Committee's interactions with the stakeholders – drug manufacturers' associations, State Drug Controllers' associations, experts and also State Governments, strong apprehensions were expressed by majority of them on the proposed switching over to centralized licensing of drug manufacturing activities in the country. Undue delays in grant and renewal of licenses, difficulties in filing of appeal by manufacturing units located far from Delhi and lack of incentives for the industry to set up their units in backward areas were the main reservations expressed. It was also argued that the existing system is superior to the proposed central licensing on the grounds that it offers better control of the drug manufacturing units as the authority has to control one State only. It was also pointed out by many State Governments and the State Drug Controllers that the fee for grant of licenses, product permission and various certificates being the only source of revenue for State Drug Departments, centralized licensing would cause loss of revenue to the State Governments. One centralised agency like CDA dealing with the issue of licensing for manufacture, distribution and sale of drugs across the country that too without the assistance of DTAB and Ayurveda Siddha Unani Drug Technical Advisory Board (ASUDTAB) was not considered a practical proposition.

9.21 **The Committee found that it was a general perception among majority of the stakeholders that with the Centralized licensing coming into effect, every activity including**

procedural formalities would be centered in Delhi leading to number of hurdles being faced by the drug manufacturing units, specially small units. The Committee, however, observes that the apprehension stands suitably addressed, keeping in view the fact that CDA through its network of Zonal and Sub-Zonal offices and port offices would have its presence in most of the States where there is significant concentration of drug manufacturing activity. This would also facilitate Centralized licensing and Good Manufacturing Practices (GMP) Certification. Besides, these offices would also take care of concerns regarding inordinate delays in issuance of licenses etc. raised by the stakeholders subsequent to centralized licensing coming into force. The Committee is of the view that in this age of IT advancement, the restructured CDSCO with its ten divisions having a well-defined jurisdiction and network of subordinate offices spread across the country, apprehension about delay factor do not seem to be genuine. The notion of the States that the existing system is superior to the proposed central licensing on the grounds that it offers better control by the States pre-supposes the existence of an efficient infrastructure and quality of enforcements in every State. The Committee observes that this assumption is far removed from the ground realities in majority of the States.

9.22 **In this regard, the Committee takes note of the specific recommendation for licensing of drug manufacturing units by the Central Drug Administration made by the Mashelkar Committee after a detailed analysis of ground realities, recommendations of earlier expert Committees and views of all the stakeholders. Issue of non-uniformity of enforcement at the State level with regard to quality control of drugs was the main factor behind such a recommendation made by all the bodies like NRHC, Hathi Committee, Estimates Committee (Seventh Lok Sabha) and Mashelkar Committee. Committee's attention has been drawn by the guiding principle driving this suggestion, aptly summarized in para 33 of the Hathi Committee Report quoted below:—**

> **"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."**

9.23 **The Committee agrees with the assessment made by all the earlier Committees that there was an urgent need for having a world class drug regulatory system in the country which can effectively handle the health concerns of one sixth of humanity. The Committee can only reiterate that wherever the health and safety of life of the people is concerned, cutting across regional/State specific interests/issues, the emphasis should be protecting the same.**

9.24 On being asked as to how the Ministry proposes to centralise the licensing activity, the Secretary, while deposing before the Committee at its meeting held on 29th July, 2008, stated that progressive central licensing through reforming and expanding the existing Central Licensing Approving Authority (CLAA) system, rather than by the State by State method, was a more feasible proposition. He clarified that in order to avoid the resultant ambiguity of jurisdiction by the Centre as well as the States; it was thought best that by including more and more health products under the existing CLAA system, it would result in a progressive increase in the number of centrally licensed items leading to a gradual shift of the licensing activity from State to Centre.

9.25 The Committee notes that presently, under the CLAA system, following items are being licensed concurrently by the State and Central licensing authorities:

– Human blood and blood products.

– Seral vaccines.

– Large volume parenterals.

– Medical devices except needle, syringes and perfusion sets.

The representatives from quite a number of drug manufacturing organisations pointed out that a lot of bottlenecks were being faced by them under the CLAA system. It was stated that undue delays in grant and renewal of licenses for the above categories of products were a constant source of discomfiture for them.

9.26 **The Committee's attention has been drawn to the following specific excerpts from the Mashelker Committee Report:—**

> ***"The matter of licensing of manufacturing units by Central Government has been considered on several occasions in the past. During* 1988-89, *the reports of poor quality of I V fluids and substandard blood made the Central Government focus on the issue of having a stricter control on these products. This resulted in the amendment of Rules to provide for dual licensing mechanism in December* 1992, *the Central authority being the License Approving Authority (CLAA) and the States being the license giving authorities. The idea was to improve the quality and implement uniform norms but the experience has not been encouraging. The change, however, has not made the desired level of impact."***
>
> ***"The National Human Rights Commission in their order of 1999 clearly stated that: the present dual system of control does not appear to have achieved desired effectiveness, therefore, Central Government must immediately take steps to examine the entire system of Licensing (including loan licensing), Certification and Complaint handling under effective Central Government control through CLAA or other suitable means".***

9.27 **The Committee observes that though the method of progressive increase in the number of items under CLAA seems to be a good measure aimed at smooth transition of the licensing activity from the States to the Centre, it has its own apprehensions regarding the timely disposal of applications, effective co-ordination with the industry, interpretation of law under the CLAA system. The facts stated above by the witnesses and supported by the findings of the Mashelkar Committee all point out that the present mechanism under the CLAA system is far from satisfactory. The Committee was also given to understand that the number of units involved was very large, volume of records need to be handled was also enormous and every unit would have to be inspected after one year. Keeping in view the tremendous strain the above-mentioned exercise was likely to have on the Central Government; transition period from State licensing to centralized licensing may be spread over a period of ten years. On Committee's showing its concern on such a long time-span, Secretary, Health admitted that it was too long a period. He assumed that every effort would be made to switch over to centralized licensing in six to seven years.**

9.28 **The Committee was surprised to note that the proposed move was in direct contravention to the roadmap in three phases drawn by the Mashelkar Committee for implementation of centralized licensing. During Phase-I, the manpower was to be strengthened and infrastructure of Central Drug Administration was to be in place. Expansion of zonal and sub-zonal offices, creation of additional infrastructure for new offices in States, creation of considerable number of additional senior level and supporting posts are the specific requirements for implementation of the above recommendation.**

During Phase-II, the licensing functions of States having minimum concentration of manufacturing units were to be shifted to the Centre, and during Phase-III, licensing in seven States having maximum concentration of drug manufacturing units (75 per cent) of licenses was to be taken over by the Central Drug Administration. All this exercise was to be completed within a span of three years.

9.29 **On being asked about reasons for not accepting this specific recommendation of the Mashelkar Committee, the Secretary informed that this issue was also discussed with Dr. Mashelkar who has agreed to the progressive transfer from the State Licensing to the Central licensing rather than going State by State. The Committee has its own reservations on not going for the roadmap having a specific time frame drawn by the Expert Committee for switch-over to centralized licensing which was the outcome of extensive interactions with all concerned based on the ground-realties.: The Committee would also like to point out that so far no plan of action having a specific time-limit has been drawn by the Ministry. As indicated by the representative of the Ministry, it can be anywhere from five to ten years. Apprehension of the Committee on this vital issue is strengthened by the fact that a reputed consultancy firm/consultant would be engaged by the Ministry for suggesting the roadmap based on the best practices available across the globe. The Committee can only conclude that against such a background, chances of things falling into place in the near future seem to be very dim. The Committee feels that the roadmaps drawn by the Mashelkar Committee is backed by sound logic and fully endorses the line of action pointed out by it for implementing the centralized licensing of drug manufacturing units. The Committee, therefore, strongly recommends that every effort should be made for implementing the same within the specified time-frame.**

9.30 An important issue that was raised by several witnesses was that the Bill was silent about the grievance redressal mechanism. It was pointed out that whereas under the present system of licensing where licenses are issued by the State Licensing Authorities, an aggrieved party can file the appeal with the State Government, the appeal shall lie with the Central Government, irrespective of the State where the unit filing the appeal is located if the licensing system is centralized. With the power to grant, renew, suspend or cancel the licenses being given to the proposed CDA, this would result in undue hardship, wastage of precious time and additional financial burden especially to small scale units located far away from the CDA. The licensee would have to file an appeal against the order of CDA before the Central Government and therefore, run to the Centre frequently for redressal.

9.31 In reply to a specific query on the issue, the Ministry has stated that the appeal would lie with the Government (Ministry of Health and Family Welfare) and the provisions in this regard will be accordingly incorporated in the proposed Bill which would read as under:—

> "Any person aggrieved by a decision of the CDA(I) passed under section 5(F) may within ninety days of the date of such decision prefer an appeal to the Central Government and the Central Government, after giving the appellant an opportunity of being heard, shall pass a reasoned order".

9.32 **The Committee is inclined to agree to the view-point of the stakeholders that they would be at a serious disadvantage in terms of undue hardship, wastage of precious time and additional financial burden especially for small scale units located far away from Delhi. Since the Centre would be carrying out its licensing operations from its various zonal and sub zonal offices placed in each State/UT, the Committee recommends that the appellate authority for grievance redressal of the aggrieved party should be placed in such offices, keeping in mind the comparative disadvantages that the small scale pharma units would otherwise face.**

9.33 **Section 5-I** provides for creation of a **Fund** that would be called **Central Drugs Authority of India Fund** which reads as follows:—

"**5-I.** (*1*) There shall be constituted a Fund to be called the Central Drugs Authority of India Fund and there shall be credited thereto—

(*a*) all grants, fees and charges received by the Central Drugs Authority under this Act; and

(*b*) all sums received by the Central Drugs Authority from such other sources as may be determined by the Central Government.

(*2*) The Fund shall be applied for meeting—

(*a*) the salaries, allowances and pensions payable to the Chairperson and other Members and the administrative expenses, including the salaries, allowances and pensions payable to or in respect of the Drugs Controller General (India) and other officers and employees of the Central Drugs Authority; and

(*b*) the expenses to carry out the objects and purposes of this Act."

9.34 The Ministry had informed the Committee that initially, the Central Government would provide grants for running of the CDA. It will have financial autonomy to the extent that it will retain the revenues earned by it to be utilised for its operational expenses. During the first 5 years, all the revenues of CDA will be met through license fee and other ancillary functions. Details about the proposed earnings of CDA as indicated by the Ministry are given as below:—

"Presently the CDSCO earns revenues through import registration fees, new drug registration, license fees etc. Once the CDA becomes functional, it is proposed to add new fees for GMP certification inspection and to increase the rate of present fees for import registration (started in 2002), new drug registration (started in 2002), license for manufacturing/ inspection/products (revised in 2001) and clinical trials (started in 2002). It has been assumed that while there would not be any regular yearly appreciable increase in the category of new drug registration and license fees, the other fee categories would show an increase of 5% per annum. While expenditure of CDA would vary from Rs.7.30 crore (in year 1) to Rs.23.67 crore (in year 10), the revenue of the proposed Authority would vary from Rs.21.31 crore (in year 1) to Rs.32.94 crore (in year 10). Hence, the net inflows of CDA would vary from Rs.14.07 crore (in year 1) to Rs.9.27 crore (in year 10). Reason for downward trend in the cash flow is because it has been calculated on the assumption that the rate of various fees would remain constant over the 10 year period. If, however, the fees were to be enhanced at a 5 yearly interval then the cash flows would undergo a change."

9.35 **The Committee notes that the proposed Fund for Central Drugs Authority will be receiving all grants, fees and charges levied for different purposes. Only initial funds are sought to be provided by the Central Government The Committee apprehends that this would be grossly inadequate. Given the fact that strengthening of the CDSCO as Central Drug Administration would require expanding the Zonal and Sub-zonal offices, creation of additional infrastructure for new offices in the States and manpower to match equally, for setting up a world class Central Drug Administration, substantive additional funds would be required for such activities. The Committee strongly feels that the Central Government will have to play a major role. In view of majority of the States facing funds constraints, the required funds will have to be provided by the Central Govt. It, therefore, suggests that like major social sector central/centrally sponsored schemes, the task of setting up a world**

class Central Drug Administration may be taken up in a mission mode. Accordingly, a Central Fund meant for Central Drug Administration with major contribution from the Centre in the form of a Corpus Fund may be set up.

9.36. **Section 5L** under new chapter lA deals with **Power to make Rules**

It provides that the Central Government may, after consultation with, or on the recommendation of the Central Drugs Authority may make rules relating to the functioning of CDA.

In view of the Committee's disagreement with the proposal for creating a separate Central Drugs Authority, Clause 5L stands void.

10. Clause 3 of the Bill also introduces another Chapter 1B, after Chapter lA, that deals with the regulation of Clinical Trials.

10.1 **Section 5N** under the new **Chapter 1B,** which speaks about conducting **Clinical Trial without Permission,** states that:—

> "5N. No person shall conduct clinical trials in respect of any drug or cosmetic except under, and in accordance with, the permission granted by the Central Drugs Authority."

10.2 It was argued by a number of witnesses that Clause 5N will bring all post marketing clinical trials and academic research to a complete halt. The surveillance studies generate useful data on local population for drugs that are not tested extensively before marketing in India. To avoid such situation, the word **"Any Drug"** used in the clause should be substituted by **"Any Investigational New Drug"**. Clinical trials should be necessary only on new drugs which were at investigational stage. It was also emphasized that the Confirmatory trials, Pilot trials, trials for submission to foreign regulatory authorities and contract research trials may be exempted from this provision.

10.3 **In the light of observations made by the Committee with regard to the definition of the term 'clinical trial', permission for conducting clinical trials of only investigational new drugs and cosmetics and medical devices may be included. Secondly, under the proposed restructured CDSCO as envisaged by the Mashelkar Committee, out of the ten divisions which would be functioning at the Headquarters, there are two separate divisions one for New Drugs and Clinical Trials, and the other for Medical Devices and Diagnostics. The Committee, accordingly, recommends that these two Divisions may be entrusted with the responsibility for granting permission for conducting clinical trials for drugs and dermatological safety studies for cosmetics, and evaluation of safety and performance of medical devices and other allied issues.**

10.4 Section 5O regarding Punishment for Conducting Clinical Trial without Permission, lays down that:—

> "5O. (*1*) Whoever, himself or by any other person on his behalf, conducts clinical trials in contravention of section 5N shall be punished with imprisonment for a term which may extend to five years and with fine which may extend to ten lakh rupees.
>
> (*2*) Whoever having been convicted of an offence under subsection (1) is again convicted of an offence under that sub-section, shall be punished with Imprisonment for a term which may extend to ten years and with fine which may extend to twenty lakh rupees."

10.5 Some of the stakeholders had pointed out that the punishment for conducting clinical trial without permission was very harsh and it was likely that the students conducting academic research in Government/Private Institutions or for post graduate courses may face such serious consequences of harsh punishment merely due to not obtaining permission from the CDA out of ignorance. In such cases liability should be fixed on the concerned institutions. It was also

suggested that a distinction was needed to be made between clinical trials conducted strictly in accordance with the Good Clinical Practices and in compliance with all ethical requirements but without obtaining permission and unauthorised clinical trials causing adverse impact or grievous hurt to the volunteers. Lesser punishment of only fine may be prescribed and in such cases they should be considered as compoundable offences.

10.6 **The Committee, after carefully weighing the contention of the stakeholders as well as of the Department, is of the view that the provisions of punishment, for conducting Clinical trial without permission should be retained. Such a provision would act as a deterrent for violators of law. The Committee is disinclined to agree that academic research would be brought to a halt by such a provision. It contends that if the punishment norms for academic research are relaxed, chances of drug manufacturing companies carrying out trials through private institutions by financially supporting them cannot be ruled out. The Committee suggests that in such cases the onus of proving themselves not guilty should be fixed on the Institutions where the students are conducting academic research.**

10.7 **The Committee would also like to point out that a careful perusal of the clause reveals that the punishment would vary with the degree and nature of violation. Thus the question of this provision being very harsh does not arise. The Committee also feels that punishments for cases related to 'drugs' and those related to 'cosmetics' should be separate and clearly defined. Similarly, those cases related to 'medical devices' should be dealt separately under a chapter concerning regulation of medical devices, as mentioned earlier.**

11. **CLAUSE-5**

11.1 **Clause 5 of the Bill seeks to omit** Section 5 of the Principal Act, which relates to constitution of the Drug Technical Advisory Board.

11.2 When asked to justify the abolition of the Drugs Technical Advisory Boards, the Ministry clarified that under the existing provisions of the Drugs and Cosmetics Act, 1940, there are two separate Drugs Technical Advisory Boards (DTABs), for the allopathic and ASU drugs. The DTAB is a broad based body wherein, in addition to persons involved in regulatory system, representatives from IMA, pharmaceutical manufacturers, Indian Pharmaceutical Associations etc. are also included. It advises the Government on matters relating to implementation of provisions of D&C Act and Rules made thereunder as well as to make suitable amendments in the Rules and Regulations as per the requirements.

11.3 Clarifying a query regarding the justifiability of replacing the highly technical eighteen-member DTAB with a small body like Central Drugs Authority, the Ministry stated that the process of translating the recommendations of this advisory body into rules and regulations inevitably results in some delay because of the procedures involved. This was sought to be streamlined by empowering the CDA which would be replacing DTAB to formulate regulations based on the recommendations of the DCC and its own expertise and analysis. It was further clarified by the Ministry that the Drug Consultative Committee would be reconstituted to include all the stake holders who were members in the erstwhile DTAB.

11.4 During its interactions, one view which was strongly advocated by all the stakeholders was that the proposal to abolish the DTAB with CDA taking its role was unjustified. It was pointed out that such a move would inevitably lead to depriving the drug industry in the country from the advice and expertise of this highly technical Board. It was also mentioned that such a proposal was not there in the Mashelkar Committee Report.

11.5 **The Committee is of the opinion that the DTAB is a highly technical body with representation of experts from various fields and whose main function is to advise the**

Central Government and the State Governments on technical matters arising out of the administration of the Act and to carry out the other functions assigned to it under the Act. Being the most important body under the Central Drug Administration, the Committee feels that DTAB should be retained. The issue has been dealt with earlier also in this Report. Hence, it recommends that Section 5 of the Principal Act which deals with the Constitution and Composition of the Drugs Technical Advisory Board (DTAB) may be retained.

12. **CLAUSE-6**

12.1 **Clause 6** of the Bill speaks of amending **certain provisions of Section 6** of the Principal Act which deals with the Central Drugs Laboratory

> **"6.** In the principal Act, in section 6,—
>
> (*a*) for the word "Laboratory", wherever it occurs, the words "Laboratory or Laboratories" shall be substituted;
>
> (*b*) in sub-section (*2*), for the word "Board", the words "Central Drugs Authority" shall be substituted."

12.2 The Ministry infonned the Committee that the Bill proposes that all the Central Drug Laboratories be placed under the CDA as bringing all the drug laboratories under CDA will facilitate proper planning, utilization of the capacities of these laboratories by restructuring and reorienting their objectives and goals. For example, at present, almost all the laboratories are notified for analyzing all categories of drugs, but some of the laboratories can be assigned with specific jobs like testing of medical devices, testing of cosmetics etc. Based on the techniques of analysis, each laboratory can be given a focus on a specific technique like chromatography, microbiology, instructional biology etc. and such focus will facilitate creation of expertise and capacity of testing. This restructuring will strengthen the CDA in evaluation of the quality of the drugs.

12.3 The Committee would like to state here that the Mashelkar Committee Report had also pointed out serious deficiencies in the State and Central Government drug testing labs. The limitations in testing of drug samples in the Government labs are related to the absence or lack of sophisticated instruments, lack of trained analysts, lack of commitment, lack of reagents, non-validated methods, shortage of funds, inadequate number of staff and in many cases a combination of more than one of these constraints. The Committee has also been given to understand that efforts made by the Central Government for setting up/upgrading their testing facilities in States under various Five Year Plans and through WHO funds, have been far from satisfactory.

12.4 **The Committee observes that, keeping in view the need for quality control of drugs across the country, the proposed move of bringing all the Central Drug Laboratories under the control of one central agency is called for. However, in view of the Committee's recommendation for having Central Drug Administration in the form of re-structured CDSCO, all the Central Drug Laboratories may be placed under the Division of Quality Control Affairs under the Central Drug Administration.**

13. **CLAUSE-7**

13.1 **Clause 7** of the Bill seeks to amend Section 7 of the Act for substituting the words **"Drugs Technical Advisory Board"** with the words **"Central Drugs Authority".** It also provides for **change in the composition** of the **Drugs Consultative Committee.**

Sub-clauses (b) (2) under the above clause states as follows:—

> "(*b*) for sub-section (*2*), the following sub-section shall be substituted, namely:—
>
> (*2*) the Drugs Consultative Committee shall consist of such number of representatives of the Central Government, industry, consumer associations, academic and research

institutions, as may be prescribed and one representative of each State Government to be nominated by the State Government concerned.";

13.2 Justifying the proposed changes in this section, the Ministry had stated that it was proposed to restructure the composition of the Drugs Consultative Committee (DCC) to make it more representative and broad-based. It would be an advisory Committee constituted by the Central Government to advise the Central Government, State Governments and the proposed CDA on any matters tending to secure uniformity throughout India or any other matter referred to it for the administration of the Drugs and Cosmetics Act. The DCC would be reconstituted to include all the stake-holders who were members in the erstwhile DTAB.

In view of the Committee's recommendations to retain DTAB at Clause 5, the proposed change at Section 7 (a) of the Act stands void. Drugs Consultative Committee as envisaged may continue.

14. **CLAUSE-18**

14.1 **Clause 18 (b) (i)** does away with the rule making powers of the Government to prescribe the qualifications and duties of the two important officials under the CDSCO–Government Analysts and Inspectors, provided under Section 33 of the Principal Act.

14.2 Witnesses were of the opinion that with the proposed Central Drugs Authority not being empowered to prescribe qualifications and duties of the Government Analyst and the qualification of Inspectors, any person without any professional qualifications would be entitled to be appointed as the Government Analyst and Drugs Inspector – by the licensing authority, a situation not desirable in the interest of effective implementation. Hence, Section 33(2) (b) and (n) should be retained.

On a specific query in this regard, the Ministry replied that the omission of clauses (b) and (n) of Section 33 (2) is an inadvertent error in typing which would be duly rectified.

15. **CLAUSE-19**

15.1 **Clause 19 of the Bill** provides for omission of Section 33 of the Act dealing with the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board.

15.2 **In view of the Committee's recommendation at Clause 5 to retain DTAB, the provision under Section 33C of the Principal Act for constitution of ASU DTAB may be retained. The proposed clause 19 of the Bill accordingly, stands void.**

16. **CLAUSE-20**

16.1 **Clause 20** of the Bill seeks to amend **section 33D** of the Principal Act which deals with the **ASU Drugs Consultative Committee.**

16.2 **In view of the Committee's recommendation to retain Drug Consultative Committee as envisaged in Section 7(2)(b) of the Principal Act, the proposed change in section 33 D (1) of the Act stands void.**

17. **In view of Committee not agreeing to the replacement of DTAB by the CDA, the consequential changes in the relevant Clauses stand void.**

18. **MISCELLANEOUS ISSUES**

1. During the course of his deposition before the Committee on the 12th August, 2008, Dr. Mashelkar was asked to apprise the Committee of the updated status of the Implementation Committee on Drug Regulatory Reform' supposedly set up by the Ministry of Health and Family

Welfare under his chairmanship. Dr. Mashelkar expressed his ignorance on the existence of any such Committee. The Committee takes serious exception to the fact that though almost a year has passed since the Ministry has informed the Committee that the process for setting up of an 'Implementation Committee on Drugs Reglliatory Reform' has been initiated, no progress seems to have been made on the issue. The Committee would like to state that the Ministry should apply caution in future and use all care and circumspection before furnishing such information to a Parliamentary Standing Committee.

RECOMMENDATIONS/OBSERVATIONS—AT A GLANCE

The Committee, after analysing the opinion of the stakeholders, is of the view that even though ASU drugs are formulated by methods #different from that used for modern allopathic drugs, the chances of harm that a drug - either modern or ASU, may likely cause are similar and cannot be ruled out. The Committee would also like to point out that definition of 'drug' as given in the Act is applicable to both allopathic and ASU drugs. The Committee, therefore, opines that Ayurvedic, Unani and Siddha drugs should not be excluded from the scope of definition of clinical trial of drugs. (Para 8.6)

The Committee is inclined to agree with the contention of representatives of the cosmetics industry that physiological and therapeutic impact of drugs and cosmetics on human body is completely different. Therefore, there is a need to separate trials of cosmetics from drugs so far as the case of ascertaining their safety and efficacy is concerned. Such a study may be carried out on human volunteers under pre-defined test conditions as per standard industry protocol to ascertain the performance safety and efficacy of a cosmetic. The Committee's attention has also been drawn by ever-increasing number of cosmetic products including Ayurvedic and herbal products flooding "the market-both domestic and international. Reports indicating harmful effects of some of such products on consumers also continue to be received. Main reason for such a situation is lack of any effective mechanism to check such products. The Committee, therefore, strongly feels that like clinical trial envisaged for drugs, similar provision should be there for regulating the dermatological safety studies for cosmetics. Necessary modification in the Bill may, accordingly, be made. (Para 8.7)

The Committee feels that the issue raised by the medical devices industry for having a separate definition of clinical trial for medical devices is very pertinent. It is convinced that owing to the distinct nature and functions of medical devices from that of the drugs, a separate definition of clinical trials for medical devices would be necessary. The Committee also takes note of the clarification given by the Ministry that medical devices are a separate and distinct category. Due to exigency, a few medical devices were being treated under the category of drugs. Now suitable amendment would be made to put these under the category of medical devices, to be defined separately in the Act. The Committee, accordingly, recommends that a separate definition of clinical trial for medical devices may be included in the Act. The Committee is also of the opinion that the definition of clinical trial for medical devices may be formulated in such a manner that it is consistent with the international standards which may read as follows:—

"Any systematic investigation* or *study in or on human subjects, undertaken to assess the safety and/or performance of a medical device" (Para 8.8)

The Committee is inclined to agree with the suggestion in view of the fact that all substances intended for use as components of a drug are included under the definition of 'drug' given in the Principal Act. Thus a product with a marketing authorization, when used or assembled in a different form, can be considered a new drug. (Para 8.9)

Therefore, the Committee recommends that the words "any drug" in Clause 2 (i) (aaii) be replaced with the words "any new drug". The Committee also observes that with

the definition of 'clinical trial' being included in the Act, there was no need of having the same in the Rules. (Para 8.10)

The Committee finds logic in the views aired by the medical devices industry that the current system is inadequate in regulating certification, quality assurance and post marketing surveillance of both imported and locally made medical devices. Given the fact that use of medical devices in healthcare is increasing day by day and also the fact that the industry was at a growing stage, proper regulation is required to meet safety and efficacy norms as also to meet global standards and competitiveness of the medical devices products. The Committee also observes that the Mashelker Committee, in its Report, had dwelt at length on the issue of regulation of medical devices in the country. It was emphasized therein that the medical devices should be specifically defined and relevant rules and guidelines framed for their proper regulation. The other two major recommendations of the Committee were (i) the setting up of a specific Medical Devices Division for proper management of approval, certification and quality of medical devices and an appropriate regulatory mechanism for certification, quality assurance and post-marketing surveillance of both imported and indigenous medical devices. The Committee is, however, surprised to note that the only action proposed in the Bill was substitution of existing definition of medical device by a more detailed definition. Another disturbing feature was continuance of medical devices under drugs. The Committee also feels that mere inclusion of medical devices in the pharmacopeias mentioned in the Second Schedule of the Act alongwith drugs will not serve the purpose. (Para 8.14)

On being asked about the appropriateness of making separate provisions for the regulation, surveillance and monitoring of medical devices, the Ministry had replied in the affirmative. It was assured that keeping in view the distinct nature and functions of medical devices, the same would be defined separately with specific provisions for their regulation, surveillance and monitoring. The Committee, therefore, recommends that suitable modifications may be made in the Act with a separate chapter covering all the related aspects of regulation of medical devices. The Committee also strongly feels that a dedicated division as recommended by the Mashelkar Committee may be set up to deal with regulation, licensing, surveillance and monitoring of uniform implementation of the laws on medical devices in the country. The Committee also recommends that a comparative analysis of the GHTF definition of medical devices and the proposed definition in the Bill may be made and should be followed by necessary modifications in the definition of 'medical device'. (Para 8.15)

The Committee fails to understand the circumstances leading to such an initiative by the Department of Science and Technology with the nodal Ministry obviously being taken unaware. The Committee can only hope that this issue is resolved at the earliest. (Para 8.16)

The Committee's attention was also drawn, both during its study visits and meetings at Delhi, with all the witnesses representing different categories of stakeholders – be it small and big pharma industry associations, various State Governments, Drugs Controllers/Inspectors/ Associations/bodies/associations from ASU sector – that recommendation of the Mashelker Committee was for a strong, well-equipped and professionally managed CDSCO, to be given the status of Central Drugs Administration and not creation of a Central Drugs Authority.

After making a comparative analysis of Mashelker Committee recommendations and the different provisions of the Bill, the Committee was surprised to note that the contention of various witnesses was justified. The Committee would like to point out the following specific recommendation made by the Mashelker Committee.

"The existing infrastructure at the Centre and States was not adequate to perform the assigned functions efficiently and speedily. Creating another authority such as a National Drug Authority (NDA) will not solve the problem at hand. It was essential to strengthen the existing organisations to enable them to undertake all the functions envisaged for NDA. A strong, well-equipped, empowered, independent and professionally managed CDSCO, which could be given the status of Central Drug Administration (CDA), reporting directly to Ministry of Health would be the most appropriate solution." (Para 9.6)

The Committee observes that the Mashelkar Committee was an Expert Committee constituted by the Government in 2003 to examine all the aspects relating to quality control of drugs and their regulatory mechanism. The Committee also notes that the aforesaid conclusive recommendation made by the Mashelkar Committee has been arrived at after very intensive consultations with all the stakeholders. Not only this, in the Questionnaire sent to all the State Drug Controllers by the Mashelkar Committee, one of the questions asked was if CDSCO was to be strengthened, then would there be still a need for a National Drug Authority. In response, 19 out of 31 States (with 4 no comments) stated that there was a definite need to strengthen the Central Administration and if CDSCO could perform the statutory functions efficiently, there was certainly no need of NDA. The Committee also takes note of the fact that out of the 19 States which responded, five were Andhra Pradesh, Goa, Gujarat, Maharashtra and Tamil Nadu which belonged to the seven States having more than 75 percent drug manufacturing units in the country. (Para 9.8)

In order to have first-hand information at the ground level, the Committee had undertaken study visits of all the States having 75 per cent of drug manufacturing units in the country. The only exception was West Bengal. This exercise of the Committee was supplemented by extensive discussions in a series of meetings held at Delhi and also feedback received in response to the press release. It would not be wrong to conclude that Committee's experience has also matched with the Mashelker Committee's findings. In view of the above assessment, the Committee is not inclined to accept the reasoning offered by the Secretary, Ministry of Health and Family Welfare for making such a major departure from the recommendations made by an Expert Committee. (Para 9.9)

The Committee would also like to draw attention to the following statement made in the Pharmaceutical Policy, 2002:—

"The Ministry of Health and Family Welfare would set up a world class Central Drugs Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective network of drugs standards enforcements administrations in the States with the CDSCO as a nodal centre, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals." (Para 9.10)

The Committee fails to understand as to why, instead of implementing the recommendations of the Mashelkar Committee for strengthening, modernizing, restructuring and reforming the existing Central Drugs Standard Control Organisation (CDSCO) into a world class system, the Government has entered into a rigmarole of setting up a new Authority. Central Drugs Authority, a small body primarily having members with administrative background taking the place of the two Drug Technical Advisory Boards having technical expertise from allopathic and ASU drug sector, is simply not acceptable to the Committee. The Committee, accordingly, recommends the setting up of a "Central Drug Administration" as an independent body under the Ministry of Health and Family Welfare with its headquarters at Delhi, with its Zonal and Sub-Zonal offices at State level, by strengthening, modernizing and restructuring the CDSCO. (Para 9.11)

The Committee observes that broadly–speaking, the proposed set up under the Central Drugs Authority is based on the set-up of Central Drug Administration proposed by the Mashelkar Committee. Ten Divisions are proposed under both the set-ups, the only difference being a separate division of Indian System of Medicine and Homoeopathy under the Ministry set-up. Another major difference between the two set-ups is that the Central Drugs Authority would be replacing the two drugs Technical Advisory Boards and performing their functions and also advising the Drug Controller General (I), who will be the Member-Secretary of CDA on all matters relating to drugs and cosmetics. Since the Committee is not in favour of creation of a separate "Central Drugs Authority", and has recommended the restructuring of CDSCO as "Central Drug Administration" - an independent body under the Ministry of Health and Family Welfare, the Central Drug Administration as suggested by the Mashelker Committee may be brought into effect as early as possible. (Para 9.13)

Representatives of the organisations from AYUSH-sector strongly advocated the need for having an Additional Drug Controller (AYUSH), keeping in view the ever increasing acceptance of AYUSH drugs. The Committee is inclined to agree with this view point. The Committee finds that the Ministry, while elaborating the proposed plan of expansion of the offices and the necessary expansion in the number of senior-level officers and supporting staff that would be required for its efficient functioning under the CDA, has stated that the post of Drug Controller (India) would be raised from the present level of the grade of Joint Secretary to Government of India to that of the grade of Additional Secretary to Government of India. It was also proposed to revive One post of Additional Drugs Controller (AYUSH) to assist DCG(I) in the quality control and regulation of ASU products, and along with it, one more post of Additional Drugs Controller (India) was proposed to be created for assisting DCG(I) in all other matters. (Para 9.14)

The Committee observes that in view of the wider mandate of a "Central Drug Administration" necessary expansion in the number of senior-level officers and supporting staff would be required for its efficient functioning. The Committee has been informed that an elaborate plan of expansion has been approved and being brought into shape. A special drive to fill up all the vacant posts in the CDSCO and the Drug Labs was already underway. 62 new posts of Drug Inspectors and 10 posts of Technical officers have already been created for strengthening of CDSCO and mitigating the problem of shortage of Drug Inspectors to some extent. The Committee observes this as a welcome measure. (Para 9.15)

Under new chapter 1A, Section 5B speaks of the term of office of Chairperson and Members of Central Drugs Authority; Section 5C relates to salaries, allowances, pensions and other conditions of service of Members; Section 5D is regarding vacancies, etc. not to invalidate proceedings and Section 5E refers to staff of the Central Drugs Authority.

In view of the Committee's disagreement with the Ministry's proposal for creating a separate Central Drugs Authority, Sections 5B, 5C, 5D, and 5E mentioned above stand void. (Para 9.16)

The Committee found that it was a general perception among majority of the stakeholders that with the Centralized licensing coming into effect, every activity including procedural formalities would be centred in Delhi leading to number of hurdles being faced by the drug manufacturing units, specially small units. The Committee, however, observes that the apprehension stands suitably addressed, keeping in view the fact that CDA through its network of Zonal and Sub-Zonal offices and port offices would have its presence in most of the States where there is significant concentration of drug manufacturing activity. This would also facilitate Centralized licensing and Good Manufacturing Practices (GMP) Certification. Besides, these offices would also take care of concerns regarding inordinate

delays in issuance of licenses etc. raised by the stakeholders subsequent to centralized licensing coming into force. The Committee is of the view that in this age of IT advancement, the restructured CDSCO with its ten divisions having a well-defined jurisdiction and network of subordinate offices spread across the country, apprehension about delay factor do not seem to be genuine. The notion of the States that the existing system is superior to the proposed central licensing on the grounds that it offers better control by the States pre-supposes the existence of an efficient infrastructure and quality of enforcements in every State. The Committee observes that this assumption is far removed from the ground realities in majority of the States. (Para 9.21)

In this regard, the Committee takes note of the specific recommendation for licensing of drug manufacturing units by the Central Drug Administration made by the Mashelkar Committee after a detailed analysis of ground realities, recommendations of earlier expert Committees and views of all the stakeholders. Issue of non-uniformity of enforcement at the State level with regard to quality control of drugs was the main factor behind such a recommendation made by all the bodies like NRHC, Hathi Committee, Estimates Committee (Seventh Lok Sabha) and Mashelkar Committee. Committee's attention has been drawn by the guiding principle driving this suggestion, aptly summarized in para 33 of the Hathi Committee Report quoted below:—

> **"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."** (Para 9.22)

The Committee agrees with the assessment made by all the earlier Committees that there was an urgent need for having a world class drug regulatory system in the country which can effectively handle the health concerns of one sixth of humanity. The Committee can only reiterate that wherever the health and safety of life of the people is concerned, cutting across regional/State specific interests/issues, the emphasis should be protecting the same. (Para 9.23)

The Committee's attention has been drawn to the following specific excerpts from the Mashelker Committee Report:—

> ***"The matter of licensing of manufacturing units by Central Government has been considered on several occasions in the past. During* 1988-89, *the reports of poor quality of I V fluids and substandard blood made the Central Government focus on the issue of having a stricter control on these products. This resulted in the amendment of Rules to provide for dual licensing mechanism in December* 1992, *the Central authority being the License Approving Authority (CLM) and the States being the license giving authorities. The idea was to improve the quality and implement uniform norms but the experience has not been encouraging. The change, however, has not made the desired level of impact."***
>
> ***"The National Human Rights Commission in their order of 1999 clearly stated that: the present dual system of control does not appear to have achieved desired effectiveness, therefore, Central Government must immediately take steps to examine the entire system of Licensing (including loan licensing), Certification and Complaint handling under effective Central Government control through CLAA or other suitable means"*** (Para 9.26)

The Committee observes that though the method of progressive increase in the number of items under CLAA seems to be a good measure aimed at smooth transition of the licensing activity from the States to the Center, it has its own apprehensions regarding the timely disposal of applications, effective co-ordination with the industry, interpretation of law under the CLAA system. The facts stated above by the witnesses and supported by the findings of the Mashelkar Committee all point out that the present mechanism under the CLAA system is far from satisfactory. The Committee was also given to understand that the number of units involved was very large, volume of records need to be handled was also enormous and every unit would have to be inspected after one year. Keeping in view the tremendous strain the above-mentioned exercise was likely to have on the Central Government; transition period from State licensing to centralized licensing may be spread over a period of ten years. On Committee's showing its concern on such a long time-span, Secretary, Health admitted that it was too long a period. He assumed that every effort would be made to switch over to centralized licensing in six to seven years. (Para 9.27)

The Committee was surprised to note that the proposed move was in direct contravention to the roadmap in three phases drawn by the Mashelkar Committee for implementation of centralized licensing. During Phase-I, the manpower was to be strengthened and infrastructure of Central Drug Administration was to be in place. Expansion of zonal and sub-zonal offices, creation of additional infrastructure for new offices in States, creation of considerable number of additional senior level and supporting posts are the specific requirements for implementation of the above recommendation. During Phase-II, the licensing functions of States having minimum concentration of manufacturing units were to be shifted to the Centre, and during Phase-III, licensing in seven States having maximum concentration of drug manufacturing units (75 per cent) of licenses was to be taken over by the Central Drug Administration. All this exercise was to be completed within a span of three years. (Para 9.28)

On being asked about reasons for not accepting this specific recommendation of the Mashelkar Committee, the Secretary informed that this issue was also discussed with Dr. Mashelkar who has agreed to the progressive transfer from the State Licensing to the Central licensing rather than going State by State. The Committee has its own reservations on not, going for the roadmap having a specific time frame drawn by the Expert Committee for switch-over to centralized licensing which was the outcome of extensive interactions with all concerned based on the ground-realities. The Committee would also like to point out that so far no plan of action having a specific time-limit has been drawn by the Ministry. As indicated by the representative of the Ministry, it can be anywhere from five to ten years. Apprehension of the Committee on this vital issue is strengthened by the fact that a reputed consultancy firm/consultant would be engaged by the Ministry for suggesting the roadmap based on the best practices available across the globe. The Committee can only conclude that against such a background, chances of things falling into place in the near future seem to be very dim. The Committee feels that the roadmaps drawn by the Mashelkar Committee is backed by sound logic and fully endorses the line of action pointed out by it for implementing the centralized licensing of drug manufacturing units. The Committee, therefore, strongly recommends that every effort should be made for implementing the same within the specified time-frame. (Para 9.29)

The Committee is inclined to agree to the view-point of the stakeholders that they would be at a serious disadvantage in terms of undue hardship, wastage of precious time and additional financial burden especially for small scale units located far away from Delhi. Since the Centre would be carrying out its licensing operations from its various zonal and sub zonal offices placed in each State/UT, the Committee recommends that the appellate

authority for grievance redressal of the aggrieved party should be placed in such offices, keeping in mind the comparative disadvantages that the small scale pharma units would otherwise face. (Para 9.32)

The Committee notes that the proposed Fund for Central Drugs Authority will be receiving all grants, fees and charges levied for different purposes. Only initial funds are sought to be provided by the Central Government. The Committee apprehends that this would be grossly inadequate. Given the fact that strengthening of the CDSCO as Central Drug Administration would require expanding the Zonal and Sub-zonal offices, creation of additional infrastructure for new offices in the States and manpower to match equally, for setting up a world class Central Drug Administration, substantive additional funds would be required for such activities. The Committee strongly feels that the Central Government will have to play a major role. In view of majority of the States facing funds constraints, the required funds will have to be provided by the Central Government. It, therefore, suggests that like major social sector central/centrally sponsored schemes, the task of setting up a world class Central Drug Administration may be taken up in a mission mode. Accordingly, a Central Fund meant for Central Drug Administration with major contribution from the Centre in the form of a Corpus Fund may be set up. (Para 9.35)

In view of the Committee's disagreement with the proposal for creating a separate Central Drugs Authority, Clause 5L stands void. (Para 9.36)

In the light of observations made by the Committee with regard to the definition of the term 'clinical trial', permission for conducting clinical trials of only investigational new drugs and cosmetics and medical devices may be included. Secondly, under the proposed restructured CDSCO as envisaged by the Mashelkar Committee, out of the ten divisions which would be functioning at the Headquarters, there are two separate divisions one for New Drugs and Clinical Trials, and the other for Medical Devices and Diagnostics. The Committee, accordingly, recommends that these two Divisions may be entrusted with the responsibility for granting permission for conducting clinical trials for drugs and dermatological safety studies for cosmetics, and evaluation of safety and performance of medical devices and other allied issues. (Para 10.3)

The Committee, after carefully weighing the contention of the stakeholders as well as of the Department, is of the view that the provisions of punishment, for conducting Clinical trial without permission should be retained. Such a provision would act as a deterrent for violators of law. The Committee is disinclined to agree that academic research would be brought to a halt by such a provision. It contends that if the punishment norms for academic research are relaxed, chances of drug manufacturing companies carrying out trials through private institutions by financially supporting them cannot be ruled out. The Committee suggests that in such cases the onus of proving themselves not guilty should be fixed on the Institutions where the students are conducting academic research. (Para 10.6)

The Committee would also like to point out that a careful perusal of the clause reveals that the punishment would vary with the degree and nature of violation. Thus the question of this provision being very harsh does not arise. The Committee also feels that punishments for cases related to 'drugs' and those related to 'cosmetics' should be separate and clearly defined. Similarly, those cases related to 'medical devices' should be dealt separately under a chapter concerning regulation of medical devices, as mentioned earlier. (Para 10.7)

The Committee is of the opinion that the DTAB is a highly technical body with representation of experts from various fields and whose main function is to advise the

Central Government and the State Governments on technical matters arising out of the administration of the Act and to carry out the other functions assigned to it under the Act. Being the most important body under the Central Drug Administration, the Committee feels that DTAB should be retained. The issue has been dealt with earlier also in this Report. Hence, it recommends that Section 5 of the Principal Act which deals with the Constitution and Composition of the Drugs Technical Advisory Board (DTAB) may be retained. (Para 11.5)

The Committee observes that, keeping in view the need for quality control of drugs across the country, the proposed move of bringing all the Central Drug Laboratories under the control of one central agency is called for. However, in view of the Committee's recommendation for having Central Drug Administration in the form of re-structured CDSCO, all the Central Drug Laboratories may be placed under the Division of Quality Control Affairs under the Central Drug Administration. (Para 12.4)

In view of the Committee's recommendations to retain DTAB at Clause 5, the proposed change at Section 7 (a) of the Act stands void. Drugs Consultative Committee as envisaged may continue. (Para 13.2)

In view of the Committee's recommendation at Clause 5 to retain DTAB, the provision under Section 33C of the Principal Act for constitution of ASU DTAB may be retained. The proposed clause 19 of the Bill accordingly, stands void. (Para 15.2)

In view of the Committee's recommendation to retain Drug Consultative Committee as envisaged in Section 7(2)(b) of the Principal Act, the proposed change in section 33D (1) of the Act stands void. (Para 16.2)

In view of Committee not agreeing to the replacement of DTAB by the CDA, the consequential changes in the relevant Clauses stand void. (Para 17)

NOTES OF DISSENT

To

The Chairman,
Standing Committee on Health and Family Welfare, Parliament of India,
Parliament House Annexe,
New Delhi.

Subject: Note of dissent on the Report on the Drugs and Cosmetics (Amendment), Bill 2007.

Dear Sir,

This is to state you that it is not possible for me as a Member of the said Committee to endorse the draft-report of the Committee on the Drugs and Cosmetics (Amendment), Bill 2007 in the present form as the principal objective of the said Bill is setting up of the "Central/National Drugs Authority" thereby centralizing the powers of the State Governments. The very intention of the Bill is to take away the powers of the State Government in terms of Licensing; this would be tantamount to centralizing the authority for Licensing in a vast country like India and might be detrimental to a healthy and balanced regulation of drugs industries in the country. This enactment will also deprive the State Governments financially by scuttling the revenues earned through issuance of licenses to the manufacturers.

Moreover, this Bill might have constitutional implications, jeopardizing the Centre-State relations and infringement on the sovereignty of the States.

Though the spirit of the Bill is acceptable and, I have no objection if Central Drug Authority is set up in place of DTAB without investing this body with powers to issue licenses under Section 18 (c) and Section-33EEC.

Therefore, considering the above aspects I, have serious reservation to support the Bill. Hope, you will appreciate the position.

With regards.

Sd/-

(DR. RAMCHANDRA DOME)

To

The Chairman,
Standing Committee on Health and Family Welfare,
Parliament of India,
New Delhi.

Dear Sir,

I would like to put the note of dissent on the report on the Drugs and Cosmetics (Amendment) Bill, 2007 for the following reasons—

(i) Formation of CDA and thereby centralizing process of Licensing, taking away the powers of State Governments is not desirable.

(ii) It will jeopardize Centre-State relation as it encroaches upon the powers of State Governments, which is against federal structure of the country.

I request you not to recommend this Bill for enactment.

Thanking you,

Sd/-

(PANNIAN RAVINDRAN)

MINUTES

II
SECOND MEETING
(2007-08)

The Committee met at 3.00 P.M. on Tuesday, the 9th October, 2007 in Committee Room ''D'', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Amar Singh — *Chairman*

RAJYA SABHA

2. Prof. P.J. Kurien
3. Shrimati Maya Singh
4. Shri Digvijay Singh
5. Shrimati Viplove Thakur

LOK SABHA

6. Shrimati Bhavana P. Gawli
7. Shrimati Maneka Gandhi
8. Shri B. Vinod Kumar
9. Shri Rajendra Kumar
10. Shrimati Susheela Bangaru Laxman
11. Shri S. Mallikarjuniah
12. Dr. Chinta Mohan
13. Shri Nihal Chand
14. Shri Pannian Ravindran
15. Shri Uday Singh
16. Dr. Karan Singh Yadav

SECRETARIAT

Shri R.B.Gupta, Joint Director

Shri T.N. Pandey, Deputy Director

Shri Dinesh Singh, Committee Officer

WITNESSES FROM MINISTRY OF HEALTH AND FAMILY WELFARE

1. Shri Deepak Gupta, Additional Secretary
2. Shri Devashish Panda, Joint Secretary
3. Dr. M. Venkateshwarlu, Drugs Controller General (India)

2. At the outset Chairman welcomed Members of the Committee and apprised them of the agenda of the meeting *i.e.* evidence of the Additional Secretary, Department of Health and Family Welfare on the Drugs and Cosmetics (Amendments) Bill, 2007. He also informed Members that another Bill, namely the Clinical Establishment (Registration and Regulation) Bill, 2007 has also been

referred to the Committee for examination and report and a Press Release inviting views of the various stakeholders on the subject would be issued shortly.

3. Thereafter, Committee heard the representatives of the Department of Health and Family Welfare on the various issues arising out of Drugs and Cosmetics (Amendments) Bill, 2007. Initially, the Joint Secretary of the Department made a brief power-point presentation on the Bill. During the course of discussion, Members raised serious reservations about the composition of the Central Drugs Authority of India (C.D.A.I) and felt that the proposed provisions relating to its composition have serious implications on the autonomy of the (C.D.A.I). The Committee also pointed out that there is no provision in the Bill for setting up of an appellate authority. Members also raised a number of other queries, some of which were replied by the witnesses. Thereafter the Committee directed the representatives of the Ministry to furnish its comments on the remaining queries shortly.

4. In order to examine the entire spectrum of the issues involved in the Bill on the issue of drug testing and other related matters the Committee decided to hear the views of some of the representatives of small and large scale pharmaceutical companies/industries on a later date.

5. A verbatim record of the proceedings was kept.

6. The Committee then adjourned at 4.15 P.M.

III
THIRD MEETING
(2007-08)

The Committee met at 3.00 P.M. on Wednesday, the 3lst October, 2007 in Committee Room ''E'', Basement, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. P.J. Kurien — *In the Chair*

RAJYA SABHA

2. Shrimati Maya Singh

LOK SABHA

3. Shrimati Maneka Gandhi
4. Shri B. Vinod Kumar
5. Shri Rajendra Kumar
6. Shrimati Susheela Bangaru Laxman
7. Shri S. Mallikarjuniah
8. Shri Rasheed Masood
9. Dr. Chinta Mohan
10. Shri Nihal Chand
11. Dr. R. Senthil
12. Dr. Arvind Kumar Sharma
13. Dr. Karan Singh Yadav
14. Shri R.L. Jalappa

SECRETARIAT

Shrimati Vandana Garg, Joint Secretary

Shri R.B.Gupta, Joint Director

Shrimati Arpana Mendiratta, Deputy Director

Shri Dinesh Singh, Committee Officer

WITNESSES

A. * * *

B. **On the Drugs and Cosmetics (Amendment) Bill, 2007**

(i) Dr. R.K.Srivastava, Director General, Health Services.

(ii) Dr. M. Venkateshwarlu, Drugs Controller General (India) represented Central Drugs Standard Control Organisation and Drugs Consultative Committee.

*** Relates to other matter.

(iii) Dr. K.R. Mani, Director, Central Research Institute, Kasuali (CRI), represented Drugs Technical Advisory Board for Allopathy.

(iv) Dr. M.C. Sharma, Director, National Institute of Ayurveda (NIA), Jaipur represented Drugs Technical Advisory Board for AYUSH.

(v) Dr. P.K. Guha, Director, Central Drugs Laboratory (CDL), Kolkata.

(vi) Dr. Gopa Ghosh, Director-in-charge, Central Drugs Laboratory (CDL), Mumbai.

2. In the absence of Chairman of the Committee, Prof. P.J. Kurien presided over the meeting.

3. The Committee discussed its future programme. Given the wider ramifications of the two Bills *i.e.* the Drugs and Cosmetics (Amendment) Bill, 2007 and the Clinical Establishments (Registration and Regulation) Bill, 2007 under its consideration, the Committee was of the opinion that there was a need to interact with a number of stakeholders and State Governments and also undertake study visits before finalizing the Reports. The Committee, accordingly, approved an action plan for the purpose.

4. Report on the Drugs and Cosmetics (Amendment) Bill, 2007 was to be presented by 22nd November, 2007. However, the Committee had proposed interaction with quite a few stakeholders involving study visits. The Committee, therefore, decided to seek extension of time for six months *i.e.* upto 22nd May, 2008 for presentation of its Report on the Drugs and Cosmetics (Amendment) Bill, 2007 and authorized Chairman of the Committee to approach Hon'ble Chairman for the purpose.

5. * * *

6. The Committee, then, heard the witnesses on the Drugs and Cosmetics (Amendment) Bill, 2007. The Drugs Controller General (India) made a brief presentation on the subject. The Chairman and Members raised queries on various aspects of the Bill, particularly the composition and autonomy of the proposed Central Drugs Authority, and functioning of the Drug Laboratories in the country. The witnesses replied to some of the queries. The Committee directed the Secretariat to forward a set of questionnaire to the Secretary, Department of Health and Family Welfare for detailed replies at the earliest on the aforesaid Bill.

7. A verbatim record of the proceedings was kept.

8. The Committee then adjourned at 5.15 P.M.

*** Relates to other matter.

IV
FOURTH MEETING
(2007-08)

The Committee met at 3.00 P.M. on Wednesday, the 5th December, 2007 in Committee Room ''A'', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Amar Singh — *Chairman*

RAJYA SABHA

2. Prof. P.J. Kurien
3. Shri Su. Thirunavukkarasar
4. Shri Lalhming Liana

LOK SABHA

5. Shrimati Bhavana P.Gawali
6. Dr. Ram Chandra Dome
7. Shrimati Maneka Gandhi
8. Shri S. Mallikarjuniah
9. Shri Pannian Ravindran
10. Dr. R. Senthil
11. Dr. Karan Singh Yadav

SECRETARIAT

Shrimati Vandana Garg, Joint Secretary

Shri R.B.Gupta, Joint Director

Shri Dinesh Singh,Committee Officer

At the outset, the Chairman of the Committee welcomed Members to the meeting and briefed them about the business pending before the Committee.

2. * * *

3. * * *

4. The Committee then discussed the future course of action concerning the examination of the two Bills, namely, the Drugs and Cosmetics (Amendment) Bill, 2007 and the Clinical Establishments (Registration and Regulation) Bill, 2007. The Chairman of the Committee apprised the members of the progress made towards examination of the said Bills and also informed them that a number of stakeholders from across the country have furnished memoranda containing their views on the Bills and have also desired to appear in person before the Committee to share their suggestions and concerns. The stakeholders who have furnished their comments and are desirous of appearing in person before the Committee include Association of Large and Small Pharmaceutical

*** Relate to other matters.

companies, NGOs, and Associations of Private Hospitals/Nursing Homes/Diagnostic Centres/ Pathological Centres. The Chairman further informed the Members that the representatives of Government Hospitals, Experts, representatives of State Branches of IMA, M.C.I., Pharmacy Council of India, ICMR, BIS etc., will also be called to appear before the Committee to share their views on the said Bills. The Committee felt that in order to examine the whole gamut of issues involved in the Bills, study tours needed to be undertaken before finalizing the Reports. Since the deadline given by the Hon'ble Chairman, Rajya Sabha to the Committee to submit its Report on the Clinical Establishments (Registration and Regulation) Bill, 2007 expires on 27th December 2007, and keeping in view the wider ramifications of the Bill and also the preoccupation of the Committee with examination of Demands for Grants 2008-09, the Committee decided to seek an extension of time for six months, *i.e.* 27th June 2008, for presenting its Report on this Bill.

5. The Committee accordingly authorized the Chairman to seek necessary permission from the Hon'ble Chairman, Rajya Sabha *** also to undertake study visit to Trivandrum, Bangalore, Chennai and Hyderabad in the second week of January, 2007, in the first phase.

6. The Committee adjourned at 3.40 P.M.

*** Relates to other matter.

V
FIFTH MEETING
(2007-08)

The Committee met at 11.00 A.M. on Friday, the 25th January, 2008 in Committee Room ''A'', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

1. Shri Digvijay Singh — *In the Chair*
2. Prof. P.J. Kurien
3. Shrimati Maya Singh
4. Shri Lalhming Liana

LOK SABHA

5. Shrimati Maneka Gandhi
6. Shri B. Vinod Kumar
7. Shri S. Mallikarjuniah
8. Shri Rasheed Masood
9. Shri Nihal Chand
10. Shrimati K. Rani
11. Dr. Arvind Kumar Sharma
12. Dr. Karan Singh Yadav

SECRETARIAT

Shrimati Vandana Garg, Joint Secretary
Shri R. B. Gupta, Director
Shrimati Arpana Mendiratta, Deputy Director
Shri Dinesh Singh, Committee Officer

WITNESSES

The Drugs and Cosmetics (Amendment) Bill, 2007

A. **Representatives of Confederation of Indian Industry**

1. Shri Alok Mishra, Area Manager International, South Asia, Johnson and Johnson
2. Shri Ajay Pitre, Managing Director, Sushrut Surgical Pvt. Ltd.
3. Shri Pavan Choudary, CEO and MD, Vygon India Pvt. Ltd.
4. Shri Ajay Maggo, Director, Finance and Accounts, Philips Electronic India Ltd.

B. **Representatives of SME Pharma Industries Confederation**

1. Shri Lalit Kumar Jain, Vice Chairman
2. Shri Jagdeep Singh, Secretary General

3. Shri J. Mathew, Representative, SME Pharma Industries
4. Shri Ramesh Arora, Confederation
5. Shri B.K. Gupta

* * *

2. In the absence of Chairman, Shri Digvijay Singh, M.P. presided over the meeting. At the outset, the Chairman welcomed Members to the meeting and apprised them about the progress made so far with regard to examination of the Drugs and Cosmetics (Amendment) Bill, 2007 and the Clinical Establishment (Registration and Regulation) Bill, 2007, including the study visit undertaken by the Committee from 7th to 14th January, 2008 to Bengaluru, Thiruvananthapuram, Chennai and Hyderabad.

3. * * *

4. In view of the fact that the Committee was yet to interact with a large number of stakeholders including Drugs Manufacturers Associations concentrated in northern and western parts of the country, the Committee decided to seek further extension of time upto the last day of the Budget Session 2008 for the presentation of its Report on the Bill. The Committee reiterated its decision taken during its study visit referred to above for undertaking another study visit to Indore, Ahmedabad, Mumbai and Goa from 12th to 19th February, 2008, on both the Bills. The Committee authorized its Chairman to seek necessary permission from Hon'ble Chairman, Rajya Sabha in this regard.

5. Thereafter the Committee heard the representatives of the Confederation of Indian Industries and SME Pharma, on the Drugs and Cosmetics (Amendment) Bill, 2007.

6. The representatives from Confederation of Indian Industries (CII), speaking on the Drugs and Cosmetics (Amendment) Bill, 2007, *inter alia*, stated that there is a need for separate provisions for regulation of medical devices, instruments, apparatus, appliances, materials etc., since provisions relating to devices cannot be clubbed with the provisions relating to drugs and cosmetics in view of the completely different characteristics of devices and equipments as compared to drugs and cosmetics. They further stated that the Government is proposing to set up the Medical Devices Regulatory Authority of India (MDRA). The MDRA being a national certifying and regulatory agency in India for medical equipment and devices would be expected to formulate appropriate guidelines. They pointed out that it was very important to ensure that there was no regulatory overlapping for the medical devices industry. It was informed that the Draft Medical Device Regulation Bill, 2006 and the proposed Medical Device Regulatory Authority (MDRA) in this bill was based on tenets of European Medical Device Directive, which was largely accepted even by the Global Harmonization Task Force (GHTF) recommendations. They stated that such an independent Act or such a separate comprehensive sub-section for medical devices within the Drugs Control Act and the Rules framed thereunder are essential for appropriate and comprehensive regulation of medical devices and that just the existing Drugs Control Act and the Rules framed thereunder (without this special comprehensive sub-section for Medical Devices) should not be made applicable to medical devices.

7. The representatives from SME Pharma were of opinion that centralizing the licensing system would lead to concentration of powers with the Central Government and would not be effective in tackling the moot problem of spurious drugs and fake drugs. They were also of the opinion that creation of zonal offices catering to four to five States would not go in the interest of the SSI and the said Bill was designed to decimate SSI by large scale Pharma industries and MNCs functioning in Pharma sector. They further contended that with the creation of Central Drug

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*** Relate to other matters.

Authority, there would be problems and difficulties in investigation of cases of sub-standard/ spurious drugs as State Drug Control Officers may not have jurisdiction to inspect the manufacturing establishments leading to difficulties in answering questions in the State Assemblies owing to its responsibility in providing quality manufacturing of medicines within the States.

8. * * *

9. * * *

10. * * *

11. A verbatim record of the proceedings was kept.

12. The Committee then adjourned at 1.00 P.M.

*** Relate to other matters.

RECORD OF DISCUSSION OF THE MEETING OF THE DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

The Committee met at 3.00 P.M. on Monday, the 11th February, 2008, in Committee Room ''D'', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Amar Singh — *Chairman*

RAJYA SABHA

2. Shrimati Viplove Thakur

LOK SABHA

3. Shrimati Maneka Gandhi
4. Shrimati Susheela Bangaru Laxman
5. Shri Pannian Ravindran
6. Shri Uday Singh
7. Shrimati Yashodhra Raje Scindia

SECRETARIAT

Shri R. B. Gupta, Director

Shrimati Arpana Mendiratta, Deputy Director

Shri Dinesh Singh, Committee Officer

WITNESSES

Representatives of Department of Health and Family Welfare

1. Dr. R. K. Srivastava, Director General, Health Services
2. Shri K. Ramamoorthy, Joint Secretary
3. Dr. H. C. Goel, Additional DGHS

2. At the outset, the Chairman welcomed Members to the meeting and apprised them about the progress made so far, with regard to examination of the Drugs and Cosmetics (Amendment) Bill, 2007 and the Clinical Establishment (Registration and Regulation) Bill, 2007, including the study visit undertaken by the Committee from 7th to 14th January, 2008 to Bengaluru, Thiruvananthapuram, Chennai and Hyderabad and the proposed study visit to Indore, Ahmedabad, Mumbai and Goa from 12th to 19th February, 2008. The Chairman also briefed them about the need to seek a second extension of time for presentation of the Report on the Clinical Establishments (Registration and Regulation) Bill, 2007. However, since the necessary quorum to transact official business could not be achieved, the Committee decided to defer taking a decision in this regard.

3. * * *

*** Relates to other matter.

4. Though there was lack of quorum, the Committee heard oral evidence of the DGHS and the Joint Secretary, Department of Health and Family Welfare on the Paramedical and Physiotherapy Central Councils Bill, 2007. Members raised a number of queries, some of which were answered by the witnesses. The DGHS was asked to furnish written replies to those queries of Members, which remained unanswered.

5. A verbatim record of the proceedings was kept.

6. The Committee then adjourned at 4.02 P.M.

XI
ELEVENTH MEETING
(2007-08)

The Committee met at 3.00 P.M. on Wednesday, the 7th May, 2008 in Room No. '63', First Floor, Parliament House, New Delhi.

MEMBERS PRESENT

1. Shri Amar Singh — *Chairman*

RAJYA SABHA

2. Prof. P.J. Kurien
3. Shri Digvijay Singh

LOK SABHA

4. Shrimati Maneka Gandhi
5. Shri Rajendra Kumar
6. Shrimati Susheela Bangaru Laxman
7. Dr. Chinta Mohan
8. Shrimati K. Rani
9. Shri Pannian Ravindran
10. Dr. Karan Singh Yadav
11. Shrimati Yashodhra Raje Scindia

SECRETARIAT

Shrimati Vandana Garg, Joint Secretary
Shri R. B. Gupta, Director
Shrimati Arpana Mendiratta, Deputy Director
Shri Dinesh Singh, Committee Officer

WITNESSES

Federation of Indian Chambers of Commerce and Industry (FICCI)

1. Shri Anjan Bose, Chairman FICCI Medical Electronic Forum,
2. Shri Ram Sharma, Country Manager-India, Nepal, Sri Lanka,
3. Shri Sanjay Banerjee, Managing Director, Zimmer India,
4. Dr. Kulwant S. Saini, Vice-President, Johnson and Johnson
5. Shri R. Kailasnath, Managing Director, CPC Diagnostics, Chennai,
6. Shri Sumati Randeo, Manager-Regulatory Affairs,
7. Shri V. K Topa, Advisor to Secretary General, FICCI,
8. Shri Bishakha Bhattacharya, Additional Director, FICCI

Voluntary Organization in Interest of Consumers' Education (VOICE)

1. Prof. Sri Ram Khanna,
2. Shri H.K. Awasthi

2. At the outset, the Chairman welcomed Members to the meeting and apprised them about the progress made so far regarding the examination of the Drugs and Cosmetics (Amendment) Bill, 2007.

3. The Committee heard representatives of the Federation of Indian Chambers of Commerce and Industry (FICCI) on the Drugs and Cosmetics (Amendment) Bill, 2007. Members sought clarifications which were replied to. The Committee also directed the representatives of FICCI to forward their comments on the Questionnaire on the Bill prepared by the Secretariat.

4. The Committee, thereafter, took oral evidence of the representatives of VOICE on the Bill. Members sought clarifications which were replied to. During the course of interaction with the representatives of VOICE, the Committee was given to understand that many African countries were being flooded with fake/substandard drugs and India was seen as one of the major fake drug manufacturing countries. The Committee decided to seek a status note in this regard from the Ministry of Health and Family Welfare.

5. Representatives of VOICE also apprised the Committee that their organization got the fairness cream of many brands tested from NABL accredited Laboratories and barring a few, the results of most of the brands including some reputed ones showed a considerable gap between their claims and outcomes of usage. The witnesses were directed to forward a copy of their report.

6. * * *

7. A verbatim record of the proceedings was kept.

8. The Committee decided to meet again at 3.00 P.M. on the 27th May, 2008.

9. The Committee then adjourned at 4.16 P.M.

*** Relates to other matters.

RECORD OF DISCUSSION OF THE MEETING OF THE DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

The Committee met at 3.00 P.M. on Tuesday, the 27th May, 2008 in Committee Room No. 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Amar Singh — *Chairman*

RAJYA SABHA

2. Shrimati Maya Singh
3. Shri Digvijay Singh
4. Shri Rajeev Shukla

LOK SABHA

5. Shri Rajendra Kumar
6. Shrimati Susheela Bangaru Laxman
7. Shri S. Mallikarjuniah
8. Dr. Chinta Mohan
9. Shri Pannian Ravindran
10. Dr. Karan Singh Yadav

SECRETARIAT

Shrimati Vandana Garg, Joint Secretary

Shri R. B. Gupta, Director

WITNESSES

I. * * *

II. **Representatives of Ayurveda, Siddha and Unani Drug Technical Advisory Board (ASUDTAB):—**

1. Dr. S.K. Sharma, Advisor (Ayurveda), Department of AYUSH
2. Dr. S.S. Handa, Former Director, RRL (CSIR), Jammu
3. Dr. P. Jaya Prakash Naraynan, Rtd. Principal, Siddha Medical College, Chennai.
4. Prof. M.C. Sharma, Director, N.I.A, Jaipur
5. Dr. V.R. Seshadri, Secretary, IMP, Co-op. Pharmacy and Stores Ltd. Chennai.
6. Dr. Asad Mueed, Director (R&D), Hamdard Wakf Laboratories, New Delhi
7. Prof. Shakir Jamil, Dean, Jamia Hamdard, New Delhi
8. Prof. Anis Ansari, Dean, Aligarh Muslim University, Aligarh

III. * * *

IV. * * *

*** Relate to other matters.

V. * * *

VI. * * *

2. At the outset, the Chairman welcomed Members to the meeting and apprised them about the progress made so far regarding the examination of the three Bills, *viz.*, the Clinical Establishments (Registration and Regulation) Bill, 2007, the Drugs and Cosmetics (Amendment) Bill, 2007 and the Paramedical and Physiotherapy Central Councils Bill, 2007.

3. * * *

4. The Committee thereafter took oral evidence of the representatives of Ayurveda, Siddha and Unani Drug Technical Advisory Board (ASUDTAB) on the Drugs and Cosmetics (Amendment) Bill, 2007. Members sought clarifications on various provisions of the Bill which were replied to.

5. * * *

6. * * *

7. A verbatim record of the proceedings was kept.

8. The Committee then adjourned at 5.03 P.M.

*** Relate to other matters.

I
FIRST MEETING
(2008-09)

The Committee met at 3.00 P.M. on Tuesday, the 12th August, 2008 in Committee Room No. 'B', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Amar Singh — *Chairman*

RAJYA SABHA

2. Shrimati Viplove Thakur
3. Shri Rajeev Shukla
4. Shrimati Maya Singh

LOK SABHA

5. Dr. Ram Chandra Dome
6. Shrimati Maneka Gandhi
7. Shri Rajendra Kumar
8. Shri R.L. Jalappa
9. Shrimati Susheela Bangaru Laxman
10. Shri S. Mallikarjuniah
11. Shri Rasheed Masood
12. Dr. Chinta Mohan
13. Shrimati K. Rani
14. Shri Pannian Ravindran
15. Shri Uday Singh
16. Dr. Karan Singh Yadav

SECRETARIAT

Shrimati Vandana Garg, Joint Secretary

Shri R. B. Gupta, Director

Shrimati Arpana Mendiratta, Deputy Director

Shri Dinesh Singh, Committee Officer

WITNESS

Dr. R.A. Mashelkar, Director General (Retired), Council of Scientific and Industrial Research

2. At the outset, the Chairman welcomed Members to the meeting and apprised them of the progress made in respect of examination of the Drugs and Cosmetics (Amendment) Bill, 2007.

* * *

*** Relate to other matters.

3. The Committee, thereafter, heard Dr. Mashelkar on the various provisions of the Drugs and Cosmetics (Amendment) Bill-2007 and Members raised certain queries related to the Bill, which were clarified by him. On being asked to apprise the Committee of the updated status of the 'Implementation Committee on Drug Regulatory Reform' supposedly set up by the Ministry of Health and Family Welfare under his chairmanship, Dr. Mashelkar expressed his ignorance on the existence of any such Committee. The Committee took serious exception to the fact that though, almost a year has passed since the Ministry's informing the Committee that the process for setting up of an 'Implementation Committee on Drug Regulatory Reform' has been initiated, no progress seems to have been made on the issue.

4. The Committee, thereafter, discussed the Clause-by-Clause provisions of the Drugs and Cosmetics (Amendment) Bill, 2007. Some Members demanded that the present system of decentralized licensing should continue as opposed to the centralized licensing system, proposed in the Bill. However, as there was lack of consensus on the issue, it was decided that the Committee would discuss the issue more elaborately at its next meeting.

5. * * *

6. Attention of the witness was also drawn to the fact that presently the drugs related aspects were being looked after by different agencies-like formulation, licensing, regulation of distribution by the Ministry of Health and Family Welfare, and manufacturing and price control by the Ministry of Chemicals and Fertilizers. It was suggested that all the aspects relating to drugs should be brought under one agency *i.e.*, the Ministry on Health and Family Welfare.

7. A verbatim record of the proceedings was kept.

8. The Committee then adjourned at 4.50 P.M.

*** Relate to other matters.

ANNEXURES

ANNEXURE-I

TO BE INTRODUCED IN THE RAJYA SABHA

21 August, 2007

Bill No. LVII of 2007

THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2007

A

BILL

further to amend the Drugs and Cosmetics Act, 1940.

BE it enacted by Parliament in the Fifty-eighth Year of the Republic of India as follows:—

Short title, and commencement.

1. (*1*) This Act may be called the Drugs and Cosmetics (Amendment) Act, 2007.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint:

Provided that different dates may be appointed for different provisions of this Act, and any reference in any such provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision.

Amendment of section 3.

23 of 1940

2. In the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), in section 3,—

(*i*) for clause (*aa*), the following clauses shall be substituted, namely:—

'(*aa*) ''Central Drugs Authority'' means the Central Drugs Authority of India constituted under sub-section (1) of section 5;

(*aai*) ''Chairperson'' means the Chairperson of the Central Drugs Authority;

(*aaii*) ''clinical trial'' means systematic study of any drug or cosmetic in human subjects to generate data for discovering or verifying its clinical, pharmacological (including pharmacodynamic and pharmacokinetic) or adverse effects with the objective of determining safety, efficacy or tolerance of the drug or the cosmetic;';

(*ii*) in clause (*b*), for sub-clause (*iv*), the following sub-clause shall be substituted, namely:-

''(*iv*) such medical device, medicated device, instrument, apparatus, appliance, material, software necessary for their application, intended for internal or external use in human beings or animals, whether used alone or in combination, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Central Drugs Authority, for the purpose of diagnosis, prevention, monitoring, treatment or mitigation of any disease or disorder; diagnosis, monitoring, treatment, alleviation of or compensation for, any injury or handicap; investigation, replacement or modification of anatomy or physiology; or control of conception, and which does not achieve its intended action primarily by any pharmacological or immunological or metabolical process, but is included in the pharmacopoeias mentioned. in the Second Schedule;'';

(*iii*) after clause (*b*), the following clauses shall be inserted, namely:-

'(*bb*) ''Drugs Controller (India)'' means the Drugs Controller (India) appointed under sub-section (*1*) of section 5E;

(*bbb*) ''Fund'' means the Fund constituted under sub-section (1) of section 5-I;';

(*iv*) in clauses (*c*) and (*e*), for the words ''Central Government'', wherever they occur, the words ''Central Drugs Authority'' shall be substituted;

(*v*) in clause (*f*), for the words ''sale or distribution'', the words ''sale or export or distribution'' shall be substituted;

(*vi*) after clause (*f*), the following clause shall be inserted, namely:—

'(*ff*) ''Member'' means a Member of the Central Drugs Authority and includes the Chairperson;';

(*vii*) in clause (*h*), in sub-clause (*ii*), for the words ''Drugs Technical Advisory Board constituted under section 5'', the words ''Central Drugs Authority'' shall be substituted.

Insertion of new Chapters.

3. In the principal Act, after Chapter I, the following Chapters shall be inserted, namely:—

CHAPTER IA

CENTRAL DRUGS AUTHORITY OF INDIA

Constitution of Central Drugs Authority.

5. (*1*) The Central Government shall, by notification in the Official Gazette, constitute an Authority to be known as the Central Drugs Authority of India.

(*2*) The Central Drugs Authority shall be a body corporate by the name aforesaid, having perpetual succession and a common seal with power, subject to the provisions of this Act, to acquire, hold and dispose of property, both movable and immovable, and to contract, and may, by the said name, sue or be sued.

(*3*) The Central Drugs Authority shall consist of a Chairperson and not more than five, but at the least three, Members, to-be appointed by the Central Government by notification in the Official Gazette.

(*4*) The headquarters of the Central Drugs Authority shall be at Delhi.

(*5*) The Central Drugs Authority may, by notification in the Official Gazette, establish its offices at Such other places in India as it considers necessary.

Qualifications of Chairperson and Members.

5A. The Chairperson and Members of the Central Drugs Authority shall be appointed by the Central Government from amongst persons who have special knowledge of, and at the least fifteen years' professional experience in pharmaceutical a industry, research or teaching, or public administration, finance or law:

Provided that a person who is, or has been, in the service of Government shall not be appointed as a Chairperson or Member unless such person has held the post of Secretary or Additional Secretary to the Government of India or any equivalent post in the Central Government or a State Government or a Public Sector Undertaking.

Term of office of Chairperson and Members.

5B. The Chairperson or Member shall hold office as such for a term of three years from the date on which he enters upon his office, and shall be eligible for reappointment for a further term of three years:

Provided that the Chairperson or Member shall not hold office as such on attaining the age of seventy years.

Salaries, allowances, pensions and other conditions of service of Members.

5C. The salaries, allowances and pensions payable to, and other conditions of service of, the Members shall be such, as may be prescribed by the Central Government.

Vacancies, etc., not to invalidate proceedings.

5D. No act or proceeding of the Central Drugs Authority shall be invalidated merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the Central Drugs Authority;

(*b*) any defect in the appointment of a person as a Member of the Central Drugs Authority; or

(*c*) any irregularity in the procedure of the Authority not affecting the merits of the case.

Staff of the Central Drugs Authority.

5E. (*1*) The Central Drugs Authority shall appoint a Drugs Controller (India), and such other officers and employees as it considers necessary for the efficient discharge of its functions and exercise of its powers under this Act.

(*2*) The salaries, allowances and pensions payable to, and other conditions of service of, the Drugs Controller (India), other officers and employee of the Central Drugs Authority appointed under sub-section (1) shall be such as may be determined by the Central Drugs Authority by regulations.

(*3*) The Drugs Controller (India) shall be the Secretary of the Central Drugs Authority.

Powers and functions of Central Drugs Authority.

5F. (*1*) The Central Drugs Authority may issue licences under clause (*c*) of section 10, clause (*c*) of section 18 and clause (*c*) of section 33EEC, and collect fees therefor.

(*2*) The Central Drugs Authority may cancel or suspend any licence issued under sub-section (*1*).

(*3*) The Central Drugs Authority shall collect charges for granting permission for conduct of clinical trials in respect of drugs and cosmetics.

(*4*) The Central Drugs Authority may constitute such committees or sub-committees as it considers essential for the efficient discharge of its functions and exercise of its powers under this Act.

(*5*) The Central Drugs Authority shall recommend to the Central Government—

(*a*) standards for drugs and cosmetics;

(*b*) the Central Drugs Laboratories for the purpose of testing drugs and cosmetics;

(*c*) measures to regulate import of drugs and cosmetics;

(*d*) measures to regulate manufacture for sale or for export or for distribution, or sale, stock or exhibition of drugs and cosmetics;

(*e*) standards for good manufacturing and laboratory practices and other such practices;

(*f*) measures to regulate clinical trials;

(*g*) amounts of fees and other charges payable under this Act;

(*h*) any other measures for the purpose of giving effect to the provisions of this Act.

(*6*) The Central Drugs Authority shall regulate its own procedure.

Powers and functions of Drugs Controller (India).

5G. (*1*) The Drugs Controller (India) shall exercise the powers conferred upon him under this Act or the rules framed thereunder or assigned to him by the Central Drugs Authority.

(*2*) The Drugs Controller (India) shall be the Chief Executive Officer and the legal representative of the Central Drugs Authority, and shall be responsible for—

(*a*) the day-to-day administration of the Central Drugs Authority;

(*b*) drawing up of proposals for the work programmes of the Central Drugs Authority;

(*c*) implementing the work programmes approved and the decisions made by the Central Drugs Authority;

(*d*) the preparation of the statement of revenue and expenditure and the execution of the budget of the Central Drugs Authority;

(*e*) the preparation of draft annual report for submission to and approval of the Central Drugs Authority.

(*3*) The Drugs Controller (India) shall have administrative control over other officers and employees of the Central Drugs Authority.

Grants by Central Government.

5H. The Central Government may, after due appropriation made by Parliament by law in this behalf, make to the Central Drugs Authority grants of such sums of money as are required by it.

Fund.

5-I. (*1*) There shall be constituted a Fund to be called the Central Drugs Authority of India Fund and there shall be credited thereto—

(*a*) all grants, fees and charges received by the Central Drugs Authority under this Act; and

(*b*) all sums received by the Central Drugs Authority from such other sources as may be determined by the Central Government.

(*2*) The Fund shall be applied for meeting—

(*a*) the salaries, allowances and pensions payable to the Chairperson and other Members and the administrative expenses, including the salaries, allowances and pensions payable to or in respect of the Drugs Controller (India) and other officers and employees of the Central Drugs Authority; and

(*b*) the expenses to carry out the objects and purposes of this Act.

Accounts and audit.

5J. (*1*) The Central Drugs Authority shall maintain proper accounts and other relevant records and prepare an annual statement of accounts in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor-General of India.

(*2*) The accounts of the Central Drugs Authority shall be audited by the Comptroller and Auditor-General of India at such intervals as may be specified by him and any expenditure incurred in connection with such audit shall be payable by the Central Drugs Authority to the Comptroller and Auditor-General of India.

(*3*) The Comptroller and Auditor-General of India and any other person appointed by him in connection with the audit of the accounts of the Central Drugs Authority shall have the same rights and privileges and authority in connection with such audit as the Comptroller and Auditor-General generally has, in connection with the audit of the Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers and to inspect any of the offices of the Central Drugs Authority.

(*4*) The accounts of the Central Drugs Authority as certified by the Comptroller and Auditor-General of India or any other person appointed by him in this behalf, together with the audit report thereon, shall be forwarded annually to the Central Government and that Government shall cause the same to be laid, as soon as may be after it is received, before each House of Parliament.

Annual report.

5K. (*1*) The Central Drugs Authority shall prepare every year an annual report in such form and manner and at such time as may be prescribed by the Central Government, giving summary of its activities during the previous year and copies of the report shall be forwarded to the Central Government.

(*2*) A copy of the report forwarded under sub-section (*1*) shall be laid, as soon as may be after it is received, before each House of Parliament.

Power to make rules.

5L. (*1*) The Central Government may, after consultation with, or on the recommendation of, the Central Drugs Authority and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Central Drugs Authority may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Central Drugs Authority shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Central Drugs Authority may make in relation to the amendment of the said rules.

(*2*) Without prejudice to the generality of the foregoing power, such rules may provide for the following matters, namely:—

(*a*) the salaries, allowances and pensions payable to, and other conditions of service of, the Members under section 5C;

(*b*) the manner and form in which the accounts of the Central Drugs Authority shall be maintained under sub-section (*1*) of section 5J;

(*c*) the form and manner in which and the time within which annual report is to be made to the Central Government under sub-section (*1*) of section 5K.

Power to make regulations.

5M. (*1*) The Central Drugs Authority may, by notification in the Official Gazette, make regulations consistent with this Act and the rules made thereunder, to discharge its functions and exercise its powers.

(*2*) In particular, and without prejudice to the generality of the foregoing power, such regulations may provide for the following matters, namely:—

(*a*) the salaries, allowances and pensions payable to, and other conditions of service of, the Drugs Controller (India) and other officers and employees of the Central Drugs Authority under sub-section (*2*) of section 5E;

(*b*) the regulation of the procedure of the Central Drugs Authority under sub-section (*6*) of section 5F.

CHAPTER IB

Clinical Trials

No clinical trial without permission.

5N. No person shall conduct clinical trials in respect of any drug or cosmetic except under, and in accordance with, the permission granted by the Central Drugs Authority.

Punishment for conducting clinical trial without permission.

5O. (*1*) Whoever, himself or by any other person on his behalf, conducts clinical trials in contravention of section 5N shall be punished with imprisonment for a term which may extend to five years and with fine which may extend to ten lakh rupees.

(*2*) Whoever having been convicted of an offence under sub-section (*1*) is again convicted of an offence under that sub-section, shall be punished with imprisonment for a term which may extend to ten years and with fine which may extend to twenty lakh rupees.

Trial of offences.

5P. (*1*) No prosecution under section 5-O shall be instituted except upon complaint made in writing in this behalf by an officer authorised by the Central Drugs Authority.

(*2*) No Court inferior to that of a Metropolitan Magistrate or of a Judicial Magistrate of the first class shall try an offence punishable under section 5-O.

Power to make rules.

SQ. (*1*) The Central Government may after consultation with, or on the recommendation of, the Central Drugs Authority and after pervious publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Central Drugs Authority may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Central Drugs Authority shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Central Drugs Authority may make in relation to the amendment of the said rules.

(*2*) Without prejudice to the generality of the foregoing power, such rules may provide for the form and conditions of the permission under section 5N, the charges payable therefor, and the cancellation or suspension of such permission in any case where any provision of this Act or the rules made thereunder is contravened or any of the conditions subject to which the permission is granted is not complied with.

Substitution of heading of Chapter II.

4. In the principal Act. in Chapter II, for the Chapter heading ''THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE'', the Chapter heading ''THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE'' shall be substituted.

Omission of section 5.

5. In the principal Act, section 5 shall be omitted.

Amendment of section 6.

6. In the principal Act, in section 6,—

(*a*) for the word ''Laboratory'', wherever it occurs, the words ''Laboratory or Laboratories'' shall be substituted;

(*b*) in sub-section (*2*), for the word ''Board'', the words ''Central Drugs Authority'' shall be substituted.

Amendment of section 7.

7. In the principal Act, in section 7,—

(*a*) in sub-section (*1*), for the words ''Drugs Technical Advisory Board'', the words ''Central Drugs Authority'' shall be substituted;

(*b*) for sub-section (*2*), the following sub-section shall be substituted, namely:—

''(*2*) the Drugs Consultative Committee shall consist of such number of representatives of the Central Government, industry, consumer associations, academic and research institutions, as may be prescribed and one representative of each State Government to be nominated by the State Government concerned.'';

(*c*) after sub-section (*3*), the following sub-section shall be inserted, namely:—

''(*4*) The Central Government may, after consultation with the Central drugs Authority, make rules prescribing the number of representatives under sub-section (*2*).''.

Omission of section 7A.

8. In the principal Act, section 7 A shall be omitted.

Amendment of section 8.

9. In the principal Act, in section 8, in sub-section (*2*), for the word ''Board'', the words ''Central Drugs Authority'' shall be substituted.

Amendment of section 10.

10. In the principal Act, in section 10, in the second proviso, for the word ''Board'', the words ''Central Drugs Authority'' shall be substituted.

Amendment of section 12.

11. In the principal Act, in section 12,—

(*a*) in sub-section (*1*), for the word ''Board'', wherever it occurs, the words ''Central Drugs Authority'' shall be substituted;

(*b*) in sub-section (*2*), in clause (*a*), the words ''the authority empowered to issue the same'' shall be omitted.

Amendment of section 16.

12. In the principal Act, in section 16, in sub-section (*2*), for the word ''Board'', the words ''Central Drugs Authority'' shall be substituted.

Amendment of section 18.

13. In the principal Act, in section 18,—

(*a*) for the words ''manufacture for sale or for distribution'', wherever they occur, the words ''manufacture for sale or for export or for distribution'' shall be substituted;

(*b*) in the second proviso, for the word ''Board'', the words ''Central Drugs Authority'' shall be substituted.

Amendment of sections 20 and 21.

14. In the principal Act, in sections 20 and 21, for the words ''Central Government'', wherever they occur, the words ''Central Drugs Authority'' shall be substituted.

Amendment of section 22.

15. In the principal Act. in section 22, in sub-section (*1*), in clause (*cca*), for the words ''manufacture for sale or for distribution'', the words ''manufacture for sale or for export or for distribution'' shall be substituted.

Amendment of sections 27 and 27a.

16. In the principal Act, in sections 27 and 27 A, for the words ''manufactures for sale or for distribution'', at both the places where they occur, the words ''manufactures for sale or for export or for distribution'' shall be substituted.

Amendment of section 31.

17. In the principal Act, in section 31, in sub-section (*1*), in clause (*ii*), for the words ''manufacture for sale, or for distribution'', the words "manufacture for sale or for export or for distribution'' shall be substituted.

Amendment of section 33.

18. In the principal Act, in section 33,—

(*a*) in sub-section (*1*), for the word ''Board'', wherever it occurs, the words ''Central Drugs Authority'' shall be substituted;—

(*b*) in sub-section (2),—

(*i*) clause (b) shall be omitted;

(*ii*) in clause (*e*),—

(*A*) for the words ''manufacture for sale or for distribution'', the words ''manufacture for sale or for export or for distribution'' shall be substituted; and

(*B*) the words ''the authority empowered to issue the same, the qualifications of such authority'' shall be omitted;

(*iii*) clause (*n*) shall be omitted.

Omission of section 33C.

19. In the principal Act, section 33C shall be omitted.

Amendment of section 33D.

20. In the principal Act, in section 33D,—

(*a*) in sub-section (*1*), for the words ''Ayurveda, Siddhaand Unani Drugs Technical Advisory Board'', the words ''Central Drugs Authority'' shall be substituted;

(*b*) for sub-section (*2*), the following sub-section shall be substituted, namely:—

''(*2*) the Ayurveda, Siddha and Unani Drugs Consultative Committee shall consist of such number of representatives of the Central Government. industry, consumer associations, academic and research institutions, as may be prescribed and one representative of each State Government to be nominated by the State Government concerned.''.

Amendment of section 33EEB.

21. In the principal Act, in section 33EEB, for the words ''manufacture for sale or for distribution'', the words ''manufacture for sale or for export or for distribution'' shall be substituted.

Amendment of section 33EEC.

22. In the principal Act, in section 33EEC,—

(*A*) in clause (*a*), for the words ''manufacture for sale or for distribution'', the words ''manufacture for sale or for export or for distribution'' shall be substituted;

(*B*) in clause (*c*),—

(*i*) for the words ''manufacture for sale or for distribution'', the words ''manufacture for sale or for export or for distribution'' shall be substituted; and

(*ii*) the words ''by the prescribed authority'' shall be omitted.

Amendment of sections 33F and 33G.

23. In the principal Act, in sections 33F and 33G, for the words ''Central Government'', wherever they occur, the words ''Central Drugs Authority'' shall be substituted.

Amendment of section 33-I

24. In the principai Act, in section 33-I, for the words ''manufactures for sale or for distribution'', the word ''manufactures for sale or for export or for distribution'' shall be substituted.

Amendment of section 33L.

25. In the principal Act, in section 33L, for the words ''manufacture for sale'', at both the places where they occur, the words ''manufacture for sale or for export or for distribution'' shall be substituted.

Amendment of section 33N.

26. In the principal Act, in section 33N,—

(*a*) in sub-section (*1*), for the word ''Board'', wherever it occurs, the words ''Central Drugs Authority'' shall be substituted;

(*b*) in sub-section (2),—

(*i*) clause (*b*) shall be omitted;

(*ii*) in clause (e),—

(*A*) for the words ''manufacture for sale'', the words ''manufacture for sale or for export or for distribution'' shall be substituted; and

(*B*) the words ''the authority empowered to issue the same'' shall be omitted;

(*iii*) after clause (*f*), the following clause shall be inserted, namely:—

''(*ff*) prescribe the number of representatives under sub-section (2) of section 33 D;''.

Amendment of section 33-O.

27. In the principal Act, in section 33-O, for the word ''Board'', the words ''Central Drugs Authority'' shall be substituted.

Substitution of new section for section 38.

28. In the principal Act, for section 38, the following section shall be substituted, namely:—

Rules and regulations to be laid before Parliament.

''38. Every rule and every regulation made 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 Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation 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 or regulation.''.

STATEMENT OF OBJECTS AND REASONS

The Drugs and Cosmetics Act, 1940 (the Act) is a consumer protection legislation, which is mainly concerned with the standards and quality of drugs and regulates the import, manufacture, sale and distribution of drugs and cosmetics.

2. The Central Government had constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelker, Director-General of the Council of Scientific and Industrial Research in January, 2003 to undertake a comprehensive examination of drug regulatory issues, including the problem of spurious drugs and to suggest measures to improve the drug administration in the country. The Committee, *inter alia*, recommended setting up of a Central Drugs Authority reporting directly to the Ministry of Health and Family Welfare and a system of Centralised licensing. The Central Government considered the recommendations of the Committee and proposes to make amendments in the Act, in order to facilitate setting up of a Central Drugs Authority and introduction of Centralised licensing for manufacture of drugs in pursuance of the said recommendations. The Drugs and Cosmetics (Amendment) Bill, 2007, *inter alia*, provides for:—

(*a*) substitutation of the ''Drugs Technical Advisory Board'' as well as the ''Drugs Technical Advisory Board for Ayurvedic, Siddha and Unani Drugs'' by the ''Central Drugs Authority'';

(*b*) insertion of a new Chapter IA with a view to providing the constitution of the Central Drugs Authority and other connected or incidental matters;

(*c*) insertion of a new Chapter IB in the Act, providing for grant of permission for clinical trials, punishment for conducting clinical trial without permission, trial of offences, etc.; and

(*d*) expansion of the compositions of the Drugs Consultative Committees.

3. Certain consequential changes in the Act are also proposed so as to make it in consonance with proposal for setting up of the Central Drugs Authority.

4. The Bill seeks to achieve the above objects.

NEW DELHI;
The 7th June, 2007.

ANBUMANI RAMADOSS.

NOTES ON CLAUSES

Clause 1 relates to short title and commencement of the Act.

Clause 2 amends section 3 of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the Act) in order to add definitions of the terms ''Central Drugs Authority'', ''Chairperson'', ''Member'', ''Drugs Controller (India)'', ''clinical trial'' and ''Fund'', amend the definition of the term ''drug'', and substitute the words ''Central Government'' in the definitions of the terms ''Government analyst'' and ''Inspector'' with the words ''Central Drugs Authority", the words "sale or distribution" in the definition of the term "manufacture" with the words "sale or export or distribution" and the words "Drugs Technical Advisory Board constituted under section 5" in the definition of the term "patent or proprietary medicine" with the words "Central Drugs Authority".

Clause 3 inserts a new Chapter, CHAPTER IA titled "CENTRAL DRUGS AUTHORITY OF INDIA" containing proposed new sections 5 to 5M and CHAPTER IB titled "CLINICAL TRIALS" containing proposed new sections 5N to 5Q.

Proposed new section 5 provides for the constitution of the Central Drugs Authority of India, its nature, composition, location of headquarters and power to set up offices in other places in India.

Proposed new section 5A provides for qualifications of Chairperson and Members of the Central Drugs Authority.

Proposed new section 5B provides for the term of office of the Chairperson and Members of the Central Drugs Authority.

Proposed new section 5C gives the power to the Central Government for prescribing the salaries, allowances, pensions payable to, and other conditions of service of, the Chairperson and Members of the Central Drugs Authority.

Proposed new section 5D provides that any vacancy in, or any defect in the constitution of, or any defect in the appointment of the Chairperson or a Member of the Central Drugs Authority or any irregularity in its procedure not affecting the merits of a case, would not invalidate its proceedings.

Proposed new section 5E gives power to the Central Drugs Authority to appoint Drugs Controller (India) and other officers and employees of the Authority and to fix their salaries, allowances and pensions. It also provides that the Drugs Controller (India) shall be the Secretary of the Central Drugs Authority.

Proposed new section 5F enumerates the powers and functions of the Central Drugs Authority.

Proposed new section 5G provides for the powers and functions of the Drugs Controller (India).

Proposed new section 5H provides for grants to be made by the Central Government to be Central Drugs Authority.

Proposed new section 5-I provides for constitution of the Central Drugs Authority of India Fund as well as what shall be credited thereto. It also provides the purposes for which the Fund shall be applied.

Proposed new section 5J provides for maintenance of proper accounts by the Central Drugs Authority and the details regarding procedure for auditing of its accounts.

Proposed new section 5K provides for preparation of an annual report by the Central Drugs Authority, which shall be forwarded to the Central Government and also laid before each House of Parliament.

Proposed new section 5L lays down the power of the Central Government to make rules, in consultation with the Central Drugs Authority, for giving effect to the provisions as contained in CHAPTER IA.

Proposed new section 5M provides for power of the Central Drugs Authority to make regulations for discharge of its functions and exercise of its powers.

Proposed new section 5N prohibits the conduct of clinical trials in respect of any drug or cosmetic without due permission from the Central Drugs Authority.

Proposed new section 5-O provides for punishment for conducting clinical trials without permission.

Proposed new section 5P provides for procedure for trial of offences under section 5-O.

Proposed new section 5Q gives powers to the Central Government to make rules, in consultation with the Central Drugs Authority, to give effect to the provisions of CHAPTER IB.

Clause 4 provides for substitution of the existing heading of CHAPTER II of the Act with "THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE".

Clause 5 provides for omission of section 5 of the Act dealing with the Drugs Technical Advisory Board.

Clause 6 amends section 6 of the Act for substituting the word 'Laboratory' with the words 'Laboratory or laboratories and the word 'Board' with the words 'Central Drugs Authority'.

Clause 7 amends section 7 of the Act for substituting the words "Drugs Technical Advisory Board" with the words "Central Drugs Authority". It also provides for change in the composition of the Drugs Consultative Committee.

Clause 8 omits section 7A of the Act.

Clauses 9 to 18 and clauses 20 to 27 amend various sections of the Act for replacing the word "Board", wherever it occurs, with the words "Central Drugs Authority", the words "manufacture for sale or for distribution", wherever they occur, with the words "manufacture for sale or for export or for distribution" and the words "Ayurvedic, Siddha and Unani Drugs Technical Advisory Board", wherever they occur, with the words "Central Drugs Authority", and to provide for new composition of the Ayurvedic, Siddha and Unani Drugs Consultative Committee.

Clause 19 provides for omission of section 33C of the Act dealing with the Ayuryedic, Siddha and Unani Drugs Technical Advisory Board.

Clause 28 substitutes new section 38 dealing with laying of every rule and every regulation made under the Act before each House of Parliament within a stipulated timeframe.

FINANCIAL MEMORANDUM

Clause 3 of the Drugs and Cosmetics (Amendment) Bill, 2007 proposes to insert, *inter alia*, new section 5A in the Drugs and Cosmetics Act, 1940 empowering the Central Government to appoint the Chairperson and Members of the Central Drugs Authority of India and new section 5C in the said Act empowering the Central Government to decide on the salaries, allowances and pensions payable to, and other conditions of service of, the Members of the Central Drugs Authority of India. Some recurring expenditure will be involved in regard to payment of salaries, allowances and pensions payable to the Chairperson and Members of the Central Drugs Authority of India. The exact amount of expenditure involved will depend on the number of Members appointed and will be met out of the revenues of the Central Drugs Authority of India.

2. It is estimated that no expenditure, either of recurring or non-recurring nature, from the Consolidated Fund of India, would be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 3 of the Bill proposes to insert new Chapters IA and IB (containing new sections 5 to 5Q) in the Drugs and Cosmetics Act, 1940. New section 5L proposes to confer power on the Central Government to make rules for giving effect to the provisions of Chapter IA after consultation with, or on the recommendation of, the Central Drugs Authority and after previous publication by notification in the Official Gazette. New section 5M proposes to confer power upon the Central Drugs Authority to make regulations consistent with the said Act and the rules made thereunder to discharge its functions and exercise its powers. New section 5Q proposes to confer power on the Central Government to make rules for giving effect to the provisions of Chapter IB after consultation with, or on the recommendation of the Central Drugs Authority and after previous publication by notification in the Official Gazette. Clause 7 of the Bill proposes to insert new sub-section (4) in section 7 of the said Act to confer power on the Central Government to make rules for prescribing the number of Central Government's representatives in the Drugs Consultative Committee under sub-section (2) of section 7 of the said Act, after consulation with Central Drugs Authority. Clause 26(b) (iii) of the Bill proposes to insert new clause (ff) after clause (f) in sub-section (2) of section 33N of the said Act, to confer power on the Central Government to make rules for the purpose of prescribing the number of Central Government's representatives in the Ayurvedic, Siddha and Unani Drugs Consultative Committee under sub-section (2) of section 33D of the said Act.

These matters are the matters of procedure and administrative detail. Hence, it is not practical to provide for them in the Bill. The delegation of legislative powers is, therefore, normal in character.

ANNEXURE

EXTRACTS FROM THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

* * * * *

3. In this Act, unless there is anything repugnant in the subject or context,— Definitions.

(*aa*) "the Board" means—

(*1*) in relation to Ayurvedic, Siddha or Unani drug, the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted under section 33C; and

(*ii*) in relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted under section 5;

(*b*) "drug" includes—

* * * * *

(*iv*) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention 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, after consultation with the Board;

(*c*) "Government Analyst" means—

(*i*) in relation to Ayurvedic, Siddha or Unani drug, a Government Analyst appointed by the Central Government or a State Government under section 33F; and

(*ii*) in relation to any other drug or cosmetic, a Government Analyst appointed by the Central Government or a State Government under section 20;

* * * * *

(e) "Inspector" means—

(*i*) in relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by the Central Government or a State Government under section 33G; and

(*ii*) in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under section 21;

(*f*) "manufacture" in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting,

finishing packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business; and "to manufacture" shall be construed accordingly;

* * * * *

'(h) "patent or proprietary medicine",—

(ii) in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5;'

* * * * *

CHAPTER II

THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE

The Drugs Technical Advisory Board.

5. (*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:—

(*i*) the Director General of Health Services, *ex officio*, who shall be Chairman;

(*ii*) the Drugs Controller, India, *ex officio*;

(*iii*) the Director of the Central Drugs Laboratory, Calcutta, *ex officio*;

(*iv*) the Director of the Central Research Institute, Kasauli, *ex officio*;

(*v*) the Director of the Indian Veterinary Research Institute, Izatnagar, *ex officio*;

(*vi*) the President of the Medical Council of India, *ex officio*;

(*vii*) the President of the Pharmacy Council of India, *ex officio*;

(*viii*) the Director of the Central Drug Research Institute, Lucknow, *ex officio*;

(*ix*) two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;

(*x*) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto;

(*xi*) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;

(*xii*) one person to be nominated by the Central Government from the pharmaceutical industry;

(*xiii*) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

(*xiv*) one person to be elected by the Central Council of the Indian Medical Association;

(*xv*) one person to be elected by the Council of the Indian Pharmaceutical Association;

(*xvi*) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government.

(*3*) The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election:

Provided that the person nominated or elected, as the case may be, under clause (*ix*) or clause (*x*) or clause (*xi*) or clause (*xvi*) of sub-section (*2*) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.

(*4*) The Board may, subject to the previous approval of the Central Government; make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(*5*) The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

(*6*) The functions of the Board may be exercised notwithstanding any vacancy therein.

(*7*) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

The Central Drugs Laboratory.

6. (*1*) The Central Government shall, as soon as may be establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter:

Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs or cosmetic or class of cosmetics shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs or such cosmetic or class of cosmetics shall be exercised by the Director of that Institute or of that other Laboratory, as the case may be.

(*2*) The Central Government may, after consultation with the Board, make rules prescribing—

(*a*) the functions of the Central Drugs Laboratory;

* * * * *

(*d*) the procedure for the submission to the said Laboratory under Chapter IV or Chapter IVA of samples of drugs or cosmetics for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in respect of such reports;

(*e*) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions;

(*f*) the matters necessary to be prescribed for the purposes of the proviso to sub-section (*1*).

The Drugs Consultative Committee.

7. (*1*) The Central Government may constitute an advisory committee to be called "the Drugs Consultative Committee" to advise the Central Government, the State-Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of this Act.

(*2*) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.

(*3*) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

Sections 5 and 7 not apply to Ayurvedic, Siddha or Unani drugs.

7A. Nothing contained in sections 5 and 7 shall apply to Ayurvedic, Siddha or Unani drugs.

CHAPTER III

IMPORT OF DRUGS AND COSMETICS

Standards of quality.

8. (1) * * * * *

(*2*) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

* * * * *

Prohibition of import of certain drugs or cosmetics.

10. 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;

(*b*) any misbranded drug or misbranded or spurious cosmetic;

(*bb*) any adulterated or spurious drug;

(*c*) any drug or cosmetic for the import of which a licence is prescribed, other-wise than under, and in accordance with, such licence;

(*d*) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or lost of active ingredients contained in it together with the quantities thereof;

(*e*) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

(*ee*) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(*f*) any drug or cosmetic the import of which is prohibited by rule made under this Chapter:

Provided that nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use:

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 import of any drug or class of drugs not being of standard quality.

* * * * *

Power of Central Government to make rules.

12. (*1*) The Central Government may, after consultation with or on the recommendation of 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:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendmept of the said rules.

(*2*) Without prejudice to the generality of the foregoing power, such rules may—

(*a*) specify the drugs or classes of drugs or cosmetics or classes of cosmetics for the import of which a licence is required, and prescribed the form and conditions of such licences, the authority empowered to issue the same, the fees payable therefor and provide for the cancellation, or suspension of such licence in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which the licence is issued is not complied with;

(*b*) prescribe the methods of test or analysis to be employed in determining whether a drug or cosmetic is of standard quality;

(*c*) prescribe, in respect of biological and organometallic compounds, the units of methods standardisation;

(*cc*) prescribe under clause (*d*) of section 9A, the colour or colours which a drug may bear or contain for purposes of colouring;

(*d*) specify the diseases or ailments which an imported drug may not purport or claim to prevent, cure or mitigate and such other effects which such drug may not purport or claim to have;

(*e*) 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 examination, test or analysis or for personal use;

(*f*) prescribe the places at which drugs or cosmetics may be imported, and prohibit their import at any other place;

(*g*) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container or any specified imported drug or class of such drug, and prohibit the import of the said drug or class of drug after the expiry of a specified period from the date of manufacture;

(*h*) regulate the submission by importers, and the securing, of samples of drugs or cosmetics for examination, test or analysis by the Central Drugs Laboratory, and prescribe the fees, if any, payable for such examination, test or analysis;

(*i*) prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs or cosmetics sought to be imported, the procedure of officers of Customs in dealing with such evidence, and the manner of storage at places of import of drugs or cosmetics detained pending admission;

(*j*) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter and the rules made thereunder of drugs or cosmetics imported for the purpose only of transport through, and export from, India;

(*k*) prescribe the conditions to be observed in the packing in bottles, packages or other containers, of imported drugs or cosmetics including the use of packing material which comes into direct contract with the drugs;

(*l*) regulate the mode of labelling drugs or cosmetics imported for sale in packages, and prescribe the matters which shall or shall not be included in such labels;.

(*m*) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any imported drug, prohibit the import of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(*n*) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any imported, patent or proprietary medicine containing such drug;

(*o*) provide for the exemption, conditionally or otherise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs or cosmetic or class of cosmetics.

* * * * *

CHAPTER IV

MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICS

Standards of quality.

16. (*1*) * * * * *

(*2*) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

* * * * *

Prohibition of manufacture and sale of certain drugs and cosmetics.

18. From such date may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—

(*a*) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute—

(*i*) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;

(*ii*) any cosmetic which is not of a standard quality, or is misbranded or spurious;

(*iii*) 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 active ingredient contained in it together with quantities thereof;

(*iv*) 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;

(*v*) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(*vi*) 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 of 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 rule made thereunder;

(*c*) manufacture for sale or for distribution, or sell, or stock or exhibit or offer 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 or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality.

* * * * *

Government Analysts.

20. (*1*) The State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas in the State and in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

* * * * *

(*2*) The Central Government may also, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

(*3*) Notwithstanding anything contained in sub-section (*1*) or sub-section (*2*), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

(*4*) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a Government Analyst under sub-section (*1*) or sub-section (*2*) of this section.

Inspectors.

21. (*1*) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may, be assigned to them by the Central Government or the State Government, as the case may be.

(*2*) The powers which may be exercised by an Inspector and the duties which may be performed by him, 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 shall be such as may be precribed.

(*3*) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be an Inspector under this section.

(*4*) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code, and shall be officially subordinate to such authority, having the prescribed qualifications, as the Government appointing him may specify in this behalf.

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Powers of Inspectors.

22. (*1*) Subject to the provisions 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,—

* * * * *

(*cca*) require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed;

* * * * *

Penalty for maufacture, sale, etc. drugs in contravention of this Chapter.

27. Whoever, himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks, or exhibits or offers for sale or distributes,—

(*a*) any drug deemed to be adulterated under section 17A or spurious under section 17B or which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to a term of life. and with fine which shall not be less than ten thousand rupees; 45 of 1860.

(*b*) any drug—

(*i*) deemed to be adulterated under section 17A, but not being a drug referred to in caluse (*a*), 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 three years and with fine which shall not be less than five thousand rupees:

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than five thousand rupees;

(*c*) any drug deemed to be spurious under section 17B, but not being a drug referred to in clause (*a*) shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which shall not be less than five thousand rupees:

Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years but not less than one year;

(*d*) any drug, other than a drug referred to in clause (*a*) or clause (*b*) or clause (*c*) in contravention of any other provision of this

Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine:

Provided that the Court may for any adequate and special reasons to be recorded in the judgment impose a sentence of imprisonment for a term of less than one year.

Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter.

27A. Whoever himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale—

(*i*) any cosmetic deemed to be spurious under section 17C shall be punishable with imprisonment for a term which may extend to three years and with fine;

(*ii*) any cosmetic other than a cosmetic referred to in clause (*i*) above in contravention of any provisions, of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year with fine which may extend to one thousand rupees or with both.

Confiscation.

31. (*1*) Where any person has been convicted under this Chapter for contravening any such provision of this Chapter or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug or cosmetic in respect of which the contravention has been made shall be liable to confiscation and if such contravention is in respect of—

(*i*) manufacture of any drug deemed to be misbranded under section 17, adulterated under section 17A or spurious under section 17B; or

(*ii*) manufacture for sale, or for distribution, sale or stocking or exhibiting or offering for sale, or distribution of any drug without a valid licence as required under clause (*c*) of section 18,

any implements or machinery use in such manufacture, sale or distribution and any receptacles, packages or coverings in which such drug is contained and the animals vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation.

* * * * *

Power of Central Government to make rules.

33. (*1*) The Central Government may "after consultation with, or on the recommendation of, 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:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government

shall take into consideration any suggestions which the Board may make the relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may—

* * * * *

(*b*) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

* * * * *

(*e*) prescribe the forms of licences for the manufacture for sale or for Distribution 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 may be issued, the authority empowered to issue the same the qualifications of such authority and the fees payable therefor; and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with.

* * * * *

(*n*) prescribe the powers and duties of Inspectors and the qualifications of the authority to which such Inspectors shall be subordinate 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;

* * * * *

Ayurvedic, Siddha and Unani Drug Technical Advisory Board.

33C. (*1*) The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board (to be called the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board to advise the Central Government and the State Governments on technical matters arising out of this Chapter and to carry out the other functions assigned to it by this Chapter.

(*2*) The Board shall consist of the following members, namely:—

(*i*) the Director General of Health Services, *ex officio*;

(*ii*) the Drugs Controller, India, *ex officio*;

(*iii*) the Principal Officer dealing with, Indian systems of medicine in Ministry of Health *ex-officio*;

(*iv*) the Director of the Central Drugs Laboratory, Calcutta, *ex officio*;

(*v*) one person holding the appointment of Government Analyst under section 33F, to be nominated by the Central Government;

(*vi*) one Pharmacognocist to be nominated by the Central Government;

(*vii*) one Phyto-chemist to be nominated by the Central Government;

(*viii*) four persons to be nominated by the Central Government, two from amongst the member of the Ayurvedic Pharmacopoeia Committee, one from amongst the members of the Unani Pharmacopoeia Committee and one from amongst the members of the Siddha Pharmacopoeia Committee;

(*ix*) one teacher in Dravyaguna and Bhaishajya Kalpana, to be nominated by the Central Government;

(*x*) one teacher in ILM-UL-ADVIA and TAKLISWA-DAWASAZI, to be nominated by the Central Government;

(*xi*) one teacher in Gunapadam to be nominated by the Central Government;

(*xii*) three persons, one each to represent the Ayurvedic, Siddha and Unani drug industry, to be nominated by the Central Government;

(*xiii*) three persons, one each from among the practitioners of Ayurvedic, Siddha and Unani Tibb systems of medicine to be nominated by the Central Government.

The Ayurvedic, Siddha and Unani Drugs Consultative Committee.

33D. (*1*) The Central Government may constitute an Advisory Committee to be called the Ayurvedic, Siddha and Unani Drugs Consultative Committee to advise the Central Government, the State Governments and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board on any matter for the purpose of securing uniformity throughout India in the administration of this Act in so far as it relates to Ayurvedic, Siddha or Unani drugs.

(*2*) The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall consist of two persons to be nominated by the Central Government as representatives of that Government and not more than one representative of each State to be nominated by the State Government concerned.

* * * * *

Regulation of manufacture for sale of Ayurvedic, Siddha and Unani drugs.

33EEB. No person shall manufacture for sale or for distribution any Ayurvedic, Siddha or Unani drugs except in accordance with such standards, if any, as may be prescribed in relation to that drug.

Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani drugs.

33EEC. From such date as the State Government may, by notification in the Official Gazette, specify in this behalf, no person, either by himself or by any other person on his behalf, shall—

(*a*) manufacture for sale or for distribution—

(*i*) any misbranded, adulterated or spurious Ayurvedic Siddha or Unani drug;

(*ii*) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true list of all the ingredients contained in it; and

(*iii*) any Ayurvedic, Siddha or Unani drug in contravention of any of the provisions of this Chapter or any rule made thereunder;

* * * * *

(*c*) manufacture for sale or for distribution, any Ayurvedic, Siddha or Unani drug, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter by the prescribed authority:

Provided that nothing in this section shall apply to Vaidyas and Hakims who manufacture Ayurvedic, Siddha or Unani drug for the use of their own patients:

Provided further that nothing in this section shall apply to the manufacture, subject to the prescribed conditions, of small quantities of any Ayurvedic, Siddha or Unani drug for the purpose of examinations, test or analysis.

Government Analysts.

33F. (*1*) The Central Government or a State Government may, by notification in the Official Gazette, appoint such person as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(*2*) Notwithstanding anything contained in sub-section (*1*), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

(*3*) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be a Government Analyst under this section.

Inspectors.

33G (*1*) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(*2*) The powers which may be exercised by an Inspector and the duties which may be performed by him and the conditions, limitations or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed.

(*3*) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an Inspector under this section.

(*4*) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code and shall be officially subordinate to such authority as the Government appointing him may specify in the behalf.

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* * * * *

Penalty for manufacture, sale, etc., of Ayurvedic, Siddha or Unani drug in contravention of this Chapter.

33-I. Whoever himself or by any other person on his behalf—

(*1*) manufactures for sale or for distribution,—

(*a*) any Ayurvedic, Siddha or Unani drug—

(*i*) deemed to be adulterated under section 33EE, or

(*ii*) without a valid licence as required under clause

(*c*) of section 33EEC,

shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than two thousand rupees;

(*b*) any Ayurvedic, Siddha or Unani drug deemed to be spurious under section 33EEA, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than five thousand rupees; or

(*2*) contravenes any other provisions of this Chapter or of section 24 as applied by section 33H or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to three months and with fine which shall not be less than five hundred rupees.

* * * * *

Application of provisions to Government Departments.

33L. The provisions of this Chapter except those contained in section 33K shall apply in relation to the manufacture for sale, sale or distribution of any Ayurvedic, Siddha or Unani drug by any department of Government as they apply in relation to the manufacture for sale, sale, or distribution of such drug by any other person

Power of Central Government to make rules.

33N. (*1*) The Central Government may, after consultation with, or on the recommendation of, the Board after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

* * * * *

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances arisen which render it necessary to make rules without such have consultation, but in such a case, the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(*2*) Without prejudice to the generality of the foregoing power such rules may—

(*a*) provide for the establishment of laboratories for testing and analysing Ayurvedic, Siddha or Unani.

(*b*) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(*c*) prescribe the methods of test or analysis to be employed determining whether any Ayurvedic, Siddha or Unani drug is labelled with the true list of the ingredients which it is purported to contain;

(*d*) specify any substance as a poisonous substance;

(*e*) prescribe the forms of licences for the manufacture drugs for sale of drugs the forms 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 and provide for the cancellation or suspension of such licences in any case where any provision of this chapter or rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with.

(*f*) prescribe the conditions to be observed in the packing of Ayurvedic, Siddha and Unani durgs including the use of packing material which comes into direct contact with the drugs, regulate the mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels;

(*g*) prescribe the conditions subject to which small quantities of Ayurvedic, Siddha or Unani drugs may be manufactured for the purpose of examination, test or analysis; and

(*gg*) prescribe under clause (*d*) of section 33EE the colour or colours which an Ayurvedic, Siddha or Unani drug may bear or contain for purposes of colouring;

(*gga*) prescribe the standards for Ayurvedic, Siddha or Unani drugs under section 33EEB;

(*h*) any other matter which is to be or may be prescribed under this Chapter.

Power to amend First Schedule.

33-O. The Central Government, after consultation with the Board and after giving, by notification in the Official Gazette, not less than three months' notice of its intention so to do, may, by a like notification, add to or otherwise amend the first Schedule for the purposes of the Chapter and thereupon the said Schedule shall be deemed to be amended accordingly.

* * * * *

Rules to be laid before Parliament.

38. Every rule made 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 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.

* * * * *

RAJYA SABHA

A

BILL

further to amend the Drugs and Cosmestics Act, 1940.

(Dr. Anbumani Ramadoss, Minister of Health and Family Welfare)

ANNEXURE-II

STUDY NOTE
PHASE I
OF
PARLIAMENTARY STANDING COMMITTEE
ON HEALTH AND FAMILY WELFARE
VISIT
TO

Bengaluru, Thiruvananthapuram, Chennai and Hyderabad

from 7th to 14 January, 2008

on

The Drugs and Cosmetics (Amendment) Bill, 2007

INTRODUCTION

The Committee in its examination of the **Drugs and Cosmetics (Amendment) Bill, 2007,** (hereinafter referred to as Bill) undertook a study visit to Bengaluru, Thiruvananthapuram, Chennai and Hyderabad from 7th to 14th January, 2008. During its study visit the Committee had interacted with various associations of large and small Pharmaceutical companies, NGOs, Consumer Fora, individuals and experts, representatives from IMA and other stakeholders who approached the Committee on the various provisions of the Bill. The list of witnesses who appeared before the Committee is given at Annexure IV. The views and suggestions expressed by different stakeholders are enumerated in succeeding paragraphs.

KARNATAKA
(Dated 07.01.08)

The Committee heard the following entities on the Bill at Bengaluru—

Indian Pharmaceutical Association, Karnataka State Branch, Karnataka Indian Medicine Manufacturers' Association, Pharmaceutical Association, Indian Hospital Pharmacists' Association, Indian Pharmacy Graduates' Association, All India Drugs Control Officers' Confederation, Karnataka Drugs and Pharma Manufacturing Associations, and, Karnataka State Pharmacy Council, and the State Government of Karnataka.

INDIAN PHARMACEUTICAL ASSOCIATION, KARNATAKA STATE BRANCH

The representatives of the IPA were opposed to the Bill. They quoted following extracts of Mashelkar Committee report stating that the report did not favour establishing the Central Drugs Authority.

> ***"There were several complex operational, legal and constitutional issues involved* in *setting up the National Drug Authority. Creating another authority will not solve the problem* at *hand".***

- The report recommended creation of strong, well equipped independent and professionally managed Central Drug Standard Control Organisation (CDSCO). **Although strengthening of Drugs Control Organisations both at Central and State level had been strongly recommended, the present Bill is silent on strengthening of the Drugs Control Organizations at State level.**

- It was their contention that if the objective of the Bill is to achieve upgradation in view of exports, uniformity of implementation, eradication of spurious and counterfeits the same can be achieved by the following:

    - **Upgradation to establish a good image of India products:**

      The process of CDSCO evaluating GMP of export units and certifying them may be strengthened. The GMP certification may be made essential for exports. Moreover, these units should have to be self upgrading in view of the respective regulatory agency audits.

- **Uniformity in implementation**

  The object of uniformity in implementation and effective quality monitoring at national level can be achieved if the CDA focuses its energy, expertise and resources in key areas like legislation, framing policies, review and monitoring of the activities of the State Drugs Control Organizations, import, clinical trials and approval of new drugs. Therefore, the powers and functions of the Central Drugs Authority should be laid down in elaborate manner to provide for the above said issues.

- To conduct training programs in Drugs Safety and Standards, technical, legal and investigation aspects for the Drugs Control Officers and all concerned.

- To prepare and periodically update a National Formulary of Fixed Dose Combinations (FDCs) for the guidance of State Licensing Authorities (SLAs). The permission to grant product licenses by SLAs will be restricted to FDCs included in such National Formulary. This will not only result in speedy disposal with minimum manpower but will also result in uniformity in grant of product permission. This will also obviate the necessity of approaching Drugs Control General of India for grant of each Fixed Dose Combination.

- **Eradication of spurious and counterfeit drugs**

  Solution to tackle spurious drugs and sub-standard drug not in centralising of licensing system but in building competence in the existing State and Central Drug Control Organisation by taking the following measures:

  A. Should strengthen CDSCO and State Organizations

  B. Reinforce the expertise for investigations through scientifically designed training programmes

  C. Formation of a Coordination Cell to coordinate between CDSCO and State on information sharing and in investigations

  D. Facilitate cooperation and coordination with connected forces like Police, CID and the Drugs Inspectors to improve and adequately investigate the complaints on spurious and counterfeit drugs.

  E. Sensitizing the professionals from ancillary industry.

Following objections and suggestions to the under-mentioned provisions of the Bill were made:

- The terms "spurious drug" "substandard drug" and "counterfeit drug" should be **defined separately.** Combining them under a single heading was like bracketing criminal offenders and miscellaneous traffic offenders in the same group.

- The Central Drugs Authority **(under clause 5 of the proposed Bill)** is proposed as a substitute for the existing Drugs Technical Advisory Board. The existing Drugs Technical Advisory Board is a technical body and is much broad based having representation of technical experts from the cross section of pharmaceutical profession. As compared to this, the Central Drugs Authority will consist of only 5 representatives to be appointed by the Central Government from amongst persons having experience in public administration, teaching, finance or law but not pharmacy field. **Therefore, establishment of Central Drugs Authority comprising non-technical persons will have adverse effect on effective implementation of the Act.**

As per the proviso to **clause 5A**, only Secretary or Additional Secretary to the Government of India can be appointed as Chairperson or member of the Central Drug Authority. This proviso disqualifies State Drugs Controller either working or retired from being appointed as a Chairperson or Member of the Central Drug Authority.

Central Drugs Authority, if established, should consist of more members and should be broader based with representation from the Central Government, State Drugs Control Organisations and Pharmaceutical Industry etc., as mentioned below:

(1) Secretary or Joint Secretary to represent following Ministry:

(i) Ministry of Health and Family Welfare

(ii) Ministry of Petroleum and Chemicals

(iii) Ministry of Small Scale Industry

(iv) Ministry of Consumer Affairs

(2) **One** representative each from the pharmaceutical industry association like OPPI, Indian Drugs Manufacturers' Association and Small Scale Industry Association

(3) **One** representative from the Consumer organizations

(4) **One** representative each from the professional associations like IPA, IHPA, IPGA, APTI and AIDCOC

(5) **One** representative from AIOCD

(6) **Five members** to be **appointed by rotation every 3 years** from amongst the State Drugs Control Organisations (Commissioner of Drug Safety as proposed).

(7) At least **three Government Analysts** from various State Drugs Control Laboratories including Director, CDL.

- Clause 5A may be suitably amended to make **officer of the rank of State Drugs Controller or Joint Drugs Controller and above with outstanding record eligible for appointment to the post of Chairperson or member of Central Drugs Authority.**

- **Clause 5B** specifies qualification and tenure of the Chairperson and members. ***However, procedure for selection and also the manner in which the Chairperson or members can be removed is not specified including the circumstances under which the Chairperson/members can be removed.*** (For eg., acquiring financial or other interest, conviction of an offence involving moral turpitude becoming physically or mentally incapable or abusing his powers etc.– as stipulated under Section 8 of Food Safety and Standards Act, 2006.

- The subject of drug is on the Concurrent List and therefore both Central Government and State Governments can legislate on the subject. The proposal will take away powers of State Governments to implement the Act effectively and monitoring the quality through licensing system, which is accepted as an effective tool for quality monitoring. The proposal is thus against the principle of federal structure outlined in the Constitution of India.

- In 1992-93 the Government of India took decision to take powers as Central License Approving Authority (CLAA) for the purpose of regulating activities of Blood Banks and Large Volume Parenterals. However, this experiment has not yielded the desired

results and has in fact, resulted in delay in grant or renewal of licenses, presumably because of the inadequate manpower in CDSCO and dilution of the responsibility.

- **Difficulties in filing appeal**

  Under **clause 5F (2)**, the CDA will have powers to suspend or cancel any license issued by it. Under Rule 85, the licencee has right to file an appeal against the order of the Licensing Authority. In this case, no specific provision is there to provide for the right of appeal. Even if the provisions of Rule 85 are taken into consideration, the licencee will have to file an appeal before CDA. This means for presenting an appeal or for arguing appeal, every licensee in this country will have to go to Delhi or zonal offices causing delay in disposal of appeals and also harassment to the licensee.

- **Constitution of Drugs Consultative Committee**

  Clause 7 of the proposed Bill makes provision for nomination on the Drug Consultative Committee. It provides for nomination from industry, consumer associations and academic and research institutions. However, **there is no provision for having representation from the professional bodies of the pharmacists.** It was, therefore, suggested that **representatives of Indian Pharmaceutical Association, Indian Hospital Pharmacists' Association, Indian Pharmacy Graduates' Association and All India Drugs Control Officers' Confederation etc., should also be included.**

Withdrawal of powers of Central Body to make rules on certain aspects

- Under **Clause 18, it is proposed to omit sub-clause (b) of Section 33 (2).** By this omission, the CDA has not been given any power to prescribe the qualification and duties of the Government Analyst and qualifications of Inspector.

  In the absence of such specific provision any person without any professional qualification would be entitled to be appointed as Government Analyst and Drugs Inspector. Such situation is not desirable and will go contrary to the premise of bringing uniformity in implementation.

- It is also proposed to **omit sub-clause (e) of Section 33 (2).** This affects the powers to prescribe qualification of Licensing Authority. The proposal to omit sub-clause (2) of Section 33 (2) will remove the empowerment to prescribe powers and duties of inspection and Licensing Authorities.

- In the event of opting for Centralization, the concept of 'timelines and 'transparency' (which are practiced in developed countries where there is centralized control) should be made mandatory. Computerization is a must to accomplish this.

Following suggestions were also made:

  - Making it mandatory that the drugs are transported and stored under prescribed conditions of temperature. This will reduce the incidences of 'sub-standard drugs'.

  - According to schedule M of the Drugs and Cosmetics Act, the shelf life of the product should be decreased to match the shelf life of the inputs used. This results in a lot of wastage which a country like ours can ill afford. This requirement is only in India and none of the Regulated country requirements specify this. As long as the expiry date of the inputs is within prescribed shelf life, the same can be used to manufacture formulations and normal shelf life can be assigned for the product. After all the responsibility of assuring quality of the formulations the shelf life assigned is with the formulator.

The representatives* of *the Karnataka Drugs and Pharma Manufacturing Associations, and, Karnataka State Pharmacy Council agreed* to *what was stated by the IPA and reiterated similar stand* on *the issues raised on the various provisions of the Bill by the IPA.

KARNATAKA INDIAN MEDICINE MANUFACTURERS' ASSOCIATION

The representatives from the above organization had also held similar views. While stating the difficulties that would manifest if the Bill under examination was to become an Act, they stated that:—

- the present proposal to have a Central Drugs Authority which would be covering all licensing activities concerning the manufacture of drugs, including drugs produced under the Indian System of Medicines (ISM). The proposal would have serious impact on the growth and survival of ISM drugs industry due to the following reasons:—

    (i) There is no set up at Central Level to take care of licensing activities of AYUSH drugs.

    (ii) The method of performing clinical trials in case of ISM Drugs is different and complex unlike that of the modern drugs. It requires technically sound persons who are well versed in the methods of manufacture and trials of the ISM drugs. Therefore, the definition of clinical trails needed to address these issues.

    (iii) There are also differences between the 'Drugs' and 'Cosmetics' prepared under ISM and these issues were also needed be given due care when the issue of clinical trails is dealt with.

- Due to reasons cited as above, it was necessary to have in the composition of the Central Drugs Authority, proper technical persons who can deal with issues related to drugs and cosmetics from ISM industries.

STATE GOVERNMENT OF KARNATAKA DATE

Following reservations on the Bill were expressed:

- The licensing of special categories of drugs, as is the present system, should be continued so that large manufacturing units would be under the jurisdiction of the Centre and small scale units may be left under the jurisdiction of the State Drug Manufacturing Licensing Authority. This they added would lead to lessening the burden of the Centre and also not task the SSI units in Pharma sector, as apprehended by them.

- The move to centralize the licensing mechanism would lead to loss of revenue to the States, and to Karnataka, to the tune of Rs. 200 lakhs per annum.

- It may not be practicable to inspect units located in remote areas of the country leading to improper surveillance, lack of authority to inspect the premises of industries and shops thereby posing embarrassing situations.

- Prosecutions against offenders have to be instituted in JMFC courts at the Taluk-levels, District courts and High Courts. Since these complaints are treated as "private complaints" by the courts, the presence of the Drug Inspector is essential on all hearing dates. Having Headquarters in Delhi would make things very difficult in such instances.

Apart from the reasons mentioned above, **the State Government has also furnished their views on the various provisions of the Bill and which have been attached to the report as Annexure-I.**

KERALA
(Date 09.01.2008)

The Committee heard the following entities on the Bill at Bengaluru,—

Kerala State Drugs Control Enforcement Officers' Association, All Kerala Pharma Traders Forum, Kerala Pharmaceutical Manufacturer's Association, Ayurvedic Medicine Manufacturers Organization of India (Kerala branch), Shri Unnikrishna Panicker, M.M. (a Senior Lecturer in Hospital and Clinical Pharmacy Medical College), Shri Chitra Thirunal Institute of Medical Science & Technology (SCTIMST), State Government of Kerala

KERALA STATE DRUGS CONTROL ENFORCEMENT OFFICERS' ASSOCIATION, ALL KERALA PHARMA TRADERS FORUM, AND KERALA PHARMACEUTICAL MANUFACTURER'S ASSOCIATION

The basic issues that arose as a response to their submissions before the Committee are:—

- The formation of CDA would lead to centralizing of the powers of licensing of manufacture of drugs that is currently vested with the State Governments and which currently the manufacturers' associations **do not want to be centralized.** It was pointed out that the Central Government has proposed to centralize the licensing system without giving weightage to the fact that the manufacture, sale and distribution of spurious drugs is a ***clandestine activity*** and that licensing should be ***de-linked*** for tackling this problem. Therefore, centralizing the licensing system is not the solution to the problem of spurious drugs.

- Presently, the State Drugs Control Administration has offices at every district place, while as per provisions in the Bill, the CDSCO will have offices only at Delhi and at zonal levels. Therefore, the applicants will face inconvenience in filing and processing of applications, in filing the appeals against the order of the licensing authority. For every small matter they will be required to go to Delhi or the zonal offices catering to four to five States, thereby causing hardships to the medium and small scale manufacturers. ***Procedural delay for processing*** **of** ***the documents for exports, may result in loss*** **of** ***business altogether.*** Attention was drawn to the procedure of Blood Bank Licensing wherein joint inspection of officers of the State as well as CDSCO are at present involved which has been causing a lot of delay in the grant of licenses.

- The Bill envisages **two different licensing authorities** *viz.* Central Drug Authority for drugs manufacturing licenses and State Drugs Control Organizations for drugs selling licenses. As a result of the proposed arrangement, the State Drugs Control Officers will face difficulties in investigations of cases of substandard or spurious drugs as they may not have jurisdiction to inspect the manufacturing establishments.

- Currently license for manufacture and sale of drugs is issued by the State Drugs Controller and involves, in the State of Kerala, inspection of the premises by the Drugs Controller/Assistant Drugs Controller along with Regional Drugs Inspector prior to issuance of manufacturing license. Subsequently, the same procedure described above is followed for routine renewal of manufacturing license and for endorsement of additional products to be manufactured. Centralizing of the licensing powers with the

proposed National Drugs Authority will, thus result in undue delay in issuing manufacturing license and endorsement of additional products since it is time consuming and expensive for the licensing authority located in Delhi to conduct inspection. ***Even if their powers*** **to** ***inspect manufacturing establishments are retained, action on the inspection reports*** **of** ***the State Drugs Control Officers may not be taken with the desired speed and effectiveness if*** **two** ***different authorities are responsible for licensing*** **of** ***manufacturing establishments and selling establishments***. In this regard attention was drawn to the difficulties already experienced in the State of Maharashtra under the Prevention of Food Adulteration Act, 1954 where the implementation is with State FDA and the licensing is with Mumbai Municipal Corporation.

It was accordingly, emphasized that manufacture, sale and distribution is a *composite activity and therefore it is necessary that only one agency is responsible for monitoring the activity* of *the manufacturers, distributors and retailers*

- After the enactment of the Bill, the entire licensing system will have to be regulated by the CDA. As a result thereof the States will loose all powers pertaining to manufacturing and sale of drugs and cosmetics along with the huge loss of revenue to the State Governments.

In view of the above, following suggestions were made:

- If the Central Government considers it absolutely necessary to establish Central Drugs Authority, then **the Food Safety and Standards Act, 2006** may be used as a **reference** and CDA may be set up on the lines of the National Food and Standard Authority. Following the scheme under Food Safety and Standard Act, 2006 **appointment of Commissioner of Drug Safety in each State** should also be made.
- ***The Central Drugs Authority and the Commissioner*** **of** ***Drug Safety should be given statutory responsibility*** **to** ***take steps*** **to** ***eradicate menace*** **of** ***spurious drug by implementing various recommendations made by Dr. Mashelkar Committee.*** The Central Drug Authority and Commissioner of Drug Safety should be legally bound to take the following measures to tackle the menace of spurious drugs.
- The uniformity in implementation can be secured through following steps:—
    - Building competency at central and state level.
    - Issuing written guidelines and manual.
    - Periodical review and monitoring by Central Drugs Authority.
    - Preparation of National Formulary of Fixed Dose Combination for the guideline of State Drugs Controllers.
- The Powers, functions and duties of the Central Drugs Authority should be laid down in an elaborate manner. It should devote its energy and resources in legislation, policy making, monitoring of implementation at State level, continuous review of the products approved at State level, import and approval of new drugs including clinical trials. The Central Drugs Authority should have powers to issue directives to the State Drugs Control Organizations. The implementation of the Act including licensing should remain with the State Drugs Control Organizations.
- ***The CDA should be in addition to the Drugs Technical Advisory Board and not as a substitute to DTAB.*** It is necessary to ensure that out of five members of CDA,

at *least* two *members are technical experts in pharmaceutical field. The State Drugs Controllers or the officers of the level of Joint Commissioner with outstanding record should also be considered eligible for appointment to the post of Chairperson or Member of the Central Drug Authority.*

- Priority needed to be accorded to strengthening of the Drugs Control Organization at State level. The Statement of Objects and Reasons should have a specific clause to focus on ***strengthening*** of the Drugs Control Organization at Central and State level. The objectives of strengthening can be achieved by incorporating provisions under the Bill for appointment of ***Commissioner* of *Drugs Safety*** in each State. He should be a technically qualified person and should be Head of the Department and controlling authority. It is necessary to strengthen Drugs Control Organizations at State level in terms of uniform organizational structure, adequate infrastructure, adequate and competent manpower.

- The Financial Memorandum attached to the Bill is vague and ambiguous. It states that "the exact amount of expenditure involved will depend on the number of Members appointed and will be met out of the revenues of the Central Drugs Authority of India". An imminent increase in the fees for the services rendered by the licensing authority is unavoidable to meet this requirement.

AYURVEDIC MEDICINE MANUFACTURERS ORGANIZATION OF INDIA (Kerala branch) brought out very pertinent issues affecting the Ayurvedic drugs industry that arose from the various provisions of the Bill before the Committee

- The proposal to have a single drug authority to cover all licensing activities pertaining to manufacture of drugs, includes AYUSH drugs also. Which would have a serious impact on the growth and survival of Ayurveda industry. The reasons cited were:—

  (i) There is no set up at Central level to take care of licensing activities of Ayurvedic drugs.

  (ii) The method of performing clinical trials in case of Ayurvedic Drugs is different and complex unlike that of the modern drugs. It requires a technically sound person who is well versed in the methods of Ayurveda. Therefore the definition of clinical trials needs to address to these issues. Moreover, there are also differences between the 'Drugs' and 'Cosmetics' in ayurveda and these issues need also be given due care when the issue of clinical trials is dealt with.

  (iii) Centralised licensing will be possible only if State level officers are equipped with adequate staff or set up.

- Since the formulations and preparation techniques for the Ayurvedic drugs and the modern drugs were different, it is necessary that there should be some technical expert from the field of Ayurveda in the composition of the proposed Committee of Central Drugs Authority. Matters pertaining to AYUSH may therefore be excluded till adequate infrastructure facilities are provided.

SHRI UNNIKRISHNA PANICKER, M.M. (a Senior Lecturer in Hospital and Clinical Pharmacy Medical College) who had appeared before the Committee as an **Expert** has provided a very succinct view on the Bill bringing out very pertinent points covering various provisions of the Bill. His **views have been appended as ANNEXURE II to this report.**

SHRI CHITRA THIRUNAL INSTITUTE OF MEDICAL SCIENCE AND TECHNOLOGY (SCTIMST)

The SCTIMST is an Institute of National Importance established by an Act of the Parliament with the objective of promoting Biomedical Technology and which has been actively involved in the **development of Medical Devices in the country.** Following suggestions/ observations were made by them:

- Since the enactment of the over the past few decades, Drugs and Cosmetics Act, 1940 was enacted and the drugs alone were regulated. ***Even though the devices also were incorporated in the definition* of *drugs, the same was not being regulated for many decades***. The Drugs and Cosmetics Act does not provide proper frame work for regulating medical devices. With the current regulations, it is insufficient to regulate the medical devices.

- "Medical devices" as generally defined covers lenses and syringes to critical life-saving and life-supporting devices like artificial heart valves and hemodialysers; the numbers are increasing rapidly every year, with the development of new advanced materials and technologies.

  However, as per the definition of 'medical devices' in the proposed Bill, all the devices from scalpel to Cathlab will be covered. Control of medical devices will require a gamut of expertise from physics to biomaterials. The Drugs and Cosmetics act has separate provisions for Unani and Siddha, the areas where the pharmacists do not have the required competence, whereas no separate provision has been made for Medical Devices.

STATE GOVERNMENT OF KERALA

The Committee interacted with the representatives of the State Government of Kerala on the Bill, whose views are as stated below:—

- The Drugs Controller stated that at present, all States have authority to issue manufacturing licences and such drugs can be sold anywhere in India or be exported. Even the State Drugs Control officials are not sure whether the details of licences printed on the labels of drugs manufactured outside the State are authenticated or not. In the case of imports of drugs, the situation remained worse. **Import license is granted by the CDSCO. Their duty ends with granting of licences. State drugs control authorities are not aware whether someone is actually licensed.** Many drugs which are **not granted permission as new drugs,** are available in the market **either as drug itself or as dietary supplements.**

- By creating a CDA, the Central Government intends to take away the licensing powers from the States and with ***no responsibility* of *enforcement,*** such a move will not strengthen the enforcement system. **A Central Government Authority with no responsibility and States with no authority and only responsibility shall always lead to confrontation.**

- The present CDSCO with four regional offices and very few enforcement staff can do practically nothing with regard to licensing, endorsement of additional products, etc. of tens of thousands of manufacturers. Till a few years back, CDSCO didn't have much work. Now import registration, Clinical trials, pharmacovigilance, and new drug approval, have all been added to their responsibility and with decreased staff strength the situation can go from bad to worse.

- **Although one of the most vital departments dealing with very confidential matters, it is mostly run by contractual staff and consultants.** So if the Central Government wants to equip the CDSCO with licensing powers of the NDA, they need at least one office in each State and ten times the present staff strength. **The CDSCO do not have the infrastructure and expertise to grant licenses.** An experiment with four offices and 30 field staff will only be a child's play. The example of licence approval of Blood Bank and IV Fluid, even without any responsibility, has proved the inefficiency.

- There is not only **non-uniformity among different States**, but also within the same State. Different Drug Inspectors of the CDSCO have different standards. While inspecting blood banks and manufacturing units, there is inordinate delay in approving licenses. It takes six months to one year to get back a license approved by the CDSCO. The situation when all manufacturing licences would be issued by CDSCO can well be imagined. Progress can be achieved only through delegation and de-centralization.

- A very pertinent point about the ***over the retail counters sales*** **of** ***drugs,*** was highlighted. Even in a place like Kerala, where they have better Drugs Control Administration, ***over the retail counters sales are not controlled properly.*** Presently, **half** the sales are effected through hospitals and clinics **without any drugs licence, supervision of pharmacists, Sales Bills and price control for drugs.** ***Even in the licensed retail stores, half*** **of** ***the laws*** like drugs should be sold through prescriptions, only qualified doctors can prescribe medicines, he should write and sign it, Bills to be issued for sale of all drugs, registers to be maintained, prescriptions to be stamped by the dealer, etc. are not enforced.

- **Certain other suggestions** on behalf of the State Government, were presented which while meeting the requirements of a strong National level Administration, will not disturb the existing Central or State establishments, rather it would increase the efficiency of the system.

    - Drugs Control Administration in many States, Union Territories as well as CDSCO is presently not independent. These Departments are working under Health Services Department. They grant Blood Bank licenses to their own bosses. The CDA should be made **an independent Department both in the Centre and in States.** Uniform designations, hierarchy and pay structure should be made in all States/Union Territory Drugs Control Administration and CDSCO.

    - The State level appointments and promotions should be only up to Assistant Drugs Controller, who shall be the licensing authority for sale licenses in the State and UT. State shall keep seniority list of Drugs Inspectors. Any promotion above Assistant Drugs Controller will only be at National level. If an ADC doesn't want promotion, he may be allowed to continue in his own State service. Once he accepts promotion he would have to serve in any State where vacancy arises. At the time of promotion to Assistant Drugs Controller, he may be given the choice to opt whether to continue in the State service or accept promotion and enter Central Services.

    - The revenue/expenditure of the Departments shall be borne by the State or Central Government, as at present is the system.

- The present CDSCO, New Delhi will continue as an CDA Headquarters under the Central Government. All State Drugs Controllers shall be under the Drugs Controller General India. The seniority list of all Assistant Drugs Controller, Deputy Drugs Controller and Joint Drugs Controllers working in the States, UT and CDSCO should be prepared and all further promotions made by the Central Government. State Drugs Controllers should be in the cadre of Deputy or Joint Drugs Controller as the case may be and the senior most Joint Drugs Controller shall be promoted as DCG (I). The Drugs Inspectors of the present CDSCO offices will continue with the functions of import licensing, port/customs offices, new product approval and as Intelligence Branch. They should not be connected with licensing. They would collect random sample of drugs, and conduct surprise inspections of manufacturing and sales premises and make prosecutions and conduct measures. Above the level of ADC, they would also be merged with the common pool.

- Indian Pharmacy Service is to be formed and they shall be posted in the Rank of Deputy Drugs Controller.

- ***There* is no *necessity* of *creating new offices;*** instead the present offices can be effectively utilized. As the heads of offices are from common pool, there would be uniformity of administration also. If there be funds, the number of field force may be increased.

- The system of Joint Licensing should be abolished, as it serves no purpose. One authority can issue license. If one particular Inspector is not competent to inspect, there is no meaning in taking him for joint inspections. To get expert opinion from any source, they need not be taken for inspections. It is not proper to take any outside person to inspect licensed premises. It is worse when one licensee is taken as an expert and inspects other licensed premises.

- If we can merge the food control administration also with Drugs Control Department, like USFDA, it will be ideal. Now in Maharashtra, Gujarat, Andhra Pradesh, Goa and CDSCO food and drugs are jointly controlled.

- The definition of devices is confusing.

- The amendment proposes issue of all sorts of licence by CDA. Formerly licensing authority and fees were dealt in the Rules. When the Act specifies CDA as the Authority and nothing is mentioned about State, it may give an idea that States are not even authorized for sale licences.

TAMIL NADU
(DATE 11.01.2008)

The Committee interacted with the following entities at Chennai—

The Pharmaceutical Manufacturers' Association of Tamil Nadu, Confederation of Indian Pharmaceutical Industry - (CIPI) Tamil Nadu Branch, State Government of Tamil Nadu, Drugs Controller Officers' Association of Tamil Nadu, Citizen Consumer and Civic Action Group-Chennai, The Indian Pharmaceutical Association (IPA) Tamil Nadu Branch.

THE INDIAN PHARMACEUTICAL ASSOCIATION (IPA) TAMIL NADU–BRANCH

The IPA is an all India body representing various sections of pharmaceutical science and pharmacy profession like, Pharmaceutical Industry, Pharmacy College, Drug Regulatory officials, Community Pharmacists, Research and Development Scholars and Pharmacy student.

The foremost submission of the IPA (Tamil Nadu Branch) was that the amendments to "The Drugs and Cosmetics Act", as proposed by the Drugs and Cosmetics Amendment Bill 2007, are unwarranted. The reasons they submitted are as below:

- Any growing country will be supported by more of decentralization of procedures and control than 'centralizing' the activities and authorities.
- In the current scenario, most of the procedures in Drug Control Department like issuing licence, renewal and granting other certificates for exports are done at State level in an excellent manner. There is no necessity to "plug" these powers from State level to an autonomous "Central Drugs Authority".
- The Regulatory officers and the drug controlling authorities in the State are well equipped and have equal expertise in their role compared to Central Drug Authorities. For technical reason, there is no necessity to transfer the licensing procedure from the State to Central level.
- Above all, there is an existing rule that that central DCGI office only can approve any new molecule or new combinations. The State authorities are currently granting license as per the standards laid down by Indian Pharmacopeias for old molecules and regular dosage forms. Centralizing this procedure will be a "Herculean task" and in that process the "Pharma Industry" particularly the small scale pharma industries will be thrown out of their business.
- IPA is not against giving "Quality Medicines" to the human kind. Any updation and training to improve the current status can be given to the existing State authorities rather than bring a new set up.
- Regional companies will have tough task in going to New Delhi or the Central Authority for grant or renewal of licences for product endorsement compared with getting approval from the "State authorities". Any how these companies are already manufacturing quality products, as per Schedule-M and for routine "Indian Pharmacopoeia" products, making them to go to "Central Drug Authorities" are uncalled for.
- ***They were* of *the view that these kinds* of *new procedures will support only bigger companies and multinational companies.*** Instead of this, the Centre can work towards **improving our current infrastructures like Inter linking of all offices across the country, giving training to the regulatory authorities along with small and medium companies about the International Standards and make them more qualified to compete with bigger companies.**
- Existing role and procedures for State Drug Control Department and Central Drug Department is more than sufficient to manufacture quality medicines in India. **We need to update and train them further on current trends rather than going for new and untested amendments in "The Drugs and Cosmetics Act".**
- Currently Form 10 is issued by the Central Drug Authorities to import pharmaceutical raw materials. The procedure to get this form is very cumbersome and the delay is very commonly seen. When existing procedure itself is putting so many burdens on the

export and import of pharma products, we should not centralize the entire licensing procedure. This will become a hurdle for the pharmaceutical companies to grow faster.

CITIZEN CONSUMER AND CIVIC ACTION GROUP, CHENNAI.

The representatives from Citizen Consumer and Civic Action Group were also opposed to the proposed amendment Bill and cited the following reasons:

- Present trends indicate that decentralization of powers benefit all sections of society till the grass-roots level. The proposed amendment to the Drugs and Cosmetics Act, 1940 abridges the powers of the State Government and attempts to set up a system consolidating all the powers to the Centre. Hence State Governments would not be able to implement the provisions of the Act effectively and the Central Government may not be in a position to address the issues of consumers effectively and speedily. Dual control systems have not proved to be either beneficial or effective in the long run.
- The proposed amendment has been initiated by citing the reason that there are inadequate infrastructural facilities in the existing system. The Central Government should not curtail the functions of the lawful authorities of the State Government for this simple reason alone. Creating another authority will not resolve the problem.
- Instead the Central Government and the State should strengthen the existing regulatory system with all the functions envisaged under the CDA.
- The funding authority should allocate additional funds and provide adequate personnel support for the betterment and effective intervention of the existing mechanism.
- This proposed single-window system requires every applicant to approach the Central Board at Delhi for obtaining or renewing license under this Act. This cumbersome process will cause inconvenience to the public and will result in undue delay. Instead, suitable standard operating procedures may be devised for the State licensing Authorities.
- The existing provisions empowering the State Governments have facilitated easy access and also ensured speedy redressal to the consumers for their grievances.
- Providing powers to the State Governments facilitates consumers, their representatives and other stakeholders to participate in decision-making and thereby ensure a conducive mechanism.
- For ensuring uniformity at the State level, the Central Government may prepare and circulate a list of comprehensive uniform guidelines to be implemented by the State Governments within a specified time-frame.

DRUGS CONTROLLER OFFICERS' ASSOCIATION OF TAMIL NADU

The Director, Drugs Control, spoke as the representative of the **Drugs Controllers Officers' Association of Tamil Nadu.** Their views are stated as under:—

- To the Proposal to bring out Drugs and Cosmetics (Amendment) Bill, 2007, the Director, Drugs Control said that the Bill totally changes the existing system and brings out a separate body. Instead, ***the focus*** **of** ***the Bill should be on the issue*** **of** ***strengthening and creating uniform organizational structure and strengthening the Drugs Control Organisation*** **at** ***Central and State level.***

- **Central Drugs Authority of India: – Clause 5(1)** of the Bill **abolishes the existing Drugs Technical Advisory Board** consisting of technically qualified professionals. **Also,** ***the Proposed Central Drugs Authority does not prescribe qualification and expertise of the professionals.*** The Central Drugs Authority comprising of non-technical persons will have limitations on handling technical matters.

  Hence the existing Drugs Technical Advisory Board has to be restored, as by abolishing the Board, the representation hitherto available from States will be abolished. Moreover, the Drug and Cosmetics Act, 1940 and its implementation is highly technical in nature and requires advisory bodies and implementing agencies comprising of technically qualified professionals.

- **To the proposed provision 5F (1) of the Bill-** "The Central Drug Authority may issue licences under clause (c) of section 10, clause (c) section 18 and clause (c) of Section 33 EEC and collect fees therefore.", it was suggested that:—

  (i) The Central Drug Authority will have the powers to grant manufacturing and selling licences **in addition to the existing powers to grant import licence** under **Section 10** of Act.

  (ii) Hitherto licenses were given for sales concerns and for manufacturing certain categories of drugs to the manufacturing units by the State Licensing Authority. By the proposed amendment the power of the State Government to issue licences has been taken away and **this will lead to major problems to the small and medium drugs manufacturing units as they have to travel all the way to Delhi even for small matters.**

  Further, this is **against the concept of decentralization of powers** to the grass root level and this amendment will make a centralized structure which will not be in public interest. The proposal is thus against the principle of federal structure outlined in the Constitution of India.

  (iii) The solution to the ***problem*** **of** ***spurious and substandard drugs*** in India lies in building competence in the State Drugs Control Organizations by strengthening them and by enhancing technical, managerial, legal and investigation skills of the officers through scientifically designed training programmes and not by centralizing of licensing system.

- Hence, the **existing set up of** State Drug Control Administration in issuing licences for certain categories **may be retained** and State Drug Control Administration should be **strengthened for effective implementation** by the following measures to be taken by the Centre:—

  (i) **Issue guidelines** on various issues so as to facilitate proper functioning of the State Drugs Control Organizations and **to ensure uniformity.**

  (ii) Take **periodical review** of the activities of the State Drugs Control Organizations by **conducting regulatory audit.**

  (iii) Setting up and monitoring the activity of Intelligence Branch to **ensure Inter-State Coordination** for eradicating menace of spurious and sub standard drugs.

  (iv) **Conduct survey of enforcement and administration of the Act in the Country.**

(v) Take necessary steps to ensure that public, consumers' associations receive rapid, reliable, objective and comprehensive information through appropriate methods and means.

(vi) **Conduct Training Programmes** in Drugs Safety and Standards, technical, legal and investigation aspects for the Drug Control officers and all the stakeholders.

(vii) **Suggest and advice in issuing Fixed Dose Combinations.**

(viii) **Strengthen Drugs Control Organizations at State level in terms of uniform organizational structure, adequate infrastructure, adequate and competent manpower.**

- **To the proposed provision under Section 18** [In the Principal Act, in Section 33 (1)] relating to "Power of Central Government to make rules on certain aspects"

(a) In sub section (1) for the word "Board" wherever it occurs, the word "Central Drug Authority" shall be substituted.

(b) In sub section (2)—

(i) **Clause (b) shall be omitted,**

(ii) in Clause (e),—

(A) for the words "manufacture for sale or for distribution" the words "Manufacture for sale or for distribution" the words "Manufacture for sale or for Export or for distribution shall be substituted shall be substituted; and

(B) the words "the authority empowered to issue the same, the qualifications of such authority" shall be omitted;

(iii) Clause (n) shall be omitted.

They remarked that the proposal to omit Clause (b) of Section 33 (2) as proposed under Section 18, which **authorizes the Central Government to prescribe the qualification and duties of the Government to Analyst and the qualifications of Inspectors,** is a serious flaw in the Bill. In exercise of these powers, the qualifications of the Government Analyst and the Inspectors have been prescribed under Rule 44 and 49 of the Drugs and Cosmetics Rules, 1945. The Central Drug Authority has **NOT been given any power to prescribe the qualification and duties of the Government Analyst and the qualification of Drugs Inspectors** and the matter has been left **ambiguous** as to which authority will be empowered to prescribe qualification and duties of the Government Analysts and qualification of Inspectors under the current Bill.

- Stating their apprehensions, they said that ***in the* absence of *such specific provision and the prescribed qualifications, any person without any professional qualifications would be entitled* to *be appointed as the Government Analyst and Drugs Inspectors,***— a situation **not desirable** in the interest of effective implementation. Hence, **Section 33(2) (b) should not be omitted as proposed,** and the powers to prescribe qualification and duties of the Government Analyst and the qualification of Inspectors **should remain with the Central Government.**

- To the proposal to **omit the words "the authority empowered to issue the same, the qualification of such authority", they disagreed,** as this will result in

withdrawing powers of Central Government to prescribe qualification of the licensing authority. In exercise of powers under Sec. 33 (2) (e), the Central Government has prescribed qualification of the licensing authority under **Rule 49 (A) of the Drugs and Cosmetics Rules, 1945.**

The Central Drugs Authority has not been empowered to prescribe qualification for the licensing authority under the proposed Bill. It is therefore **unclear as to which authority will be empowered to prescribe qualification for the licensing authority.** In the absence of such specific professional qualification, ***any person without any professional qualifications would be entitled to be appointed*** as the licensing authority–a situation, **undesirable** for effective implementation of the Act. **Hence, they suggested that the words "qualification of such authority" should not be omitted from clause (e) of Section 33(2).**

- **Omission of clause (n) of Section 33(2) of the Act will empowers the Central Government to prescribe powers and duties of Inspectors and the qualification of the Controlling Authority, was not acceptable.** In exercise of these powers, the Central Government has prescribed duties of the Drugs Inspectors under Rule 51 and 52 and has also prescribed qualification of the Controlling Authority under Rule 50 (A) of the Drugs and Cosmetics Rules, 1945.

  The Central Drugs Authority has not been empowered to prescribe qualification for the licensing authority under the proposed Bill. Such situation is not desirable for effective implementation of the Act.

  Hence, clause (n) of Section 33(2) should also not be omitted, as proposed. The powers to prescribe qualification of the controlling Authority, licensing authority, and powers to prescribe qualification and duties of Government Analyst, powers to prescribe qualification and duties of Drugs Inspectors should remain with the Central Government.

STATE GOVERNMENT OF TAMIL NADU

The State Government representatives opposed the Bill stating that the formation of Central Drugs Authority would lead to huge losses of revenue collected by way of Licence Fees and Fines. The CDA which is going to be the APEX body (Central Licensing Authority) is a single body collecting entire National revenue generated by every State Drug Control department. This will lead into the non-development of Pharmaceutical Industries in the State and cause unemployment of Pharmacy Professionals.

- They reiterated what was already stated by the **Drugs Controllers Officers' Association of Tamil Nadu.** Their contention was that by the creation of Central Drugs Authority, the stakholders will be put under tremendous pressure in getting their licences and resolving their day to day problems. The Small Scale Manufacturers in the State will have to go to Delhi for getting their Licences and the endorsement of Products. They will be facing a lot of problems and hardships and unnecessary delay too. This hidden cost would lead to escalating the price of the products which will burden the consumers financially and defeat the objective of providing quality medicines at cheaper cost to the people.

- For any complaint regarding quality of the products or their price, consumer will have to approach Central Drugs Authority which would be situated in Delhi only and there would be no immediate Taluka/District Level Authorities to redress their grievances.

- Already for every State there is Drugs Control Department is established and functioning. State Drugs Control Departments are already decentralized by giving their licensing powers to their zonal level offices for effective control and for the speedy disposal of License Applications in order to benefit the manufacturers/traders and the people. Hence, transfer of powers to a central authority is no required.
- Drugs Technical Advisory Board constituted at present is representing various. professionals from each State advising from time to time to the Government of India for implementation of the Drugs and Cosmetics Act and rules thereunder. This is being scrapped by formation of Central Drugs Authority, consisting only of 5 people who are appointed by the Government of India and who are without any professional qualification. Moreover, the representative character of DTAB is being replaced by the lack of proper representation from various States. Under the circumstances, the decision taken by the Central Drugs Authority on the technical matters may be adverse to some States.
- Government of India constituted many committees like Bhatia Committee, Chopra Committee, Hathi Committee and recently Dr. Mashelkar Committee. All suggested various measures to strengthen the State Drug Control Administration and Central Drug Standard Control Organization for the prevention of spurious/adulterated/Misbranded Drugs. They have not suggested centralization of Licencing system.
- Their opinion was that the aim of forming Central Drug Authority appeared to be only snatching away the Licencing Power of the State as there were no suggestions for the quality improvement or prevention from the menace of spurious drugs. There were no suggestions for strengthening the State Drugs Testing Laboratory for testing the samples and reporting immediately to ascertain their quality.

CONFEDERATION OF INDIAN PHARMACEUTICAL INDUSTRY – (CIPI), TAMIL NADU BRANCH

The views submitted by the representatives from CIPI are as follows:

- The proposed amendments to the Drugs and Cosmetics Act are based on the recommendations of Dr. Mashelkar Committee suggesting that a Central Drugs Authority is to be constituted. However in Para 13.0 of the Report, it was only suggested that the drugs control organizations to be strengthened and no where the committee had recommended that Central Drug Authority is to be constituted. It has recommended only Central Drugs Administration headed by DCG (I) under para 5.8.6.
- It was also pointed out that the **composition** of the Central Drugs Authority is **vague and non-technical persons can be appointed.** The Bill does not clarify as to what role the said authority will play in the implementation of the Drug and Cosmetic Act. It was felt that the CDA would become a place where retired bureaucrats can be posted. The quantification of the members has not been given and it is very vague. The Mashelkar Committee has not recommended such authority and that the purpose of such authority could not be understood.

Centralizing of Powers

- India is the only unique country in the world where they have different systems of medicines *i.e.*

  (a) Ayurvedic System of Medicine

(b) Siddha System of Medicine

(c) Unani System of Medicine

(d) Allopathic System of Medicine

(e) Homoeopathic System of Medicine

The Homoeopathic and Allopathic Systems were introduced in the last century by the British during their rule in India. All the five systems of Medicine are co-existing and used by the patients for different ailments.

- The DTAB Drug Technical Advisory Board both for Allopathic and Indian Systems of medicine and Homeopathy in the proposed Bill is to be abolished and no alternative mechanism has been proposed. The DTAB was constituted with **large number of experts not belonging to the Ministry** and who were independent. In fact the industry was asking for additional representation to have a forum to express its opinion and views. By abolishing the same the powers have been centralized on the drug controller and this is a fall back to the colonial times. This does not encourage transparency and widespread consultation which is the need of the day. Even in revenue like Income Tax, Central Excise and Customs etc. public views are sought and given importance. **The Mashelkar Committee, in fact, has not recommended the abolition of the DTAS at all.**

Financial Outlay

- They went on to submit that the Department has grossly misled the Parliament on the Financial Memorandum attached to the Bill, saying that no expenditure of non-recurring in nature would be form the Consolidated Fund of India, which is travesty of the truth.
- It has also been stated that **"Under clause-5 (1)** a fund will be created and expenditures would be carried out from the above fund. It is pertinent to note that the Central Drug Authority, which is proposed to be constituted, is to perform a Sovereign Function, *i.e.* Implementation of the Drugs and Cosmetics Act. No other body, which performs Sovereign function *viz.* Factories Act, Weights and Measurements Act etc. are able to function only from the fees received and all the expenditures are met by the respective Governments either State or Central and fees constitute only a very small portion of income. They went on to cite the details of staffing of the Drugs Control Department of different States, which may be examined as an example, the total expenditure which would be far in excess of the fees and the Central Government has to meet the funding requirements and in this they suggested that Point No. 6.1.11 of Dr. Mashelkar Committee Report may be referred.

  They pointed out further that if the licensing powers for the manufacturing of Drugs were to be transferred from State Government to a Central Authority, the staffing of the Authority has to be increased enormously and the numbers of staff have to match the existing staff from the State Government.

  Regarding opening of Zonal Offices, they opined that such offices needed to be opened in all States depending upon the number of manufacturers located in that area. All of these would lead to increase in the cost.

Indian Systems of Medicine

- They stated that in the proposed Bill, no due representation seems to be given to Indian Systems of Medicine. Taking into account the number of manufacturers in the Indian

Systems of Medicine and in fact, a special Department, AYUSH has been constituted in the Ministry of Health and Family Welfare to deal with ISM an important issue seems to have been missed out in the proposed Bill.

- They were of the view that there were other amendments proposed in the Bill which were also objectionable and also lacked clarity such as:—
    - Section 33(2) has been proposed to be abolished, which authorized the Government to prescribe the qualification of Drug Inspectors and Government Analysts under the Drugs and Cosmetics Act, 1940.

THE PHARMACEUTICAL MANUFACTURERS' ASSOCIATION OF TAMIL NADU

- The Pharmaceutical Manufacturers' Association of Tamil Nadu, have **opposed** to the **proposed** amendment Bill. Their views have been appended to the report as ANNEXURE III.

ANDHRA PRADESH

The Committee interacted with the following entities at Hyderabad—

Consumer Care Centre, Hyderabad , Federation of Drug Traders, A.P. - (FEDTAP), Drugs Control Administration of Andhra Pradesh, Drugs, Inspectors' Association-Andhra Pradesh, Sri C. Gopalakrishna Murty, Director, Drugs Control Administration (Retired), Government of Andhra Pradesh (EXPERT), D. Hanumantha Rao, Ex-Director, Drugs Control Administration (EXPERT), Varaprasad Reddy, Managing Director, Shanta Biotechnics Limited, C.V. Narasimha Rao, President, District Consumer Information Center, Secunderabad, Organisation of Pharmaceutical Manufacturers, and Vimta Labs.

CONSUMER CARE CENTRE, HYDERABAD

The representatives of the Consumer Care Center were of the view that there is no mention of any control over prices in the Bill. It must also be added under the duties of the Central Drugs Authority. The common complaint of consumers is that the pharmaceutical companies are fixing the prices without any relation to the cost of manufacture. In the context of the Bill they were of the opinion that—

- **Clause 2 (iv)** should be redrafted so as to read such medical devices, medicated devices, instruments, apparatus, appliances, materials etc., instead of being singularly dealt with.
- **Clause 5(1)** doesn't speak of forming State Drug Authorities. There is no clarity of the role of the present State Drug Controllers. It may not be proper to make the Central Drugs Authority an autonomous body and make it a monopolistic one. Centralisation and concentration of powers in a single Authority may not prove productive in the long run. The present Department of Drug Control Administration in the States should be allowed to function as the State offices. The States must continue to have powers to grant and cancel licences. The Bill seems to take away the right of the State Drug Control Administration.
- **Clause 5-1 (1) (b)** mentions that the CDA can receive funds from such other sources. There is no clarity as to what such other sources may be. There is every possibility that the CDA might turn to the pharmaceutical firms for funds. If that happens, the CDA will be subservient to the drug manufacturers. The industry might also face harassment if they do not release funds.

- **Clause 5 A** says only persons who have special knowledge of, and at the least fifteen years' professional experience in pharmaceutical industry, research or teaching, or public administration, finance or law can be appointed as Members. The second paragraph says that only persons who have held the post of Secretary of Additional Secretary to the Government of India or any equivalent post in the Central Government or a State Government or a Public Sector Undertaking can be appointed. As only I.A.S. officers can be appointed as Secretary or Additional Secretary, clause 5A seems to exclude I.P.S. and other officers. Hence, the words "Finance and Law" may be deleted and the words experience in Drug Administration should be inserted.

FEDERATION OF DRUG TRADERS, A.P. - (FEDTAP)

The views of the representatives from FEDTAP are as follows:—

- **Amendment to Rule 65 (15) (b):**

  They stated that the existing **definition** "The description of 'Chemists and Druggists' shall be displayed by such licensees who employ the services of a 'registered pharmacist'." may be replaced by ***"The description of 'Chemists and Druggists' shall be displayed by such licensees who employ the services of a registered pharmacist or a competent person with matriculation and* 4 *years experience in dealing with drugs or holds a degree with one year's experience in dealing with drugs."***

Section 18 - Contraventions

- Under prohibition of manufacture and sale of certain drugs, manufacture for sale, or stock or exhibit (or offer) for sale or distribute "Any drug which is not of standard quality or is misbranded under Sec. 17, adulterated under Sec. 17 or spurious under Sec. 17 (b).", has been proposed.

Their contention was that a chemist can't be expected to know the quality of drug he purchases however faces certain punishment and to save himself he must comply *in toto* with Sec. 19 (3).

Therefore, in the existing provision in the Bill:—

"that he acquired the drug of cosmetic from a duty licensed manufacture, distributor or dealer thereof;" amendments may be made as follows:

"That he acquired the drug or cosmetic from a duly licensed manufacturer, Authorized distributor" **(the words "or dealer thereof' may be deleted).**

- The amendment proposed is to add the word "authorized" before distributor and to delete the words-"or dealer thereof" following distributor. This will ensure that Spurious/Misbranded/Adulterated drugs, manufactured by unlicensed/unlawful/ unauthorized persons of criminal nature, can't enter into the market as distribution channel stands closed forever for them.

- Another step, to achieve the objective of keeping the market clean, would be to **implement sub rule (2) of Rule 64 which enjoins that Licensing Authority shall screen the applicant and if not satisfied with his antecedents, he may refuse granting licence.**

By implementing the aforesaid sub-rule (2), purchases from unauthorized sources even from so called licensed dealer can be cut off thus, and supply of drugs violating Section 17 naturally dries up.

However such instances of rejection of application for license do not appear to be happening. Hence, the need is to strictly implement sub-rule (2) so that bad characters and anti-social elements cannot enter the market in the garb off licensed dealers need to be ensured.

DRUGS CONTROL ADMINISTRATION OF ANDHRA PRADESH

The representatives of Drugs Control Administration provided the Committee the following views during the meeting. They were of the view that certain provisions of the Bill were welcome measures while there were others which were objectionable.

Broadening the definition of drug under section 3(b) (iv) of the principal Act:

- The proposed definition in the Bill for 'Drug' is comprehensive and is good. The Broadening of the definition of drug under section 3(b) (iv) of the principal Act is a welcome measure.
- Introduction of a new Chapter I B covering Clinical Trials in detail is also a welcome move in the proposed Bill. As new drug molecules after thorough scientific evaluation are essential for the health management system, the proposed Bill has definite proposals and steps for thorough examination of drugs under clinical trials before they are permitted to be manufactured for sale in the country.

Establishment of Central Drugs Authority:

- Chapter 1 (A) clause 5 in the proposed Bill speaks of the structure of C.D.A, as envisaged consisting of Chairman and not more than 5 members, but at least 3 members. The eligibility criteria specified therein suggests that a person without pharmaceutical background or/and without experience in the enforcement of drug laws can become a member or chairman in the C.D.A.
    - This is quite opposite to what exists presently in the D&C Act, as specific qualifications are prescribed for licensing/controlling authorities which emphasizes for appointment of a person with a pharmacy qualification for discharging such duties. So this is not in tune with the present day requirements for a technically oriented enforcement agency.
    - The upper age limit for members/Chairman of CDA is given as 70 years which is greater than the upper age limit of a Supreme Court Judge, and which isn't acceptable.
    - The Bill proposes to replace Drugs Technical Advisory Board with the CDA. **The present Act has Drugs Technical Advisory Board consisting of <u>16 categories of persons</u> with varied scientific/technical background and experience among its members.** They advise the Central and State Governments in technical matters. The composition of CDA is not as scientifically sound as DTAB and may result in activities not based on sound scientific background. Further, **the Bill dispenses off with Ayurveda, Siddha and Unani Drugs Technical Advisory Board** which may result in activities related to these drugs, not in a very scientific manner, because the matter pertaining to AYUSH drugs requires special scientific knowledge and techniques.
- Presently, the power of amending the D&C Act and Rules is within the purview of the Central Government. Now, as per the proposed Bill at **Section 5 (L),** if the Central

Government makes any rules without consulting CDA, shall have to consult CDA within 6 months and shall consider the suggestions given by CDA. **In view of the above, the present D&C Act may not be disturbed.** As the proposed CDA will result in centralization of power which is contrary to A.P. Government, vision of Prajalavaddhaku palana (Administration to the door steps of the public).

- Further ***the license fee presently available*** **to** ***the Government*** **of** ***A.P., as revenue*** **to** ***the tune*** **of** ***15.00 crores, will be diverted to Central Government.***
- The present role of DCG (I) and CDSCO is sufficient in achieving the uniform implementation of D&C Act with coordination among the various State Drugs Control Originations.
- The present provisions of D&C Act are in tune with the federal structure of our country. Hence, from the proposed Bill Chapter 1.A may be omitted.
- As such it appears that in no way that the CDA as envisaged in the proposed Bill is better than the existing system of Drugs Control in the country and do better in controlling the spurious drugs movement than present Drugs Control set up in the country.

DRUGS INSPECTORS' ASSOCIATION OF ANDHRA PRADESH

The suggestions put forth by the representatives from the Drugs Inspectors' Association are stated as follows:—

- Appointment of Commissioner of Drug Safety in each state was called for. The Scheme under Food safety and Standard Act, 2006 should also be referred while making provision for appointment of Commissioner of Drug Safety in each State.
- The Central Drugs Authority at national level should be established with powers and functions in such a manner so that the legislative scheme and the division of responsibilities between the Central Government and the State Government are not tinkered with. ***The CDA should be in addition to the Drugs Technical Advisory Board (DTAB).*** It is necessary to ensure that out of five members of the Central Drugs Authority **at least two members** must necessarily be technical experts in Pharmaceutical field. ***The State Drugs Controller or the officers of the level of Joint Commissioners with outstanding record should also be considered eligible for appointment to the post of Chairpersons/Member of the Central Drugs Authority.***
- The **powers, functions and duties** of the Central Drugs Authority should be laid down elaborately. It should devote its energy and resources in legislation, policy making, monitoring of implementation at state level, continuous review of the products approved at state level, import and approval of new drugs including clinical trials. It should have powers **to issue directives** to the State Drugs Control Organisations. The ***implementation*** of the Act, including licensing should remain with the State Drugs Control Organisations.
- Priority should be given to strengthening of the State Drugs Control Organisations. ***The Statement of Objects and Reasons should have specific clause to focus*** **on** ***strengthening of the Drugs Control Organisations at Central and State level.*** For achieving the objective of strengthening of Drug Safety in each State, the Commissioner of Drug Safety should be a technically qualified person and should be head of the department and controlling authority. It is necessary to strengthen Drugs Control Organisations at state level in terms of uniform organizational structure, adequate infrastructure, adequate and competent manpower.

SRI C. GOPALAKRISHNA MURTY, Director, Drugs Control Administration (retired), Government of Andhra Pradesh. (EXPERT)

- The policy of the Government, in general, is to decentralize powers of licensing. Therefore, instead of centralizing the licensing of manufacturing by creating Central Drugs Authority, the Government **should strengthen the existing Drugs Control Organisation at the center and create more effective regional offices throughout the country and continue the existing setup.**
- They should **monitor the implementation** of the Act **for uniformity in all the States. Periodic review of implementation** for the effective uniform enforcement by sufficiently augmenting CDSO with the staff which will lead to uniform implementation of the Act.
- The Central Drugs Authority is to be constituted, the functions, responsibilities and duties should be clearly specified.
- Constitution of the CDA with **five members is inadequate** and a wider body may be constituted with **persons having experience in the enforcement of the Act** as members, as they will have a better understanding of the various problems in enforcement.

D.HANUMANTHA RAO, Ex-Director, Drugs Control Administration (EXPERT)

Who appeared before the Committee, had the following observations to make on certain provisions of the Bill:—

- CLINICAL TRIALS: He was of the opinion that the proposed definition of clinical trial includes a systematic study of any Drug or Cosmetic. Presently, clinical trial is defined under Rule 122-DAA of Drugs and Cosmetic Rules, 1945. The proposed definition covers Cosmetics. It is submitted that Cosmetics are not studied through systemic study. Hence, inclusion of Cosmetics in the definition is to be deferred. **Cosmetics are studied for their safety, but not for their efficacy.** A reference to the Rules governing Cosmetic products in the European Union may be of use of knowing about the safety studies of Cosmetics. **Therefore, the definition as exists under rule 122-DAA may be retained.**
- It is also seen that DTAB is proposed to be replaced by Central Drug Authority of India. While DTAB is a statutory body of individuals who are highly talented in their own field of specialization either in Pharmaceutical Sciences or in medical Sciences, the present proposed C.D.A. does not have members with such academic qualifications etc. **Though the proposed Bill says qualifications of the Chairperson and the members, no qualifications are prescribed under cluase 5A.** It is also seen from the said section that persons having experience in Public Administration, Finance or Law are also eligible to hold the position of a Chair person or a member, **though they are not directly involved in drug development/enforcement activities or any field related thereto.** Hence, the purpose of creating C.D.A. for uplifting the standards of the Drugs and Cosmetics in our country may not be achieved. ***Further, the age limit of 70 years for the members is also* to *be reconsidered since it is more than the age of superannuation of any Government servant.***
- The proposed **clause 5F (I)** empowers only the Central Drugs Authority to issue licences under Section 10(c), Section 18 (c) and Section 33 EEC(c) of the Drugs and Cosmetics Act, 1940. **In other words, all the licences either for import,**

manufacture for sale or sell or stock or exhibit or offer for sale of all drugs including household remedies are to be issued by Central Drugs Authority. The proposed amendment is **contrary to the present provisions of Law** and challenges the policy of the Government to reach the public though its services. It is to be noticed that the proposed amendment concentrates at Centralization instead of decentralization.

- **Clause 5F(5)(b)** empowers the Central Drugs Authority to recommend to the Central Government – the Central Drugs Laboratories for the purpose of testing Drugs and Cosmetics. **This provision should be read as "classes of drugs or cosmetics" to be tested/analysed instead of "drugs or cosmetics".**

- The proposed amendment excludes offer for sale which is existing in section 18 of the Drugs and Cosmetics Act, 1940. The same may please be included.

- **Chapter 1B Clause 5N** proposes to replace Rule 122-DA of the Drugs & Cosmetics Rules, 1945.

- **Clause 5O (1)** proposes a penal provision for conducting clinical trials ***without the permission granted and issued.*** It is seen from the said provision that **only the sponsor is made liable for a violation under Clause 5N leaving the person who had actually conducted the clinical trials.**

  Therefore, in Clause 5N, the words ***"as well as the Organisation/Institution actually conducting the clinical trials"*** may be inserted.

- Under Clause 5P (1), the authority of authorizing for launching prosecution rests with the Central Drug Authority. Since the Drugs Controller (India) shall have administrative control over the Officers and employees of the C.D.A., it is suggested that the authority of authorizing for launching prosecutions may be shifted to the Drugs Controller (India), instead of C.D.A.

  It is also submitted that the proposed amendment is contrary to the provisions of Section 32 of the Principal Act.

- It is suggested to include the word **Export** in Chapter IV and Section 18 of the Principal Act. However, it is seen that the **provisions related to export** are not included in the proposed amendment. **Since Chapter III of Drugs and Cosmetics Act, 1940 relates to imports another section namely Section IIIA may be incorporated pertaining to Export of Drugs and Cosmetics.**

- The purpose of amendment to the present Drugs and Cosmetics Act, 1940 is to ensure the quality and safety of drugs and cosmetics available to public with an idea of improving the quality of health services and safe use of cosmetics respectively. This can be better achieved by improving the present system of Drugs Control Administration in the county by making necessary amendments as and when required. **The menace of control of spurious drugs can also be controlled better by amending the Act with higher degree of punishment to all involved in the violation.**

- Therefore, it is **suggested** to strengthen the existing system rather than redesigning the policy afresh. In other words, the introduction of Central Drugs Authority may not achieve the Aims and Objectives of the Drugs & Cosmetics Act, 1940 in any better manner than the existing one.

VARAPRASAD REDDY, Managing Director, SHANTA BIOTECHNICS LIMITED, who represented the aforesaid industry, had the following comments to make on the Bill.

- Clause 2 (aaii)

  "Clinical trial means systematic study of any drug or cosmetic in human subjects to generate data for discovering or verifying its clinical, pharmacodynamic or pharmacokinetic) or adverse effects with the objective of determining safety, efficacy or tolerance of the drug or the cosmetic".

  The definition of clinical trials, according to him, required clarifying several issues such as whether the current definition incorporates clinical trials that are conducted for food substances or food derivatives (oils, nutritional supplements etc.) under its jurisdiction of this definition and whether permission for conduct of such trials is also required. Hence he suggested that the nature of biologicals needed to be ***identified*** and ***included*** in the definition of a drug or expand the present definition to include all types of biologicals as against the present mention of the word *"biotechnology derived",* in the definition.

- **Chapter 1A Clause 5F (3)**

  "The Central Drugs Authority shall collect charges for granting permission for conduct of trails in respect of drugs and cosmetics."

  Clarity as to whether the proposed charges as mentioned above would vary with different aspects of clinical trials – the phase of the proposed trial, the number of centers and the number of patients.

- **Chapter 1 B Clause 5N**

  "No person shall conduct clinical trials in respect of any drug or cosmetic except under, and in accordance with the permission granted by the Central Drug Authority."

It was opined that the Bill should contain provisions regarding **fixing of some time frame** for the Authority for providing **permission for the trials,** on the similar lines as various international regulatory agencies.

Similarly, the Bill should also **clearly mention** as to whether

(i) the above rule applies universally to all the phases of trials,

(ii) the outcomes of the post marketing safety observational studies,

(iii) whether it would be required to seek permission to start such studies or can the studies be initiated, and

(iv) whether it would be required to submit such reports to the Authority.

C.V. NARASIMHA RAO, PRESIDENT, DISTRICT CONSUMER INFORMATION CENTER, SECUNDERABAD

- In **Clause 5 (3)** dealing with the **composition of the CDA** it was suggested that without ambiguity it may be explicitly stated that the membership may be either three or five members.

- In **Clause 5A** dealing with the **Qualification of the Chairperson and Members,** it was suggested that their qualifications need to be strictly from the Pharma field, but not from Public Administration, Finance or Law areas.

- In **Clause 5B** dealing with the age limit for the Chairman and members of the CDA, it was suggested that **the proposed age of seventy is not desirable.** The age limit should be made 60 years instead of 70 years.
- **Clause 5D** dealing with the **validation of the act or proceeding of the CDA,** it was suggested that the said clause needed to be deleted totally, as this provided an unasked opportunity for the people who commits defects and irregularities blanket cover.
- In the old **Clause 5, the DTAB comprised of members from different fields.** It was suggested that likewise provisions may be made in the proposed authority, **including one member from a consumer organization,** as this Act is supposed to be a Consumer Protection Legislation.
- **Under Clause 5L,** time frame may be fixed for framing rules (as, for several Acts the framing of rules has taken years together).

ORGANISATION OF PHARMACEUTICAL MANUFACTURERS

The representatives for the aforesaid organization were of the opinion that when decentralization of administration is the order of the day, making CDA the only licensing authority would result in the increased time and cost to SSI and thereby hardships to them. They were of the opinion that creating CDA won't result in eradication of spurious drugs as the problem was essentially an outcome of failure of proper monitoring mechanism across the country among the States/UTs. By centralizing the licensing procedure, exodus of SSIs to Delhi and neighboring States would be fuelled. Global standards, according to them, could be met with appropriate amendments to the existing D&C Act from time to time and that central licensing would not be a cure for the same.

They further contended that the proposed Bill was an attempt to drive out SSI from Pharma sector, consequently enabling MNCs and large companies to take over their market share. It was the lack of information and credible statistics that was responsible for driving the present proposed Bill. **The charge of 35% spurious drugs and largely attributing to SSI has not been proven.** For implementing the uniform applicability of the existing Act, the DCGI is vested with sufficient powers.

Many of the suggestions made by Dr. Mashelkar Committee needed to be incorporated in the administrative system like active co-operation between the manufacturers, wholesalers, retailers, doctors and others to curb spurious drugs. As proposed in the aforesaid report, **Special proposed court (Fast Track) may be established to deal with the violators and punish them severely.** This is possible within the existing provisions of the present Act.

It was **suggested** that the Bill may be dropped in toto **and the recommendations of Dr. Mashelkar Committee may be incorporated in the present Act** providing no external influences to sidetrack the administrative machinery, as this Pharmaceutical industry should be strictly governed by scientific principles.

VIMTA LABS

- **Chapter 1B Clause 5N, and, 2 (c) of the Statement of Objects and Reasons of the Bill refers to "clinical trials" and related issues.**

  It was suggested that **time lihes for granting permission for clinical trials especially when scope of clinical trials has been broadened to include cosmetics and medical devices should be mentioned in the Bill.**

- In **Chapter II Section 5** of the **Original Act**, in addition to the members of the DTAB mentioned therein, it was suggested that **persons from Contract Research Organizations** who would be **testing Drug Substance, Drug Product, Medical Devices, Evaluate Diagnostic Kits and equipments should be made a part of this body** as a bridge between Sponsors (national and international) and regulatory body, as work related to research and development is delegated by Sponsor to CRO and technical issues need representation complying with international guidance.

  Hence, they were of the opinion that the DTAB may not be replaced at the outset.

- In CHAPTER II Sections 6, 7 and 7A, persons from Contract Research Organizations **who would be** testing Drug Substance, Drug Product, Medical Devices, Evaluate Diagnostic Kits and equipments should be made a part of this body **as a bridge between Sponsors (national and international) and regulatory body, as work related to research and development is delegated by Sponsor to CRO and technical issues need representation complying with international guidance.**

- **Chapter III Section 12 (g) of the Original Act,** for **Investigational drugs** it was stated that it would **not be possible to provide the date of expiry of potency as stability studies with pivotal batches may not be over and decisions are based only on the accelerated stability data and insistence on date of expiry is not meaningful in such cases.** They stated that this clause would hold logic for marketed drugs but not for drugs under investigational stage which needed to be imported for conducting comparative clinical studies.

- **In Chapter IV Section 18 proviso**

  "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 or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality.",

  and in **Section 20 (1),** " The State Government.....in the notification.",

  it was suggested that **functions of Central Drugs Laboratories can be assigned to competent CROs so as to reduce burden on few Government laboratories provided Central Drug Authority considers a CRO competent to undertake such activity.** This will add to overall efficiency. This will comply with above provisions as well.

ANNEXURE-III

STUDY NOTE
PHASE II
OF
PARLIAMENTARY STANDING COMMITTEE
ON HEALTH AND FAMILY WELFARE
VISIT
TO

Indore, Ahmedabad, Mumbai and Goa
from 12th to 19th February, 2008

on

The Drugs and Cosmetics (Amendment) Bill-2007

INTRODUCTION

The Committee in its examination of the **Drugs and Cosmetics (Amendment) Bill-2007,** (hereinafter referred to as Bill) undertook a study visit **to Indore, Ahmedabad, Mumbai and Goa from 12th to 19th February 2008.** During its study visit, the Committee had interacted with various associations of large and small pharmaceutical companies, NGOs, Consumer Fora individuals and experts, representatives from IMA and other stakeholders on the various provisions of the Bill. The list of witnesses who appeared before the Committee is given at Annexure IV. The views and suggestions expressed by different stakeholders are enumerated in succeeding paragraphs.

MADHYA PRADESH

The Committee met with the following entities at Indore on the 13th February, 2008. **Representatives of Madhya Pradesh Chemists and Druggists Association, Ranbaxy Labs Limited, India, M.P. Small Scale Drug Manufacturers' Association, Indore, M.P. Pharmaceutical Manufacturers' Organization (M.P.P.M.O), Pithampur Audhyogik Sangathan, and Abhyas Mandal.**

REPRESENTATIVES OF MADHYA PRADESH CHEMISTS AND DRUGGISTS ASSOCIATION

Following objections to the Bill were highlighted by the representatives from the above organisation:—

- Under Clause 5 of the Bill, it is proposed to establish a Central Drugs Authority which would be substituting the Drugs Technical Advisory Board and Ayurvedic, Siddha and Unani Drugs Technical Advisory Board. ***It was not desirable*** **to** ***create*** **a** ***Central Drugs Authority by substituting the Drugs Technical Advisory Board constituted under Section*** **5 of** ***the Drugs and Cosmetics Act, 1940 and Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted under Section 33-C*** **of** ***the Act*** **as** ***both these statutory bodies are broad based and are highly technical*** **in** ***nature,*** while the proposed Central Drugs Authority would have ***only five members*** **to** ***be appointed by the Central Government.*** Further as per the **provisions** of Clause 5 of the Bill, the Central Government **is not bound to appoint technical experts on the Central Drugs Authority.** The Drugs and Cosmetics Act, 1940 and its implementation is highly technical in nature and requires the advisory bodies comprising of technically qualified experts.

- Clause **5B** specifies ***tenure*** of the Chairperson and members of the proposed CDA. However, procedure for selection and also **the manner in which the Chairperson or members of the Central Drugs Authority can be removed is not specified.**

- Under **Clause 5E** of the proposed Bill, the Central Drugs Authority is authorized to appoint Drugs Controller (India) and other officers. However, **the qualification for appointment to the post of Drugs Controller (India) is not stipulated.** Similarly, **the manner in which the Drugs Controller (India) would be selected** is also **not** provided under the said clause. **This would give absolute power to the Central Drugs Authority to select any person to the post of Drugs Controller (India).**

- Though the Statement of Objects and Reasons of the Bill declares the intention to centralize only manufacturing licenses, **Clause 5F** of the Bill indicates that the Central Drugs Authority would have powers to grant the **manufacturing and selling licenses for all categories of drugs including Ayurvedic, Siddha and Unani medicines.** The CDA **would also have powers to grant cosmetics manufacturing licence to cosmetics.**

- In view of the provisions of **Clause 5F,** the Central Drugs Authority can also take over the **selling licensing.** Such a step would lead to much inconvenience and hardship to the dealers.

- Presently, the licensee can file an appeal against the order of the Licensing Authority before the State Government. **Once the powers to grant, renew, suspend or cancel the licenses are given to Central Drugs Authority, the licensee would have to file an appeal against the order of Central Drugs Authority before the Central Government. This means, the licensee would have to go to Delhi for filing an appeal and also on all dates of hearing till the appeal is finally decided. This would undoubtedly result in delay in disposal of appeals and also result in inconvenience and additional expenditure to SSIs.**

Suggestions made are as follows:—

- Instead of creating an additional authority, it is **desirable to strengthen the existing Central Drug Standard Control Organization (CDSCO)** creating separate divisions and by making stronger, well-equipped, independent and professionally managed body.

- **The Central Drugs Authority, if established, should be more broad based,** by having **representatives from concerned Ministries, Industry and Technical Experts in the field of pharmaceutical industry, professional associations and consumer associations. At least two representatives of AIOCD should be included in the proposed CDA.**

- Having regard to the **federal** structure of the country, and the division of the responsibility between the Central Government and State Governments, it is desirable to have an apex body at the national level similar to the National Food Authority established by the Central Government under Food Safety and Standards Act, 2006. **Health being State subject, all necessary powers and responsibilities should be shouldered by the State Governments also.**

- ***The Central Drugs Authority or* a *CDSCO should focus* on *legislation, policy review and monitoring, import, regulating clinical trials and approval* of *new drugs.***

- ***The implementation, including licensing, should remain with the State Government* as *per the existing practice. Even if the Central Government decides* to *centralize the licensing system, the powers* to *grant, renew and cancel licenses for sale and distribution should remain with State Governments.***

- ***The procedure for selection* of *Chairperson and members* of *Central Drugs Authority needs* to *be incorporated in the Bill.***

- The **Selection Committee** comprising of **senior Secretary from the Central Government and an eminent technocrat and Chairperson, Union Public Service Commission needs to be constituted.**

- **Clause 5B** should have a **provision to stipulate the circumstances in which the Chairperson or members of the Central Drugs Authority can be removed.** For

e.g. a Chairperson or the member should be disqualified or removed if he acquires financial interest or other interest affecting his functioning or if he abuses his position.

- The **qualification and the experience for appointment** to the post of Drugs Controller (India) should be Incorporated under **Clause 5E,** or an **additional Clause** making it obligatory for the Central Drugs Authority to appoint as Drugs Controller (India), a **person having prescribed qualification and experience under Rule 50A of the Drugs and Cosmetics Rules, 1945 should be incorporated.**

  Such provision is necessary,* as *by omitting the words "the qualification* of *such authority" under Section* 33 (e) of *the Act, the Central Government's power* to *prescribe qualification* of *the licensing authorities have been withdrawn.

- Top most priority should be given to implementation of various recommendations of Dr. Mashelkar Committee **especially on strengthening of Drugs Control Organizations at State level.** This is necessary to curb the menace of spurious drugs.

- The Central Drugs Authority should be given the statutory responsibility to take all necessary steps to curb the menace of spurious drugs.

RANBAXY LABS LIMITED, INDIA

The representatives from Ranbaxy Labs was supportive of the views of the previous organisation. However, they stressed upon the issue of ensuring speedy and cost effective development and marketing of quality medicine, which was one of the mandates of the proposed Bill, *i.e.*, to control the menace of spurious and sub-standard drugs.

They made the following recommendations to reinforce the scientific rationale of the Rules and Regulations which do not compromise patient safety, brings the regulations in line with internationally agreed principles, and remove ambiguities/irritants that are not conducive for speedy and cost effective development and marketing of quality medicine:—

- There is lack of uniformity of laws/regulations across the States, Which are either unreasonably strict or too liberal. Hence, steps should be taken to ensure uniformity of implementation of the existing laws.

- Definition of **new drug** needs to be revisited. It needed to be compared with definitions given in USA/EU. **In all regulations, clarity of definitions is required to prevent inconsistent interpretations.**

- **Consistency between Narcotic Drugs and Psychotropic substances (NDPS Act) and Drugs and Cosmetics Act do not seem to be there. Also, there is no clarity as to which is the final authority to resolve an issue in the event of discrepancy.**

- The schedules under the existing Act needed to be aligned to facilitate manufacture and export of NDPS drugs.

- Ranbaxy Labs favoured the system of **self-certification** stating as it would **obviate the need to testing by a Qualified Analyst under the regulatory authority.** This concept was similar to concept of **Qualified Person** in EU.

- Clarity on herbals, ayurvedic preparations and issues on their standardization, quality standards etc., should be made and in this regard, the regulations in Germany may be referred.

- Definitions of Drugs *vis-a-vis* Dietary Supplement/Neutraceuticals is needed. Uniformity is also needed in the administration of Foods/Dietary supplements, which are under FDA in some States and under Muncipality under other States.
- Limitation of the Shelf-Life of the formulation based on the API shelf-life is not rational, since greater stability is often imparted through formulation of the API. **Provision for extension of shelf life through retesting close to expiry should be made a part of the regulation.**
- **Manufacture of primary packaging (foils), rubber stoppers, ampoules, etc should be governed by the Drugs and Cosmetics Act and Rules.** This will ensure quality in the packaging of drugs and provide increased shelf-life. Also it will address the issue of sub-standardisation of drugs due to improper storage.
- Toxicity studies in India should be on the same lines as in EU and the US. A toxicological study in India is exhaustive. Moreover, in India we have to conduct Toxicity studies before Preclinical and Clinical studies. Whereas, in EU or US, the Toxicity studies can be conducted simultaneously with preclinical or clinical studies. This is so, because requirement of Toxicity studies may vary from phase to phase.

ABHYAS MANDAL

The organisation is a non-political voluntary organistaion of social and cultural activities. They had the following **suggestions** to make on the Bill.

- **Clause 5(3)** of the Bill states that three members are to be appointed by Central Government by notification in the official gazette.
- It was suggested that for the sake of convenience ***a zone*** **of** ***three*** **to** ***four States*** may be formed and **one member** fulfilling **the requisite qualifications as in Clause 5A** may be taken as a member so as to give adequate representation to every zone.
- With regard to composition of CDA under Clause 5A, it was suggested ***that if all the members or anyone*** **of** ***them is from public administration it may be ensured that he/she/they possess qualifications and/or adequate experience*** **of** ***pharmaceuticals and its related branches including those*** **of** ***Pharmaceutical chemistry, Micro Biology, Bio Technology.*** This is essential in order to overcome the problem of manufacture and marketing of sub-standard drugs, spurious drugs. Because such people from public administration not having the said qualification would have to depend solely on the reports/feed back given to them by the technically qualified.
- To the proposed **Clause 5E (1)**, it is suggested that for efficient discharge of functions and exercise of powers of CDA, its officers, **other than the Inspectors** in the Central Government or in State Governments, **need to be notified as Inspecting authorities** so as to enable them to visit any pharmaceutical formulation/basic drug manufacturing unit and make their own judgment about the WHO GMPI all statutory compliances. At present, *the Drugs Controllers are not the notified Inspecting authorities. They can visit the manufacturing units for inspection only if accompanied by* a *notified Drug Inspector.* **But for compliance of this, it is essential that every Drug Controlling Officer has to have the qualifications mentioned in Rule 50 A of the Drugs and Cosmetics Rules 1945.**

PITHAMPUR AUDHYOGIK SANGATHAN

The above organistaion, a representative body of large, medium and small scale industries in the district of Dhar and Indore, cited that since Indore is the first fully

functional multi-product SEZ and a lot of industries were upcoming from the Pharma sector in the area, it was of the opinion that a separate Licensing Authority and an independent Central Zone Office of the DCGI be established in Indore.

M.P. SMALL SCALE DRUG MANUFACTURERS' ASSOCIATION, INDORE and M.P. PHARMACEUTICAL MANUFACTURERS' ORGANIZATION (M.P.P.M.O).

Both these organisations had made identical submissions as indicated below:—

- Their submission was that the creation of Central Drug Authority with powers to issue licenses under **Clause (c)** of **Section 18** and **Clause (c)** of **Section 33EEC** and collect fees therefor is violative of the Constitution of India where responsibility of health matters rests with the States. Whereas the power to issue license under **Clause (c)** of **Section 10** may lie with the Central Authority. And the Bill is also violative of the Government of India Act..1935.

- The **substitution of the "Drugs Technical Advisory Board" by the "Central Drugs Authority"** is also unreasonable, illogical in as much as that ***the qualification* of *the Central Drugs Authority has not been prescribed and the experience* in *Pharmaceutical Industry, research or teaching should be compulsory.*** The intention in the later part of **clause 5A and provisio thereto** *clearly indicates placement* of *non-pharmacy persons* as *chairperson/members in* CDA.

- Undoubtedly and also as observed by the 'Mashelkar Committee', ***there* is *immense shortage* of *expert professionalists* in *States/UT and Central Drugs Control establishments. The Government laboratories are also ill equipped, with improper infrastructure and lack* of *proper expert staff and technicians.***

- These **shortcomings** deserve to be **addressed first with top priority instead of making new rules which would further complicate the industry/trade.**

- It would neither **be reasonable nor justifiable to centralize the powers to grant/ renew licenses for manufacture of drugs in the country.**

- **The present structure** of licensing by States/UT Drugs Authorities **should be continued.** The **monitoring** by the Central Dugs Standard Control Organization (CDSCO) should be made **more effective.**

- **The powers to issue licenses/Approval/permission for Blood Bank, LVP, New Drugs etc, as already with DCGI, may remain as it is but its monitoring needs to be more stronger.**

- ***Branded drug formulations and their compositions, claims being made, indications, advertisements, devices, clinical trials, post marketing surveillance, import/export etc.*** are **the sectors** where CDSCO should involve itself more effectively. The recent example that thousands of Fixed Dose Combinations, conveyed under the definition of New Drug have been licensed by State Authorities unauthorisedly without clearance by DCGI and all such thousands of branded FDCs are being manufactured and marketed by hundreds of so called reputed companies for the last nearly two decades is enough to substantiate our statement.

- Government should ensure that **the entire licensing and issuance of various certificates by the State/UT should be computerized and interconnected.**

- CDSCO be entrusted the important assignment to study various judgments delivered by Courts in the country in respect of alleged violation of Drugs and Cosmetics Act/Rules

in an unbiased manner and also to suggest/recommend their implications to States/UT Drugs Authorities.

- Thousands of prosecution cases are pending in various trial courts of the country, where as per assessment, more than 90% are bound to result in acquittal, should be reviewed objectively by the CDSCO with representation of the Industry/Trade and Law Authorities and deserving cases should be withdrawn. This process if accepted and adopted would result in availability of working hours with the field officers to look into other important matters in the implementation and enforcement of the Act/Rules.
- The substitution of **sub-section (2)** in **Section 7** is a **welcome move** provided ***decisions taken in the meetings are made mandatory for enforcement throughout the country.***
- Thousands of branded medicines under the garb of "Ayurvedic", "Herbal", "Food Supplement", Defective/Outdated/Rejected Devices etc. are available in the market, majority of them violative of the existing Act and Rules. No check is there due to 'shortage of honest, dedicated, knowledgeable, trained Inspectorate Staff. Besides that, **many State Food and Drug Authorities are being headed by non-technical persons despite several judgments against such appointments by High Courts.**
- An **important area** of **monitoring the Drugs Price (Control) Order 1995 is not taken seriously by the CDSCO.**
- That ***the licensing powers enforced by CDSCO, for certain categories* of *drugs, even today, are not uniform and in certain cases violate the provisions* of *the Act/Rules.***
- A recent nationwide survey to map the extent of fake drugs like the mission conducted by DCGI/CDSCO should be carried out **at regular intervals by adopting different methods.**
- **(M.P.PMO) also suggested that a** distinct definition for the Drugs Contravening patent and copyrights may be introduced in the Drug and Cosmetics Act. Contravention of this rule should be dealt under the Patent and Copyright Act.

GUJARAT

The Committee heard the following entities at Ahmedabad on 14th February, 2008.

Representatives of the Federation of Gujarat State Chemists and Druggists Associations, Food and Drugs Control Administration, Gujarat, Indian Drug Manufacturers' Association, Gujarat State Board, and Medical Disposable Manufacturer's Association.

REPRESENTATIVES OF THE FEDERATION OF GUJARAT STATE CHEMISTS AND DRUGGISTS ASSOCIATIONS.

Following drawbacks of the Bill were highlighted:

- As per the Statement of Objects and Reasons, the Central Government proposed to establish the Central Drugs Authority on the basis of recommendations made by Dr. Mashelkar Committee. However, from the report of the said Committee, it is seen that Dr. Mashelkar Committee had not favoured establishing the Central Drugs Authority. The Committee had recommended creation of a strong, well equipped independent and professionally managed Central Drug Standard Control Organization (CDSCO) which may be given a status of the Central Drug Administration.

- It is **not desirable** to create a Central Drugs Authority by substituting the Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 and Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted under Section 33-C of the Act. ***Both these statutory bodies are broad based and are highly technical*** **in** ***nature.*** **On** ***the other hand, the proposed Central Drugs Authority will have only five members*** **to** ***be appointed by the Central Government.***

- As per **Clause 5,** the **Central Government is not bound to appoint technical experts on the Central Drugs Authority.** The Drugs and Cosmetics Act, 1940 and its implementation is highly technical in nature and requires the advisory bodies having technically qualified experts.

- **Clause 5B** specifies tenure of the Chairperson and members of the Central Drugs Authority. However, procedure for their selection and removal is not specified.

- **The qualification for appointment to the post of Drugs Controller (India) and procedure for his selection needs to be provided under Clause 5E.** Otherwise it will give absolute power to the CDA to select any person to the post of Drugs Controller (India).

- Though the Statement of Objects and Reasons of the Bill declares the intention to centralize only manufacturing licenses, **Clause 5F** indicates that the Central Drug Authority **will have powers to grant the manufacturing and selling licenses for all categories of drugs including Ayurvedic, Siddha and Unani medicines.** The Central Drugs Authority will also have powers to grant manufacturing licenses to cosmetics. Such a change will lead to much inconvenience and hardship to the dealers.

- **At present, the licensee can file an appeal against the order of the Licensing Authority before the State Government.** Once the powers to grant, renew, suspend or cancel the licenses are given to Central Drugs Authority, the licensee will have to file an appeal against the order of CDA before the Central Government. **He will thus have to go to Delhi for filing an appeal and also on all dates of hearing till the appeal is finally decided.** ***This will not only result in delay in disposal*** **of** ***appeals but will also result in inconvenience and additional expenditure*** **to** ***AIOCD members.***

- The Bill does not address the issue of strengthening the Drugs Control Organizations at Central and State level though Dr. Mashelkar Committee had strongly recommended strengthening of Drugs Control Organizations in India.

Following are the suggestions made by the Federation:—

- Instead of creating an additional authority, it is desirable to strengthen the existing Central Drug Standard Control Organization (CDSCO) as recommended by Mashelkar Committee and as declared in Pharmaceutical Policy, 2002. A strong, well-equipped, independent and professionally managed CDSCO with separate divisions need to be there.

- The Central Drugs Authority if established **should be more broad-based having representatives from concerned Ministries of the Central Government, State Drugs Control Organizations, pharmaceutical industry and technical experts in the field of pharmaceutical industry, professional associations and consumer associations.** The AIOCD should be included in the proposed CDA.

- Having regard to the federal structure of the country and the division of the responsibility between the Central Government and State Governments, it is desirable

to have a Central Drugs Authority as an apex body at the national level similar to the National Food Authority established by the Central Government under Food Safety and Standards Act, 2006.

- **The Central Drugs Authority or a CDSCO should focus on legislation, policy review and monitoring, import, regulating clinical trials and approval of new drugs.**

- The **implementation, including licensing, should remain with the State Governments** as per the existing practice. Even if the Central Government decides to centralize the licensing system, power to grant, renew and cancel licenses for sale and distribution should remain with the State Governments.

- The procedure for **selection of Chairperson and members of Central Drug Authority needs to be incorporated in the Bill.** The Selection Committee, comprising of Senior Secretary from the Central Government and the eminent technocrat and Chairperson, Union Public Service Commission need to be constituted.

- **Clause 5B** should have a **provision to stipulate the circumstances in which the Chairperson or members of the Central Drugs Authority can be removed.** For *e.g.* a Chairperson or a member should be disqualified or removed if he acquires financial interest or other interest affecting his functioning or if he abuses his position.

- The **qualification and the experience for appointment** to the post of Drugs Controller (India) should be incorporated under **Clause 5E** or an additional Clause making it obligatory for the Central Drugs Authority to appoint as Drugs Controller (India), a person having prescribed qualification and experience under Rule 50 A of the Drugs and Cosmetics Rules, 1945 should be incorporated.

  Such provision is necessary as by omitting the words "the qualification of such authority" from Section 33 (e) of the Act, the Central Government's power to prescribe qualification of the licensing authorities has been withdrawn.

- Top most ***priority should be given* to *implementation*** of various recommendations of Dr. Mashelkar Committee especially on strengthening of Drugs Control Organizations at State level. This is necessary to curb the menace of spurious drugs.

- The Central Drugs Authority should be given the statutory responsibility to take all necessary steps to curb the menace of spurious drugs and ensuring uniformity in implementation of the Act throughout the country. **The Central Drugs Authority should issue a written manual and guidelines to ensure uniformity.**

FOOD AND DRUGS CONTROL ADMINISTRATION, GUJARAT

The Commissioner, Food and Drugs Control Administration, Gujarat, drew the attention of the Committee to the following proposed amendments:

Under **Clause 5F (1) -** The Central Drugs Authority may issue licence under Clause (c) of Section 10, Clause (c) of Section 18 and Clause (c) of Section 33EEC, and collect fees thereof.

Under **Clause 5F (2) -** The Central Drug Authority may cancel or suspend any licence issued under Sub-section (1)

Suggestions made are as follows:—

- Licensing and regulatory functions *where no or minimum discretion is required* may remain with the State- *e.g.* Sales License.
- Licensing and regulatory functions **where the required technical competence can be available with the States may remain with the States.**
- The above said functions be so divided among Center and State that Public Interest, Quality and genuine interest of the pharmaceutical industry are safeguarded to the maximum possible extent.
- The **legislative scheme under Food Safety and Standards Act, 2006 may be followed by setting up CDA as apex body at national level and Commissioner for Drug Safety in each State.**
- Accreditation and involvement of good State Drug Control Administration may be provided for.
- **The virtues of the Drug Technical Advisory Committee constituted under Section 33C should be retained.**
- **Clinical trial for Indian Systems of Medicines may be rationalized.**
- Punitive provision needs to be rationalized.
- **Loopholes in the investigation and testing like contradictory testing results, saving clause for the dealers (Section 19) may be plugged.**

  It was also **suggested** by their office that **additional gaps** needed to be addressed, such as:—

  ➢ Blood banks needed a special focus as secondary and tertiary health care depends on blood bank/storage facility.

  ➢ A large number of blood banks remain un-inspected due to inadequate number of officers.

  ➢ Inclusion of Medical Devices and Diagnostic test should be reviewed.

  ➢ Presently there is no separate division for approval. This matter should be looked into more closely. Draft Medical Device Regulation Bill, 2006, published by the Department of Science and Technology, Government of India should be used as a reference.

  ➢ Medical Device Regulatory Authority of India (MDRA) to be established by Central Government. MDRA shall regulate and monitor import, manufacture, sale, usages, and disposal etc. of medial devices. So Medical Devices should be excluded from the ambit of the Bill.

INDIAN DRUG MANUFACTURERS' ASSOCIATION, GUJARAT STATE BOARD

Proposal to establish Central Drugs Authority:—

- They were of the view that **instead of creating** an additional authority, it is desirable to **strengthen the existing** Central Drug Standard Control Organization (CDSCO) as recommended by Dr. Mashelkar Committee and as declared in Pharmaceutical Policy, 2002.

- **It is not desirable to create a Central Drugs Authority by substituting the Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 and Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted under Section 33-C of the Act.** Both these statutory bodies are broad based and are highly technical in nature. On the other hand, the proposed Central Drugs Authority will have only five members to be appointed by the Central Government. ***The provisions*** **of** ***Section*** **5 of** ***the proposed Bill indicate that the Central Government is not bound*** **to** ***appoint technical experts*** **on** ***the Central Drugs Authority.*** The Drugs and Cosmetics Act, 1940 and its implementation is highly technical in nature and requires the advisory bodies comprising technically qualified experts. **Central Drugs Authority, if established, should be broader based. The Central Drugs Authority should have representatives from concerned Ministries of the Central Government, State Drugs Control Organization, Pharmaceutical Industry and Technical Experts in the field of pharmaceutical industry, professional associations and consumer associations.**

- ***Following the legislative scheme under Food Safety and Standards Act, 2006 by creating Central Drugs Authority*** **as an** ***apex body*** **at** ***the national level similar*** **to** ***the national food authority established by the Central Government under Food Safety and Standards Act, 2006, and drug commissioners*** **at** ***the State levels would be*** **a** ***desirable measure.***

- The Central Drugs Authority or a CDSCO ***should focus*** **on** ***legislation, policy review and monitoring, import, regulating clinical trials and approval*** **of** ***new drugs. The implementation, including licensing, should remain with the State Government*** **as** ***per the existing practice.***

- The proposal to centralize the licensing system is a marked shift from the existing system and clearly defined division of responsibility between Central Government and State Government. The system of legislation, policy, review and monitoring by the Central Government and implementation by the State Government is followed in all Central Acts like Prevention of Food Adulteration Act, 1945, Standards of Weights and Measures Act, 1976, Drugs and Cosmetics Act, 1940 etc. enacted by the Central Government on the Concurrent List of the Constitution. **The view in this regard was that the present scheme and division of the responsibility should be left undisturbed.**

- **The IDMA, other professional associations and most of the State Drugs Controllers had opposed the proposal to centralize licensing system before Dr. Mashelkar Committee. However, Dr. Mashelkar Committee recommended for centralizing the licensing system in a phased manner overruling the objections referred to above.**

- Centralizing the licensing system will lead to concentration of the powers in the hands of the Central Government. **The CDSCO does not have sufficient manpower to undertake this responsibility. The CDSCO has offices only at Delhi and at zonal level as against the offices of the State Drug Control Organizations at every district place.** This inadequate manpower and infrastructure will create many problems to the stakeholders.

- The proposal to centralize licensing system will lead to delay and therefore harassment to the stakeholders. ***The applicants will*** **face** ***inconvenience in filing and processing*** **of** ***applications*** **as** ***the applicants will have*** **to** ***approach zonal offices. The***

manufacturers will also face difficulties in getting the product permission. The delay in getting licenses and product permission especially for export will adversely affect business and growth* of *the pharmaceutical industry.

- At present **the licensee can file an appeal** against the order of the Licensing Authority before the State Government. Once the powers to grant, renew, suspend or cancel the licenses are given to Central Drugs Authority, **the licensee will have to file an appeal against the order of Central Drugs Authority before the Central Government. This means, the licensee would have to go to Delhi for filing an appeal and also on all dates of hearing till the appeal is finally decided.** This would not only result in delay in disposal of appeals but will also result in inconvenience and additional expenditure to the pharmaceutical industry.

- From the press reports, it is understood that the Finance Ministry has indicated its **unwillingness to sanction large number of posts for Central Drugs Authority. It is also proposed to increase license fees, product permission fees and import registration fees so as to make the Central Drugs Authority self sufficient. This would put unnecessary additional financial burden on the pharmaceutical industry.**

Clinical Trials:—

- The definition of the term **"Clinical Trials"** under **Clause 2(aaii)** is **substantially different** from the **existing definition** of clinical trials under Rule 122DAA of the Drugs and Cosmetics Rules, 1945. The proposed definition covers not only drugs but also cosmetics.

- ***The word "Any Drug" used in the definition* of *clinical trial should be substituted by "Investigational new drug". Such change is necessary* to *harmonize the requirements for clinical trial with the international guidelines* on *Good Clinical Practices.***

- The proposed **Clause 5N** will bring all post marketing clinical trials and academic research to complete halt. The surveillance studies generate useful data on local population for drugs that are not tested extensively before marketing in India.

  To avoid such situation, we ***suggest*** *that the word* ***"Any Drug"*** *used in* ***Clause 5N*** *should be substituted by* ***''Any Investigational New Drug".***

- **Confirmatory trials:** These trials are conducted on marketed products so as to confirm their efficacy and safety from other relevant parameters. **Since these products are already marketed we feel there is no need to seek permission to conduct such clinical trials. Confirmatory trials that are performed before actual launch of the product can also be exempted.**

- **Pilot trials:** Pilot trials, specifically in case of Bioequivalence studies are usually performed so as to ascertain the viability of clinical trials. Such trials are of exploratory nature and are usually conducted on small number of subjects. **Accordingly, such trials may be excluded from the requirements of clause 5N.**

- **Trials for Submission to foreign regulatory authorities:** As stated above, exports from Indian pharmaceutical industry are increasing over years. One of the pre-requisite of commencement of export is registration of the drug with Ministry of Health/ Regulatory Affairs of the importing country. The registration dossier consists data on clinical trials performed on the drug. As this data is meant for submission to the

regulatory authorities of importing country, the trial is conducted as per the guidelines of the respective country. Hence such clinical trials may not be required to obtain permission from CDA.

- Similarly, multiple trials may be performed with different reference drugs for the respective importing country. As these are extension of the originally performed trials, such trials also may be exempted from the requirements of the permission by the CDA.

- **Contract research trials:** One of the most expanding areas in pharmaceutical industry is contract research projects. **India is expected to become a hub for clinical trials by 2010.** Leading global pharmaceutical companies are outsourcing their contract research projects including clinical trials from India. All such trials are conducted as per the requirements and protocol of such sponsors. **These sponsors are complying with the requirements of the relevant regulatory authorities outside India or these trials are performed as per the in-house requirements of the sponsor.** Hence these trials also may be excluded from these requirements.

- **The Bill proposes to cover the clinical trials for cosmetics also. However, the requirements of cosmetic registration are totally different from drugs and therefore the clinical evaluation of cosmetics would not be the same as required for drugs.**

  It is therefore **suggested** that at this stage, **the proposal to cover the clinical trials of cosmetics should be dropped.** For this purpose, the words **"Cosmetics"** used in the definition of clinical trial **under Clause 2(aaii) and used in Clause 5N should be omitted.**

- Under **Clause 5(O)** of the Bill, the punishment of imprisonment for a term which may extend to 5 years and with fine which may extend to Rs. 10,00,000/- is provided. **This punishment is very harsh.** It is likely that the students conducting academic research in Government institutions or for post-graduate thesis may face such serious consequences of harsh punishment merely on account of not obtaining permission from the Central Drugs Authority out of ignorance.

  It is, therefore, **suggested** that a **distinction needs to be made** between **clinical trials conducted strictly in accordance with the Good Clinical Practices and in compliance with all ethical requirements without obtaining permission,** and **unauthorized clinical trials** causing adverse effect or grievous hurt to the volunteers. ***Harsh punishment* as *proposed under Clause 5(0) is justified in case* of *unauthorized clinical trials resulting in grievous hurt* to *the volunteers.*** However, for clinical trials conducted without permission but in compliance with Good Clinical Practices should have lesser punishment **of only fine** and should be considered as compoundable offence.

Other suggestions:

– The word used in the proposed definition of devices indicates that **it includes ancillaries in terms of software and mechanical applications.** Therefore, it should be **treated as an independent entity out of definition of drugs category. This is necessary as Rule 122A and Schedule Y requirement for approval would not apply to it unless it contains medication.**

The definition of devices under Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940 should accordingly be omitted and a separate clause 3(b)(b) defining

'Medical Devices' should be incorporated under the Drugs and Cosmetics Act to define medical devices as an independent entity.

– Priority to implementation of various recommendations of Dr. Mashelkar Committee especially on strengthening of Drugs Control Organizations at state level should be given.

- strengthening of Drugs Control Organizations at central and State level
- enhancing competency of the officers through continuous training
- providing uniform organizational structure at State level
- issuing written manual and guidelines
- regular audit of the state regulatory agencies
- preparation of national formulary of fixed dose combinations for guidance of State Drugs Controllers.

Rakanpur Santej Pharma Manufacturers' Association, Small Scale Indian Drug Manufacturer's Association, Gujarat Ayurved Aushadh Manufacturers Association, and Surendranagar Pharmaceutical Manufacture's Association had all submitted similar objections and views on the various provisions of the Bill as made by Indian Drug Manufacturers' Association, Gujarat State Board.

MEDICAL DISPOSABLE MANUFACTURER'S ASSOCIATION

- The representatives from the above organisation were of the opinion that the word **"medical devices"** used in the proposed definition in the Bill indicates that it includes ancillaries in terms of software and mentioned applications.

  They, therefore **proposed** that the **definition of devices** under **Section 3(b) (iv)** of the Drugs and Cosmetics Act, 1940 should be omitted and a **separate clause 3(b) (b) defining "Medical Devices" should be incorporated under the Drugs and Cosmetics Act to define medical devices as an independent entity.** They further advocated that **clarity** should be given regarding ***specifications*** and ***manufacturing practices*** regarding medical devices. However, it is very important that **the regulation be done by the State Drug Authority and not the Central Drug Authorities as the draft Act suggests.**

- The proposed Central Drugs Authority will have **only five members to be appointed by the Central Government.** The **provisions** of **Clause 5 F(1)** indicate that the Central Government **is not bound to appoint technical experts on the CDA.** However, the Drugs and Cosmetics Act, 1940 and its implementation are highly technical in nature and **require the advisory bodies comprising technically qualified experts.**

  Central Drugs Authority if established should be **broader based**. It should have representatives from concerned Ministries of the Central Government, State Drugs Control Organizations Medical Qevice Industry and Technical Experts in the field of medical device industry, professional associations and consumer associations.

Rest of the suggestions, of the above organisation, relating to the division of the responsibilities between the Center and the State authorities and the role and responsibility of the CDA proposed or the existing CDSCO were similar to what was already stated by the Indian Drug Manufacturers' Association, Gujarat State Board.

MUMBAI

The Committee met with the following entities at Mumbai, on 16th February, 2008.

National Integrated Medical Association, Mumbai, Organisation of Pharmaceutical Producers of India, The Indian Pharmaceutical Association, Vicco Laboratories, Mumbai, Ayurvedic Drug Manufacturer's Association, SSI Pharma Association, and All India Small Drug Manufacturer's Association.

NATIONAL INTEGRATED MEDICAL ASSOCIATION, MUMBAI.

The representatives from NIMA were of the opinion that there was no necessity to bring forth the Bill to create CDA and that the existing provisions in the Act were good enough to address the reasons cited by the Government to bring forth the amendment Bill. Following suggestions on amendments of 'the Drugs and Cosmetics' (Amendment) Bill-2007 were made.

- Under Clause **5(0) regarding clinical Trials** the punishments appear to be exorbitant. They should be rational. Punishments should start with warning, and then fine or punishment should be given.
- Under **Clause 20-(b) (2)** at least one representative of ISM (Indian Systems of Medicine) should be included in the Committee.

Chapter II

- Section (5) (2) of the Act gives the composition of the Drugs Technical Advisory Board, which is sought to be replaced by CDA. However it was suggested to continue with this Board with the addition of following members:—

    1. President, Central Council of Indian Medicine (*ex officio*) CCIM
    2. Director (CCRAS) Central Council for Research in Ayurved and Siddha. *(ex officio)* CCRAS

    The reason cited was that these are highly qualified technocrats in ISM, Therefore, it was necessary that their representation be there in the DTAB.

Representative of the National Integrated Medical Association are also proposed to be included in the Board. The reason stated was that since Indian Medical Association, which is a private body of allopathic practitioners, is given representation, on the same basis **National Integrated Medical Association (NIMA) is also an independent private organization of about 5 Lacs Ayurved, Siddha & Unani Practitioners, with branches all over the country. Hence their representation is justifiable.**

- **Clause 33 C (2) of the Act which speaks of the ASUTA Board which is proposed to be replaced by CDA,** it was suggested that this Board should also include

    – President of the Central Council of Indian Medicine (CCIM)

    – Director, Central Council of Research in Ayurved and Siddha (CCRAS)

    The reason cited was that since the above-suggested members are highly qualified research experts and are advisors to the Government in Indian System of Medicine, their presence in the Board was justified.

    It was further suggested that the Board should also include the President of the National Integrated Medical Association (NIMA).

ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA.

The representatives from the above organisation stated that as communicated earlier by them, **OPPI supports the initiative of the Government to consider the recommendations of Dr. Mashelkar Committee and make amendments in the Act to facilitate the creation of a Central Drugs Authority (CDA) and introduce centralized licensing for the manufacture for sale, export or distribution of drugs.**

- The formation of the Central Drugs Authority (CDA) would provide the following significant benefits to the Industry and also to the Government:
- Achieving uniform interpretation of the provisions of the Drugs and Cosmetics Act and Rules.
- Standardizing procedures and systems for drug control across the country.
- Enabling coordinated nationwide action against spurious and substandard drugs.
- Upholding uniform quality standards with respect to exports to foreign countries from anywhere in India.
- Implementing uniform enforcement action in case of banned and irrational drugs.
- Creating a pan-Indian approach to drug control and administration.
- Evolving a single-window system for pharmaceutical manufacturing and research undertaken anywhere in the Country.

It was emphasized that a single Central Authority that administers and regulates both pharmaceutical manufacturing and pharmaceutical research is an absolute necessity in India's bid to be a global hub for drug discovery. Till the formation of CDA, *registration and marketing authorization for all new drugs and fixed-dose combinations should only be granted by Drugs Controller General of India (DCGI).* There should be a smooth transition from the existing regulatory environment to the proposed CDA. **All necessary infrastructures along with the required personnel must be in place so that all permissions are granted to applicants within stipulated timeframe.**

Suggestions on the various provisions of the Bill are given as below:

The definition* of *clinical trials under Clause* 2 *(aaii) indicates that all clinical trials that would be conducted in the country would need prior permission from the CDA. This may be practically difficult and really not necessary since there would be a number of trials which would be conducted with an already approved drug/product (in approved indications with appropriate marketing authorization).

It was suggested to **that the definition of clinical trials be modified** to **include only studies with an investigational new drug** wherein the term **investigational new drug** *would not only imply* a *pharmaceutical form being used* as a *reference in* a *clinical trial that does not have* a *marketing authorization, but would also include* a *product with* a *marketing authorization when used* or *assembled in* a *way different from the approved form and the results* of *which may be used for label enhancement/alteration.*

- It was also suggested that explicit permission prior to initiation needs to be taken only for trials involving investigational new drugs (including new dosage forms) which do not have a marketing authorization for the indication in which the clinical trial is intended to be conducted.

THE INDIAN PHARMACEUTICAL ASSOCIATION

They supported the stand taken by the Government regarding further amending of the Drugs and Cosmetics Act 1940 by substituting the Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB) by the Central Drugs Authority (CDA) based on the recommendations of Dr. Mashelkar Committee Report. The constitution of Central Drugs Authority, according to them, would certainly bring more discipline and rational approach in the licensing process and maintain uniformity in the standards of drugs, which in turn would be a step further in the healthcare of our society.

Following general observations were made:—

- Looking at the large number of drug manufacturing units in India, the existing facilities available for the issuance of the licenses with **the Central Government appears to be inadequate,** hence it is necessary to develop up-to-date infrastructure at various places, may be even at districts. **The coordination between the licensing Authority (CDA) and enforcement by the State FDA needed to be explained in detail.**
- Considering the advancement in the manufacturing of the pharmaceuticals, the global regulatory requirements and the policy of the Government to promote export of medicines, **the technical staff required to support the licensing authority should be qualified, competent and having expertise in the field of pharmacy, pharmaceutical engineering, clinical pharmacy and pharmaceutical management.** To cater these needs the Government should focus on human resource development and train the qualified persons in various disciplines of pharmacy profession.
- The Indian Pharmaceutical Association (IPA) is the only national professional body of pharmacists and has had representation on DTAB for many years. **The IPA was instrumental in bringing advancements in terms of pharmacy education, pharmaceutical research and regulatory issues through continued education process. It could be a good reason for giving representation to IPA on CDA.**

Suggestions on the Bill are as follows.

- **Composition** of Central Drugs Authority", should **be atleast Chairperson with 5 members for meaningful decision.**
- **To the proposed Clause 5A on the subject of** "Qualification of Chairperson and Members", it was suggested that **preferably the CDA should consist of two persons from pharmaceutical industry, one from research, one from pharmacy education preferably pharmacologist and one from public administration or from finance or law.**
- **To the proposed Clause 5B on the subject of** "Term of office of Chairperson and Members", it was suggested that the word **"further"** be substituted by **"one more term" and the age limit should be limited to 65 years instead of 70 years.**

VICCO LABORATORIES, MUMBAI

The following points were raised by the members from VICCO LABS:—

- The proposal to establish Central Drugs Authority and centralizing the licensingpowers in CDA is inconsistent with the selective approach adopted under Drugs and Cosmetics Act, 1940. The proposal is a marked deviation from the approach adopted by the Government of India by creating an independent Department of AYUSH headed by the Secretary.

- Different bodies such as AYUSH Pharmacopoeia Committee, ASU Drug Consultative Committee (ASU-DCC) and ASU Drug Technical Advisory Board (ASU-DTAB) ensure effective consultation process with the stakeholders and proper inputs from the experts in the field.
- At State level the ASU Sector is administered by the Food and Drug Administration or the Directorate of Indian Systems of Medicine and Homoeopathy. There is also a State Licensing Authority appointed for the purpose of approving individual drug licenses and manufacturing premises. Only recently, the Department of AYUSH has taken certain initiatives to streamline the process of grant of product permission for Patent and Proprietary medicines.
- *There is also an inbuilt legislative mechanism in the definition* of *the Ayurvedic drugs under* ***Section 3(a) and 3(h) (i)*** of *the Act to ensure quality, safety and efficacy.* By *virtue* of *these definitions it is mandatory for the manufacturers to follow the method and to use ingredients listed in the authoritative text books. The existing regulatory system is thus effective and the proposal to form* a *Central Drugs Authority for getting the ASU Sector does not have merit in the scheme proposed in the Bill.*
- The proposed Bill does not provide adequately for technical experts from the ASU stream in the constitution of the Central Drugs Authority. The current provision of ASU-DCC and ASUD TAB is undermined by their replacement by the CDA. The formation of the Central Drugs Authority for the ASU Sector is certainly not a progressive reform based step but actually a set back.
- Due to the unique nature of the ASU Sector in comparison to modern pharmaceutical industry, the current proposal to include the ASU sector in the scheme of Central Drugs Authority is an unnecessary and a retrograde step. ASU Sector should be excluded from the implications of the proposed Central Drugs Authority.
- If the need to establish Central Drug Authority is considered absolutely necessary following suggestions may kindly be taken into consideration:—

Clinical Trial

- The Bill seeks to regulate all **clinical trials** and will cover clinical trials of Ayurvedic, Siddha and Unani medicines in view of the exhaustive and inclusive definition of the term Clinical Trial in the Bill. In the absence of any provisions under the existing Drugs and Cosmetics Act, 1940 and Rules, 1945 for regulating clinical trials such inclusive definition to cover Ayurvedic, Siddha and Unani medicines is not consistent with the Act and Rules. Therefore, Ayurvedic, Unani and Siddha medicines should be excluded from the scope of definition of clinical trial under the Bill.
- **The proposed Central Drugs Authority should be in addition to the AYUSH DTAB and not substitute to it.**
- The Central Drugs Authority at national level **should focus on legislation, policy, review. The licensing and implementation should remain with the State Licensing Authorities.**

AYURVEDIC DRUG MANUFACTURER'S ASSOCIATION

The representatives from the above organisation offered the following suggestions:—

1. The Central Drugs Authority will have powers to grant, suspend or cancel the licenses leading to concentration of powers in the hands of the Authority. The Ayurvedic, Siddha and

Unani drugs industry which is mostly small scale and middle scale and located at district places and in rural area will face major difficulties in filing of application for grant of licenses, its follow up and filing of appeals etc.

2. Replacement of a highly technical body (AYUSH DTAB) by the bureaucratic body-Central Drugs Authority is a retrograde step. The Government of India having realized the need to have selective and focused approach on Ayurvedic, Siddha and Unani Drugs sector has established an independent Department of AYUSH headed by the Secretary.

- ***The current scheme of approval at State level by the State Licensing Authority* is *adequate and is satisfactory in service of the ASU Sector.*** Providing for the Central Drugs Authority to administer this category of medicines would be an **irrelevant administrative extrapolation sans rationale. No new formulation** can be approved as a Classical Medicine in the ASU Sector **unless due process is followed with the approval** of the respective Pharmacopoeia Committee's, consultation with the ASU-DCC and final decision with the ASU- DTAB. **Therefore centralizing licensing for this class of medicines is infact an unnecessary exercise.**

- AYUSH drugs are licensed by the Licensing Authority at State level assisted by a Committee of experts which approves the medicines. Provisions exist whereunder sufficient technical information is furnished by the manufacturers regarding "proof of concept" and quality control standards being enforced for such drugs. AYUSH drugs are formulated with ingredients mentioned in the authoritative texts and whose quality standards are prescribed in the pharmacopoeia. **This scheme as provided is definitely superior and more relevant to the proposed in setting up of a CDA under the Bill. Moreover to imagine that a Committee of experts constituted at Central level, even if, sufficiently armed with staff and infrastructure, will be superior and focused and can consistently handle the load efficiently in comparison to 36 such Committees at State level is far fetched. *Thus, Centralizing the licensing process for this class* of *ASUH drugs will be* an *exercise that will bring great hardship* to *the ASUH Sector.***

- The proposed Bill does away with the current provision of *ASU-DCC* and *ASU-DTAB* by replacing the *ASU-DTAB* by the CDA **and reconstitution of the *ASU-DCC.***

- Creation of Excise duty free zones has already resulted in shifting of industry to Himachal Pradesh, Uttaranchal and Sikkim. **Due to concentration of licensing powers, the industry may further shift to Delhi for the sake of convenience in handling licensing issues. This will also lead to migration of ancillary industry and will result in loss of large number of jobs.**

- **Dr. Mashelkar Committee had recommended centralizing the licensing system mainly on the ground of securing uniformity in implementation.** The **issue of uniformity** appears to have been raised **only for concentrating licensing power in the hands of the Central Government.** It is an established fact that Central Departments like Income tax and Central Excise etc. are more effective in the States where the State machinery is well organized and effective. **CDSCO is also more effective in the States where the Drugs Control Organizations are well organized and strong.**

Clinical Trial

- The term Clinical Trial is substantially different from the existing definition of Clinical Trial under Rule 122DAA of the Drugs and Cosmetics Rules, 1945. **The**

definition now covers not only drugs but also cosmetics. Therefore, it will be applicable to all drugs and cosmetics. **The definition does not use the term "New Drug" or "New Cosmetics".** The definition will include any activity to determine safety, efficacy or tolerance of the drugs and cosmetics. This means the bioequivalence or bioavailability studies will also be covered. The definition does not make **specific reference to the definition of drug** under **Section 3(b)** of the Act. Therefore, it appears that it will be also applicable for the clinical trials of Ayurvedic, Siddha and Unani drugs. It is important for us to understand that Ayurvedic, Siddha and Unani medicines are not formulated on the lines of the modern medicines. So paradigm of assessing ASU medicines efficacy and utility needs a different approach and should not be coupled or extrapolated with a policy guide similar to one intended for modem medicine as described in Schedule Y. ***However, Chapter IV A* of *the Act and relevant Rules framed* to *regulate quality and safety do not have any provision with reference* to *clinical trials.* Therefore, it is necessary to exclude Ayurvedic, Unani and Siddha medicines from the scope of definition of clinical trial under the Bill.**

- ***In view* of *our submissions in the opening paragraph, we submit that the Ayurvedic, Unani and Siddha medicines should be excluded from the scope* of *the Bill.***
- The scheme under the Food Safety and Standards Act, 2006 is ideal in the context of our federal structure and in the context of division of legislative powers of the Central and State Governments. Therefore, if the Central Government considers it absolutely necessary to establish Central Drugs Authority it should be like National Food and Standard Authority established under the Food Safety and Standards Act, 2006.

  The scheme under Food Safety and Standard Act, 2006 should also be followed by making provision for appointment* of *Commissioner* of *Drug Safety in each State.

- The Central Drugs Authority at national level should be established with powers and functions in such a manner that the legislative scheme and the division of responsibilities between the Central Government and State Governments is not tinkered with. **The CDA should be in addition to the Drugs Technical Advisory Board and not substitute to DTAB.** It is necessary to ensure that **out of five members of the Central Drugs Authority, at least two members are technical experts in pharmaceutical field.**
- **The Central Drugs Authority *should devote its energy and resources in legislation, policy making, monitoring* of *implementation at State level, continuous review of the products approved* at *State level, import and approval* of *new drugs including clinical trials.* The implementation of the Act including licensing should remain with the State Drugs Control Organizations.**
- Priority should be given to **strengthening of the Drugs Control Organizations at State Level.** ***The Statement* of *Objects and Reasons should have specific clause* to *focus* on *strengthening* of *the Drugs Control Organizations* at *Central and State level.* The objectives of strengthening can be achieved by incorporating provisions under the Bill for appointment of Commissioner of Drugs Safety in each State** who should be technically qualified person and should be head of the department and controlling authority.

SSI PHARMA ASSOCIATION

The representatives from SSI Pharma were of the opinion that—

- The scheme under the Food Safety and Standards Act, 2006 is ideal in the context of the federal structure and in the context of division of legislative powers of the Central and State Government.
- The Central Drug Authority at national level **should be established with powers and functions** in such a manner so that the **legislative scheme and the division of responsibilities between the Central Government and State Governments are not tinkered with.**
- **The CDA should be in addition to the Drugs Technical Advisory Board and not substitute to DTAB.**
- It is necessary to ensure that out of **five members of the Central Drugs Authority,** at ***least two members*** are **technical experts in pharmaceutical field.** The State Drugs Controllers or the officers of the level of Joint Commissioners with outstanding record should also be considered eligible for appointment to the post of Chairperson or Member of the Central Drugs Authority.
- **The Central Drugs Authority should devote its energy and resources in legislation, policy making, monitoring of implementation at State level, continuous review of the products approved at State level, import and approval of new drugs including clinical trials. The implementation of the Act including licensing should remain with the State Drugs Control Organizations.**
- Priority should be given to **strengthening of the Drugs Control Organization at State Level.** *The Statement and Objects and Reasons should have specific clause to focus on strengthening* of *the Drugs Control Organizations at Central and State level.* The objectives of strengthening can be achieved **by incorporating provisions under the Bill for appointment of Commissioner of Drugs Safety in each State** who should be a technically qualified person and should be head of the department and controlling authority.
- **The Central Drugs Authority and the Commissioner of Drug Safety should be given statutory responsibility to take steps to eradicate menace of spurious drugs by implementing various recommendations made by Dr. Mashelkar Committee, such as —**
    - Building competency at Central and State level. Issuing written guidelines and manuals.
    - Periodical review and monitoring by Central Drug Authority.
    - Preparation of National Formulary of Fixed Dose Combination for the guideline of State Drugs Controllers.
- The problem of spurious drugs is a clandestine activity and licensing should be de-linked for tackling this problem. Hence, centralizing the licensing system is not the solution to the increasing problem,

ALL INDIA SMALL DRUG MANUFACTURER'S ASSOCIATION

The representatives of the above organisation had the following comments to offer in the context of the Bill:—

- They **agreed** with the recommendation of **setting of a Central Drugs Authority;** but **differed** with the **recommendation of a system of Centralized Licensing.**

- In their opinion, the Bill is **contradictory** to the **purpose** of the Bill itself. At one end, the Bill desires to **improve** drug administration (which is possible by **empowering** the **implementing authority** *i.e.* the State Drug Administration) while at the other end the Bill is intending **to take away the licensing authority from the State administration to the Centre** by introducing Centralized Licensing System for manufacturers.

- The manufacture of spurious drugs is a secret criminal activity conducted by the criminals in the business and it is never done by a licensed manufacturer. The licensed manufacturer is controlled at the level of district by a Drug Inspector and in many cases by Assistant Commissioner. Many a times the licensed manufacturer is a **source of information** of such activities to the drug inspector. ***The licensing authority is the biggest tool in the hands* of *State administration* to *have* a *control* on *the manufacture* of *Drug, formulation because* of *which the Drug Inspector is in contact with the manufacturing fraternity and* if the authority is taken away at Centre by introducing the central licensing system, the State Drug Administration will loose its control and the problem would surely magnify.**

- It is a well-known fact that if we desire to improve the administration, it is possible by decentralization rather than by centralization. It is the experience of the corporate world that if they desire to have better controls, it is possible by delegating the authority with responsibilities to the branches; it can not be *vice versa*.

- States like Maharashtra, Gujarat, Goa, Andhra Pradesh and Karnataka are having better controls in Drug Administration as compared to other States. **Therefore the CDA should concentrate more on the States where the Drug Administration is weak instead of taking away authority from the better controlled States.**

- **If the manufacturing Licensing is taken away to the Centre, for follow up, for getting manufacturing Licenses our District level manufacturers cannot afford to have an Office at Delhi or also cannot afford to stay for few days at Delhi for each License.**

- Attention of the Committee was drawn to the situation which was prevailing prior to 1990 in Maharashtra. Before 1990, all the Licenses of the State were issued from Bombay and there was lot of delay and problems faced by the manufacturers. Only after realizing the problems, the Government of Maharashtra had formed 11 divisions in the State of Maharashtra and the problem was controlled to a great extent. After formation of the State Drug Administration, it took a very long time, nearly four decades, to have the present control in Maharashtra. The State has a team of well trained Drug Inspectors. Assistant Commissioners and Joint Commissioners to control the activities of drug manufacturer. The Bill does not intend to make use of this team and is planning to create a new team which may take another 40 years to have proper control.

Following suggestions were also made:—

- CDA should be formed and they should have direct control on the State Administration for **implementation of the policies** of the Centre by deputing few officers at the State for a periodical inspection.

- A **separate wing** should be provided in CDA for control of **spurious drugs.** The **wing should act like CBI,** supported **by the State I. B. Department.**

- To have the uniformity in the formulations, CDA should prepare a **National Formulary,** which will contain all approved formulations by CDA. This book should be made available at all State F.D.A. Offices for issuing the product License numbers **License other than the formula mentioned in the book should be granted by the State.** This will achieve the object of uniform formulation throughout the country. **The book should be updated by CDA with regular frequency to include the revised formulations.**
- There should be a system of issuing **no objection certificate** from State Drug Authority for marketing the new formulations granted by **other State authority,** so that if any State authority **deviates** from CDA guidelines, the marketing of the product in the State can be controlled by the other State authority in their State.

GOA

The Committee held interactions at GOA on 18th February, 2008.

GOA PHARMACEUTICALS MANUFACTURERS' ASSOCIATION

The representatives from the above organisation stated the following with respect to the various provisions of the Bill.

- The genesis of Central Drugs Authority (CDA) stems from Dr. Mashelkar Committee Report. However, Dr. Mashelkar Committee is vague on this aspect and under para 13.0, it only suggested that the Drugs Control Organizations be strengthened and no where the Committee had recommended that Central Drugs Authority be constituted. They have recommended only Central Drugs Administration headed by DCG (I) under para 5.8.6.
- Going by the spirit of Dr. Mashelkar Committee Report, **instead of creating an additional Authority, the existing Central Drug Standard Control Organization (CDSCO) should be enforced to create a strong, well equipped and professionally managed CDSCO with, if necessary, independent cells therein to monitor the various aspects of National Pharmaceutical Industry.**
- The proposal to substitute Drugs Technical Advisors Board as well as Ayurvedic, Siddha and Unani Technical Advisory Board by CDA is **not at all suitable because both these Statutory Bodies are broad based and extremely technical in nature.** The CDA is expected to have **only 5 members** to be **appointed by the Central Government,** which again **is not bound to appoint Technical Experts** on CDA. The implementation of Drugs and Cosmetics Act 1940 is highly technical in nature and requires Advisory Bodies cited as above comprising of technical qualified Experts as at present. **CDA, under its proposed form lacks this expertise and would be ill equipped to handle the technical aspect of the Allopathic as well as Ayurvedic, Siddha and Unani Drugs which have deep roots in India unlike in USA.**

  Under the present system of licensing, the Central Government through Central Drug Licensing has complete control on the licensing for manufacturing the following categories of drugs.

  (i) Large volume Parenterals.

  (ii) Blood Bank.

  (iii) Blood products.

(iv) Sera and Vaccines.

(v) Recombinant DNA derived drugs.

(vi) New Drugs as defined under Rule 122 (E) of Drugs and Cosmetics Rules.

(vii) Import of Drugs (API and formulation) for marketing in the Country.

This goes to establish that even now, the Central Licensing Authority has control over the manufacturing of a substantial part of the drugs available in the Country. And further, the Central Licensing Authority has complete control on the import of Bulk Drugs and their formulation for marketing in the Country. Only that fraction of drugs which are not covered under the above 7 categories are being permitted for manufacture by the State Licensing Authorities. Therefore, no significant objective is visualized for creating a Centralized Licensing System. This would only result in **concentration of powers** with a single entity and **would result in considerable amount of hardships to small and medium scale manufacturers located in Goa.**

- They further stated that Drugs and Cosmetics Act 1940 and Rules framed there-under have adequate provisions for the Central Licensing Authority to have an effective control over State Licensing Authorities who are at present the licensing authorities for manufacture of Drugs in their respective States. ***These powers can be exercised by Central Licensing Authority under section* 33 *especially under para 33(p)* of *the Act.*** **Therefore objective of control over the standards for drugs and cosmetics including manufacturing, GMP, GLP can be achieved without creating a separate Central Licensing Authority.**

- Further creation of a Central Regulatory Authority would not be in conformity with the Federal structure of our country where there is a clear demarcation of responsibility between the Central Government and the State Government. **Manufacturing, sale and distribution are a composite activity. Therefore, there should be single regulator for these activities.** The Bill envisages having **two different Regulators, which would result in confusion and overlapping of responsibilities.**

- Under the present system of licensing where licenses are issued by the State Licensing Authorities, **an aggrieved party can file the appeal with the State Government.** If the licensing system is centralized as proposed in the amendment Bill, **the appeal shall be with the Central Government irrespective of the State where the unit filing the appeal is located.** This would result in **undue hardship,** wastage of precious time and additional financial burden especially to small scale units of the type located in Goa.

- Under the proposed system of licensing where the licenses are to be issued by CDA, the units in Goa **would not be able to afford the expenses and time and do not have resources and skills to pursue their matters in New Delhi amidst the vast magnitude of such issues that would come there from all over India.** Such a Centralized Licensing System as proposed would only lead to delay, hardships to most of the units located in Goa of the type described in the Preamble. Such units from Goa would also face difficulty in getting products permission especially for export which also requires various certificates for registration of the products in the buying country without which export cannot take place.

- The Drugs and Pharmaceutical Industry is a non-polluting safe industry for Goa, which has limited resources of land and other inputs but logging impressive growth of employment generation and contribution to the Revenue of the State. Hence this Sun-rise Industry needs to be nurtured at this stage for the benefit of the State of Goa

and its people. The ease and speed that our local Units experience in access to the Local Licensing Authority cannot be offered by transferring its functions to another authority located in New Delhi.

- **The establishment of such Regulatory Authority in New Delhi would extend logistical benefits to the units located in or around New Delhi but create logistical hurdles for units located outside New Delhi, especially in place like Goa resulting in red-tapism and its consequential ill- effects.** The fledgling Pharma Industry in Goa would be subject to suffocation and strangulation as it would have to face geographical hurdle to compete with large Global players for its survival and subsistence.

- The proposed CDA is being empowered to **regulate All Clinical Trials** by modifying the definition of Clinical Trials under its **Section 2(aaii)** from what it is at present under Rule 122 DAA of Drugs and Cosmetic Rules 1945. The word Clinical Trials under this Section should be differentiated by substituting the words **"Investigational New Drugs" in place of "Any Drug".** This is because the Clinical Trials of the nature of Confirmatory Trials, Pilot Trials, Trials for submission to foreign Regulatory Authorities, Multiple Trials are only extensions of the originally Conducted Trials or Trials conducted as per the requirement of the foreign buyers and need not be controlled by the proposed CDA.

Medical Devices

- The words used in the proposed definition indicate that **it includes ancillaries** in terms of software and mechanical applications. **Therefore, it should be treated as an independent entity out of definition of drugs category.** This is necessary as Rule 122 A and Schedule Y requirement for approval **would not apply to it unless it contains medication.**

  The definition of devices under **Section 3(b) (iv)** of the Drugs and Cosmetics Act, 1940 should be omitted and a separate **clause 3 (b) defining 'Medical devices' should be incorporated under the Drugs and Cosmetics Act to define medical devices as an independent entity.**

- It is felt that the idea of establishing CDA is mooted on the lines of US FDA which is not relevant to our set-up since we have:

  (a) Ayurvedic Systems of Medicines,

  (b) Siddha Systems of medicines,

  (c) Unani Systems of Medicines,

  (d) Homeopathy Systems of medicines,

  (e) Allopathetic Systems of medicines,

  having strong roots in our country and operating parallel to allopathic system.

- The CDA that is proposed to be formed **would not be able to handle all the issues related to other systems of medicines prevalent in Goa and in India and as such units in Goa would face hardships in contacting and following their Regulatory Authority located at Delhi for day-to-day administrative issues.**

- **The present Regulatory system should be maintained, re-enforced to meet the same objectives which are envisaged for CDA.**

- To clear the apprehension of the Industry it was emphasized that the above Bill should be sent back to the Health Ministry for clarification:
    (i) Abolition of technical body like DTAB
    (ii) Steps taken to nurture Indian System of medicines
    (iii) Stipulation of time limit for development of required infra-structure.
    (iv) Exact functions of the proposed CDA and its governing body
- It appears that the proposal of the Bill is biased towards USFDA which cannot be applied to the Indian Scenario and units in Goa would face many hardships and growth strangulation if the proposed CDA is established and enforced.

Financial Outlay:

The mode of **funding of expenses to CDA is not very clear** and Ministry of Finance should make appropriate arrangement for the same. If the burden thereof is passed on to the Industry, most of the Units in Goa would not be able to bear the expenses.

ANNEXURE-IV

LIST OF WITNESSES AT NEW DELHI CONCERNING THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2007

NEW DELHI
9th October, 2007

Representatives of Department of Health and Family Welfare

1. Shri Deepak Gupta, Additional Secretary
2. Shri. Devashish Panda, Joint Secretary
3. Dr. M. Venkateshwarlu, Drugs Controller General (India)

31st October, 2007

1. Dr. R.K. Srivastava, Director General, Health Services.
2. Dr. M. Venkateshwarlu, Drugs Controller General (India) represented Central Drugs Standard Control Organisation and Drugs Consultative Committee.
3. Dr. K.R. Mani, Director, Central Research Institute, Kasauli (CRI), represented Drugs Technical Advisory Board for Allopathy.
4. Dr. M.C. Sharma, Director, National Institute of Ayurveda (NIA), Jaipur represented Drugs Technical Advisory Board for AYUSH.
5. Dr. P.K. Guha, Director, Central Drugs Laboratory (CDL), Kolkata.
6. Dr. Gopa Ghosh, Director-in-charge, Central Drugs Laboratory (CDL), Mumbai.

25th January, 2008

1. Shri Alok Mishra, Area Manager International, South Asia, Johnson and Johnson
2. Shri Ajay Pitre, Managing Director, Sushrut Surgical Pvt. Ltd.
3. Shri Pavan Choudary, CEO and MD, Vygon India Pvt. Ltd.
4. Shri Ajay Maggo, Director, Finance and Accounts, Philips Electronics India Ltd.

} Confederation of Indian Industry

5. Mr. Lalit Kumar Jain, Vice Chairman
6. Mr. Jagdeep Singh, Secretary General
7. Mr. J. Mathew
8. Mr. Ramesh Arora
9. Mr. B.K. Gupta

} SME Pharma Industries Confederation

11th February, 2008

10. Dr. R. K. Srivastava, Director General, Health Services	}	Department of Health and Family Welfare
11. Shri K. Ramamoorthy, Joint Secretary		
12. Dr. H. C. Goel, Additional DGHS		

7th May, 2008

FEDERATION OF INDIAN CHAMBERS OF COMMERCE AND INDUSTRY (FICCI)

1. Mr. Anjan Bose, Chairman FICCI Medical Electronic Forum,
2. Mr. Ram Sharma, Country Manager-India, Nepal, Sri Lanka,
3. Mr. Sanjay Banerjee, Managing Director, Zimmer India,
4. Dr. Kulwant S. Saini, Vice-President, Johnson and Johnson
5. Mr. R. Kailasnath, Managing Director, CPC Diagnostics, Chennai,
6. Ms. Sumati Randeo, Manager-Regulatory Affairs,
7. Mr. V. K Topa, Advisor to Secretary General, FlCCI,
8. Ms. Bishakha Bhattacharya, Additional Director, FICCI

1. Prof. Sri Ram Khanna	}	Voluntary Organization In Interest Of Consumer' Education (Voice),
2. Shri H.K. Awasthi		

27th May, 2008

Representatives of Ayurveda, Siddha and Unani Drug Technical Advisory Board (ASUDTAB):—

1. Dr. S.K. Sharma,	Advisor (Ayurveda), Department of AYUSH
2. Dr. S.S. Handa, Former Director,	RRL (CSIR), Jammu
3. Dr. P. Jaya Prakash Naraynan,	Rtd. Principal, Siddha Medical College, Chennai.
4. Prof. M.C. Sharma,	Director, N.I.A, Jaipur
5. Dr. V.R. Seshadri,	Secretary, IMP, Co-op. Pharmacy and Stores Ltd. Chennai.
6. Dr. Asad Mueed,	Director (R&D), Hamdard Wakf Laboratories, New Delhi
7. Prof. Shakir Jamil,	Dean, Jamia Hamdard, New Delhi
8. Prof. Anis Ansari,	Dean, Aligarh Muslim University, Aligarh

12th August, 2008

Dr. R.A. Mashelkar, Director General (Retired), Council of Scientific and Industrial Research

ANNEXURE-V

LIST OF WITNESSES AT PLACES OF STUDY VISIT

STUDY VISIT PHASE-I

BENGALURU(KARNATAKA)
(7th January, 2008)

1.	Shri K.R. Ravi Shankar, President	Karnataka Drugs and Pharmaceutical Manufacturers' Association
2.	Shri Jatish Shetty, Secretary	
3.	Shri Sunil,	
4.	Shri C.P. Bothra,	
5.	Shri J.P. Mady,	
6.	Shri Suresh Khanna,	
7.	Shri K.R.P. Shenoy,	
8.	Shri J.S.D. Pani, secretary	Karnataka Indian Medicine Manufacturing Association
9.	Shri Vijay Kumar	
10.	Shri Madhusudan	Indian Pharmaceutical Association
11.	Shri Sailesh Siroya	
12.	Shri Rajesh Jagdale	
13.	Shri Ravinder Nath Guru,	Consumer Care Society
14.	Shri Y.V. Aswathanarayana,	
15.	Shri D.A. Gundu Rao,	Karnataka State Pharmacy Council.
16.	Shrimati Prema. S	Consumer Rights Education and Awareness Trust (CREAT)
17.	Shrimati Usha Ganesh,	Additional Chief Secretary, Government of Karnataka

THIRUVANANTHAPURAM (KERALA)
(9th and 10th January, 2008)

1.	Shri S. Gopalakrishnan Nair, President,	Ayurvedic Medicine Manufacturers Organization of India, Thiruvananthapuram
2.	Dr. D. Ramanathan, General Secretary	

3. Shri C.S. Satheesh Kumar, President 4. Shri Shaji M. Varghese, Vice-President 5. Shri Subhas V. Menon, Secretary	Kerala State Drugs Control Enforcement Officers' Association
6. Shri K.P. Purushothaman, General Secretary,	Kerala Pharmaceutical Manufacturers' Association
7. Shri T.M. Thomas, Chairman 8. Shri Milton J. Thalakottur, General Secretary	All Kerala Pharma Traders Forum State Committee, Kannakulam, Trissur.
9. M. George, Drug Controller, Kerala	
10. Shri Unnikrishna Panicker, M.K.	Senior Lecturer in Hospital and Clinical Pharmacy (Medical College) Thiruvananthapuram, Kerala
11. Shri R. Ashok Kumar, 12. Dr. S.K. Jawahar	Shree Chitra Thirunal Institute of Medical Science and Technology, Trivandrum
13. Shri C.V. Narasimha Rao,	President, District Consumer Information Center, Secunderabad

CHENNAI (Tamil Nadu)
(11th January)

1. Shri T.S. Jaishankar, Chairman 2. Shri M. Malleshwara Rao 3. Shri K. Babuji 4. Shri S. Ravichandran	Confederation of Indian Pharmaceutical Industry
5. Shri R. Murugan, Secretary 6. Shri R.S. Jayaraman Rajan, 7. Shri S.M.K. Kitchani 8. Shri Sundar	Indian Drug Manufacturers Association
9. Shri B.Sethu Raman, president 10. Shri D. Parthasarathy 11. Shri M.D. Varatharajan 12. Shri M.R Chandra Mohan	Pharmaceutical Manufacturers Association
13. Shri G. Selvaraj 14. Shri M. Dhilip Kumar	Indian Pharmacy Graduates Association

15. Shri C.V. Ramaiah
16. Shri N. Selvaraj
17. Shri K. Kannan
18. Shri V. Muthukrishnan
19. Shri T.P. Gurumoorthy
20. Shri M. Sarangapani

} Experts from Drug Control Administration

21. Shri Rajesh Bhandari
22. Shri S. Sabapathy
23 Shri J. Jayaseelan
24. Dr. V. Ravichandran
25. Shri Mohd. Yousuf

} Indian Pharmaceutical Association, Chennai

26. Shrimati Shobha Iyer, Deputy Director (CAG) Citizen Consumer and Civic Action Group
27. Shri T. Desikan, CONCERT
28. Shri T. Duraisingam, Chairman, FEDCOT
29. Dr. K.G. Russia, Consumer Protection Forum
30. Shri M.R. Krishnan, Consumer Association of India, Chennai

31. Shri R. Babapallery, President
32. Shri J. Jayasedan, Secretary

} Indian Pharmaceutical Alliance

33. Shri C.V. Ramaih, Retd. Director of State Drugs Controller
34. Shri N. Kannan, Rtd. Drug Controller
35. Shri N. Selvaraj, Director of Drugs Control (Rtd.)
36. Shri T.P. Gurumoorthy

} Experts from Drug Control Administration

37. Shri R.S. Anbu Ilango, Director
38. Shri K.S. Gnanasekaran, Deputy Director
39. Shri M. Baskaran, Deputy Director
40. Shri T. Rajendran, AD
41. Shri K. Bangaruranjan, AD
42. Shri K. Sivabalan, AD

} Directorate of Drug Control (Tamil Nadu)

43. Shri P.W.C. Davidar, Special Secretary to Government, Department of Health and Family Welfare

HYDERABAD (ANDHRA PRADESH)
(13th and 14th January, 2008)

1. Justice B. Subhashan Reddy, Chairman, AP State Human Rights Commission
2. Shri M. Narayana Reddy, President, Bulk Drug Manufacturers' Association
3. Shri Ravi Uday Bhaskar, President, Drug Inspector's Association
4. Shri D.Hanumantha Rao
5. Shri C. Gopala Krishan Murooty

   } Ex-Director, Drug Control Administration, AP
6. Shri K.L. Meena, Drug Controller, A.P.
7. Shri B. Hari Babu, President, Federation of Drug Traders, Andhra Pradesh
8. Shri P. Koteshwara Rao, President
9. Shri V.S. Chakravarthi

   } Organization of Pharmaceutical Manufacturers
10. Shri Varaprasad Reddy, MD, Shanta Biotechnics
11. Dr. Vassi Reddy, VIMTA Labs.
12. Shri C.V. Narasimha Rao, President
13. Shri Kodanda Rao, President

    } District Consumer Information Centre
14. Mrs. Rajam Ganeshan, Secretary, Consumer Care Centre, Hyderabad

STUDY VISIT PHASE-II

INDORE (MADHYA PRADESH)
13th February 2008

1. Shri Ramesh Shah, President
2. Shri Sanjay Jain, Secretary

   } M.P. Pharmaceutical Manufacturers' Organization
3. Dr. Darshan Kataria, Secretary, Pithampur Audhyogik Sangathan, Indore
4. Shri Sunil Makoday, Abhyas MandaI Indore
5. Shri T.S. Bhandari, M.P. Ayurvedic Medicine Manufacturers Association, Indore
6. Shri Goutam Chand Dhing, President
7. Shri Rajiv Singhal, General Secretary

   } Madhya Pradesh Chemists and Druggists Association
8. Shri R. A. Sharma, President
9. Shri Himanshu Shah, Secretary

   } M.P. Small Scale Drug Manufacturers' Association

AHMEDABAD (GUJARAT)
14th February 2008

1. Shri Jashvant P. Patel, President
2. Shri Pratapbhai A. Doshi, Chairman — Federation of Gujarat State
3. Shri Pradip Trivedi, Secretary — Chemists and Druggists Association
4. Shri J.S. Shinde, Gen. Secretary

5. Shri S.N. Chokshi, Chairman, Indian Drug Manufacturers Association
6. Shri Ashwin Shah, President, Rakanpur Santej Pharma Mfg. Association

7. Shri Jaman Malvia, President — Small Scale Indian Drug Manufacturers
8. Shri Haiderali Sayad, Secretary — Association

9. Shri Prabodhbahi V. Shah, President — Gujarat Ayurved Aushadh Manufacturers
10. Shri Punarvasu Agnihotri, Secretary — Vaidhya Association

11. Shri Atu1 J. Shah, Chairman, Surendranagar Pharmaceutical Manufacturers Association

12. Mr. M.M. Saiyad, President — Medical Disposable Manufacturers
13. Shri Mahendra Patel, General Secretary — Association

14. Shri Prashant H. Pandya, Secretary General, Gujarat Pharma Small Scale Industries Association

15. Shri Deepak Padia, President, Indian Small Pharmaceutical Manufacturers Association

16. Dr. M.M. Patel, Principal, Kalol Institute of Pharmacy

17. Shrimati Mona Khandhar, Commissioner, Food and Drug Control Administration, Gujarat

MUMBAI (MAHARASHTRA)
16th February 2008

1. Shri R. Hariharan, Secretary-General, Indian Soap and Toiletries Makers' Association

2. Shri S.W. Despande, Director General
3. Shri Ravi Kant, President — All India Drugs Control Officer's Confederation
4. Shri Uday Bhaskar, Secretary-General

5. Dr. S.N. Parchure, President
6. Dr. V.J.Thakurdesai, Secretary-General
7. Dr. V.D. Purohit, Treasurer — National Integrated Medical Association
8. Dr. V.D. Bharadwaj, Vice-President
9. Dr. A.M. Khan, Joint Secretary

10. Shri Tapan Ray, Director General, Organization of Pharmaceutical Producers of India

11. Mr. Shashikant D. Joag, General Secretary, Indian Pharmaceutical Association

12. Dr. T. S. Malvankar, President
13 Mr. Gaman B. Shah, Vice-President — Federation of Small Scale
14. Mr. Vinay S. Baranth, Secretary — Pharma Industries of India

15. Shri Vinay Baranth, President, — S.S.I. Pharma Association
16. Mr. Gamanbhai B. Shah, President — Small Drug Manufacturers Organization
17. Mr. N.R. Shah, Secretary — of India
18. Mr. A.K. Burman, Secretary

19. Shri S.R. Salunkhe, President, Drugs Inspectors Welfare Association (DIWA)

20. Shri P.R. Uttarwar, President
21. Shri D.V. Giri, Vice-President — F.D.A. Class-I Officers Association
22. Shri S.T. Patil, Secretary

23. Shri V.J. Savani, President
24. Shri H.P. Gorasiya, Vice-President — Bhavnagar Drug Manufacturers'
25. Shri Kanubhai Harsora, Secretary — Association (BDMA)

26. Shri Sanjeev Pendharkar, Director, Vicco Laboratories

27. Shri D.G. Shah, Secretary-General, Indian Pharmaceutical Alliance

28. Shri S.B. Shinde, Joint Secretary, All India Small Drug Manufacturers' Association

29. Shri Pramod Sharma, President
30. Shri Subhartee Dey, Vice-President — Ayurvedic Drug Manufacturers' Association
31. Shri Ranjit Puranik, Secretary

GOA
18th February, 2008

32. Shri D.R. Salgaocar, President — Goa Pharmaceutical Manufacturers'
33. Shri Arun Naik, Vice-President — Association

Printed at : Bengal Offset Works, 335, Khajoor Road, Karol Bagh, New Delhi-110005.