REPORT OF THE WORKING GROUP ON DRUGS & FOOD REGULATION FOR THE 12TH FIVE YEAR PLAN

WG-4: DRUGS & FOOD REGULATION

WG-4

No. 2(6)2010-H&FW
Government of India
Planning Commission

Yojana Bhavan, Sansad Marg
New Delhi – 110001
Dated 9th May 2011

OFFICE MEMORANDUM

Subject: Constitution of working group on Drugs and Food Regulation for the Formulation of the Twelfth Five Year Plan (2012-2017)

With a view to formulate the Twelfth Five Year Plan (2012-2017) for the Health Sector, it has been decided to constitute a Working Group on Drugs and Food Regulation under the Chairmanship of **Shri K. Chandramouli, Secretary, Ministry of Health & Family Welfare.** The composition and the terms of reference of the Working group would be as follows:

1.	**Shri K.Chandramouli, Secretary(HFW), MoHFW**	**Chairperson**
2.	Secretary, Dept. of Health Research, Govt. of India	Member
3.	Secretary, Dept. of Bio-technology, Govt. of India	Member
4.	Secretary, Department of Pharmaceuticals, Government of India	Member
5.	Director General of Health Services, Government of India	Member
6.	Additional Secretary Drugs & Food MoHFW	Member
7.	Sh. V.K.Tiwari, Adviser (Nutrition), MoHFW	Member
8.	Principal Secretary (H&FW), Himachal Pradesh	Member
9.	Principal Secretary (H&FW), Maharashtra	Member
10.	Medical Superintendent , AIIMS, New Delhi	Member
11.	Medical Superintendent, Safdarjung Hospital, New Delhi	Member

12.	Medical Superintendent, Dr. Ram Manohar Lohia Hospital, New Delhi	Member
13.	Prof. M.C. Gupta Dean Pharmacology, B D Sharma PG Institute of Medical Sciences, Rohtak	Member
14.	Director, National Institute of Pharmaceutical Education and Research (NIPER), Chandigarh	Member
15.	Dr. G. Bhubaneswar, Dean, Sri Chitra Institute Tirunal Institute of medical Sciences, Trivandrum	Member
16.	State Drug Controller, Gujarat	Member
17.	State Drug Controller, Karnataka	Member
18.	Representative of Department of Agriculture, Government of India	Member
19.	Representative of Department of Commerce, Government of India	Member
20.	Representative of Department of Food Processing, Government of India	Member
21.	CEO, Food Safety & Standards Authority of India (FSSAI)	Member
22.	ADG (Prevention of Food Adulteration), FSSAI	Member
23.	Drug Controller General of India	Member
24.	CEO, Tamil Nadu Medical Services Corporation (TNMSC)	Member
25.	Ms. Sunita Narain, Director, Centre for Science and Environment, New Delhi	Member
26.	Dr. Narendra Gupta, Prayas, Rajasthan.	Member
27.	Dr. Usha Gupta, Dept. of Pharmacology, Maulana Azad Medical College, New Delhi	Member
28.	Ms. Leena Menghaney, Médecins Sans Frontières, New Delhi	Member
29.	Dr. Mira Shiva, Director, Initiative for Health Equity & Society New Delhi	Member
30.	Dr. Jacob Puliyel, Head of Paediatrics, St. Stephens Hospital, New Delhi	Member

31.	Mr. S Srinivasan, Low Cost Standard Therapeutics (LOCOST), Vadodara Gujarat	Member
32.	Dr. Gopal Dabade, Dharwad, Karnataka	Member
33.	Dr. Anant Phadke, Society for Assistance to Children in Difficult Situation (SATHI), Pune	Member
34.	Mr. Ambrish Kumar, Adviser (Health) Planning Commission	Member
35.	**Joint Secretary (Drugs), MoHFW**	Member Secretary

Terms of References

1. To review the drug & food regulatory mechanism in the country to ensure providing quality, safe drugs and wholesome food in the country.
2. To review the incidences of anti-biotic/anti-microbial resistance and suggest measures for rational prescription of drugs especially anti-biotics.
3. To review and suggest measures for promotion of generic drugs.
4. To review the progress of Pharmaco Vigilance programmes and suggest measures to strengthen the same.
5. To review the existing manpower in CDSCO/FSSAI and suggest measures for further strengthening.
6. To review the Drug & Food testing labs under the Central Government and suggest measures for their strengthening.
7. To review the existing manpower in of food & drug regulations in States and suggest measures for further strengthening including financial assistance.
8. To review the Drug & Food testing labs in States and suggest measures for their strengthening including financial assistance.
9. To suggest modifications in policies, priorities under the drug & food regulatory framework during the 12th Five Year Plan.
10. To indicate the financial outlay required for the implementation of the initiatives stated above during the 12th Plan.
11. To deliberate and give recommendations on any other matter relating to the topic.
12. The Chairman may constitute various Specialist Groups/ Sub-groups/ task forces etc. as considered necessary and co-opt other members to the Working Group for specific inputs.
13. Working Group will keep in focus the Approach paper to the 12th Five Year Plan and monitorable goals, while making recommendations.
14. Efforts must be made to co-opt members from weaker sections especially Scheduled Castes, Scheduled Tribes and minorities working at the field level.

15. The expenditure towards TA/DA in connection with the meetings of the Working group in respect of the official members will be borne by their respective Ministry / Department. The expenditure towards TA/DA of the non-official Working group members would be met by the Planning Commission as admissible to the class 1 officers of the Government of India.
16. The Working group would submit its draft report by 31st July, 2011and final report by 31st August, 2011.

(Shashi Kiran Baijal)
Director (Health)

Copy to:

1. Chairman, all Members, Member Secretary of the Working Group
2. PS to Deputy Chairman, Planning Commission
3. PS to Minister of State (Planning)
4. PS to all Members, Planning Commission
5. PS to Member Secretary, Planning Commission
6. All Principal Advisers / Sr. Advisers / Advisers / HODs, Planning Commission
7. Director (PC), Planning Commission
8. Administration (General I) and (General II), Planning Commission
10. Accounts I Branch, Planning Commission
11. Information Officer, Planning Commission
12. Library, Planning Commission

(Shashi Kiran Baijal)
Director (Health)

REPORT

OF

THE WORKING GROUP

ON

DRUGS & FOOD REGULATIONS

FOR FORMULATION OF 12TH FIVE YEAR PLAN

MINISTRY OF HEALTH & FAMILY WELFARE

DEPARTMENT OF HEALTH & FAMILY WELFARE

CHAPTER – 1

DRUGS REGULATION

(I) STRENGTHENING OF DRUG REGULATORY MECHANISMS AT THE CENTRE AND IN THE STATES

Strengthening of Drugs Regulatory Mechanism at the Centre and in the States

Summary – Strengthening of Drugs Regulatory Mechanisms is one of the major public health interventions. This ensures that safe, efficacious and quality drugs are made available to the people. Keeping in view the recommendations of the Mashelkar Committee, it is important that the infrastructure, both physical and human resource, both at the Centre as well as in the States is substantially augmented. A more transparent and effective monitoring of Clinical Trials is required. Regulation and control of all medical devices needs to be tightened. The proposed financial outlay for these activities is Rs. 6256 cr, for the Centre and the States which includes manpower augmentation, creation and upgradation of labs, setting up of new offices of drugs regulatory control, strengthening Pharmacovigillance and creating awareness among people (care givers and receivers) regarding safe drugs both at the Centre and in the States. For providing financial and human resource support to the States, a Centrally Sponsored Scheme is proposed.

Background

Drug Regulatory System in India.

One of the main interventions of the Central Government to achieve its Public Health objectives is to ensure that drugs available to the public are safe, efficacious and conforms to prescribed quality standards. Regulatory control over the quality, safety and efficacy of drugs in the country is exercised through a central legislation called the Drugs and Cosmetics Act, 1940 and the Rules made thereunder. Licensing of manufacturing and sales premises is looked after by the State Governments while imports, permissions for marketing of New Drugs in the country, and for conduct of Clinical Trials, are mainly the responsibilities of the Central Government.

Indian Pharmaceutical Industry is one of the most vibrant sectors of Indian Industry. It has been growing at the rate of 11-12%. It is the 3rd largest in the world by volume and 13th in value. The total size of the Indian Pharmaceutical Industry is about Rs 100, 000 crore out of which exports account for Rs 42 000 Crore and the rest is the size of the domestic market. It is 8% of global production and 2% of world pharma market.

The sub-group is of the opinion that problems in the drug regulatory system in the country are mainly in the following areas:

- Inadequate manpower at the State and Central level
- Inadequate or weak drug control infrastructure at the State and Central level
- Inadequate testing facilities

- Non-uniformity of enforcement of law and regulation
- Lack of training to regulatory officials
- Lack of data base
- Inadequate IT services

These problems have got further accentuated with the increasing growth of the Pharma Industry in the country.

RECOMMENDATIONS

A. Strengthening of CDSCO :

1. The Central Government should create additional posts for uniform and effective implementation of Drugs and Cosmetics Act and Rules thereunder :

The additional posts are required :

i. To comply with recommendations of Dr.Mashelkar Committee report (one Drugs Inspector for 50 manufacturing units and one Drugs Inspector for 200 Sale premises)

ii. To regulate all medical devices (at present only 14 notified medical devices are regulated under the said Act)

iii. To regulate Clinical Trials effectively (Clinical Trial Site inspections etc)

iv. To implement effective pharmacovigillance program

v. To implement the Antibiotic policy.

vi. To effectively regulate export and import of drugs/cosmetics/medical devices.

Additional manpower – CDSCO would require 1045 additional posts, to regulate the pharmaceutical market in the country. For this, Rs 45 crore is required per annum. The details of additional posts required for CDSCO and its financial requirements is at Table - 1

For 5 years, Rs 51 X 5 = **Rs 255 Crore is required for additional man power(Salary Component only) for CDSCO and Rs 375 Cr is required for existing manpower of CDSCO, Indian Pharmacopoeia Commission and the National Institute of Biologicals (Salary, TA, Chemicals/Reagents etc)**

Total manpower and other establishment Costs for CDSCO, IPC, NIB is Rs 255 cr + 375 Cr = Rs 630 Cr

Additional manpower is also required for the following:

S.No	Manpower	Cost	Total
1	For Newly Created Laboratories	200 personnel at Cost of Rs 9 Cr per annum. For 5 years: 9X5= Rs 45 Cr	For 8 labs Rs 45X8= Rs 360 Cr

2	For up gradation of existing laboratories	100 personnel at the Cost of Rs 4.5 Cr per annum. For 5 years: Rs 4.5X5=22.5 Cr	For 6 labs Rs 22.5X6= Rs135 Cr
3	For Mini Labs	25 personnel at the cost of Rs1.1 Cr per annum For 5 years: Rs 1.1X5= Rs 5.5 Cr	For 20labs Rs5.5X20= Rs110 Cr
4	For Mobile labs	10 personnel at the cost of Rs 0.45 Cr per annum For 5 years: Rs 0.45X5= Rs 2.25 Cr	For 50 vans Rs 2.25X50= Rs 112.5 Cr Say Rs 113 cr
5	For Pharma Research Laboratory	100 personnel at the Cost of Rs 4.5 Cr per annum. For 5 years: Rs 4.5X5=22.5 Cr	For one lab Rs 22.5 Cr
6	For National Training Academy	For 50 personnel at the cost of Rs 2.25 Cr per annum For 5 years: Rs 2.25X5= Rs11.25 Cr	For one Academy Rs 11.25 Cr.
7	For E-governance	For 50 personnel at the cost of Rs 2.25 Cr per annum For 5 years: Rs 2.25X5= Rs11.25 Cr	Rs 11.25 Cr
8	Cosmetics Lab	For 100 personnel at the cost of Rs 4.5 Cr per annum For 5 years Rs 4.5 cr X 5= Rs 22.5 Cr	For 5 labs Rs 22.5 cr X 5 = 112.5 Cr Say Rs 113 Cr
9	Diagnostic kits lab	For 50 personnel at the cost of Rs 2.25 Cr per annum For 5 years: Rs 2.25X5= Rs11.25 Cr (Say Rs 11 Cr)	For 3 labs Rs 11 Cr X 3= Rs 33 Cr
10	Medical devices lab	For 50 personnel at the cost of Rs 2.25 Cr per annum For 5 years: Rs 2.25X5= Rs11.25 Cr (Say Rs 11 Cr)	For 5 labs Rs 11 Cr X 5 = Rs 55 Cr
	Total	4300 personnel	Rs 964 Cr

2. The Central Government should construct new CDSCO offices at Ahmadabad, Jammu, Bangalore, Indore, Goa, Guwahati and New Delhi (independent building).

The approximate financial outlay for these offices would be **Rs 35 Crore** (Rs 5 crore each X 7 offices) **(Table-2)**

3. For upgradation of existing CDSCO offices**, Rs 60 Cr** is required. (Rs 3 crore each office X 20 offices **(Table-3)**
4. For creation of Mini labs at Ports(both at Sea and Air ports where drugs are imported /exported) **Rs 96 Crore** (Rs 8 crore each lab X 12 ports) **(Table-4)**
5. The Central Government should create new Central Drugs Testing Laboratories to strengthen testing capacity. It is proposed that having regard to expanding Pharma Industry in the country the Central Govt should set up 8 new laboratories at the cost of Rs 40 Crore each amounting to **total Rs 320 Crore (Table-5)**
6. The Central Government should upgrade existing CDSCO's 6 labs at the cost of Rs 15 Cr each. The financial outlay is Rs 15 Cr X 6 **= Rs 90 Crore**
7. The maintenance and running cost of the each lab (@ Rs. 2 Cr) for five years period would be Rs 10 crore each.

   For 6 existing labs Rs 10 Cr X 6 = **Rs 60 Crore**

   For 8 new labs (for two years) Rs 4 Cr X 8 = Rs 32 Cr

   Total Rs 60 cr + 32 Cr = **Rs 92 cr**
8. There is a need to establish CDSCO Training Academy for updating knowledge and skills of the regulatory officials. The approximate cost for creating of CDSCO Training Academy would be **Rs 50 Crore**. **(Table-7)**
9. Effective management of the issues on spurious drugs lies with the Drug Regulatory Agencies at the Centre and in the States. The menace of spurious drugs would be checked by providing mobile drug testing laboratories. The cost of each mobile drugs testing lab would be Rs 5 Cr and there is a need of 20 such laboratories all over India. The cost is Rs 5 Cr X 20 = **Rs 100 Crore (Table-8).**
10. Although many Central Drugs Laboratories have adequate facilities for testing of drugs (quality) as per the prescribed standards, these laboratories are not well equipped to test foreign (contaminated) substance in drugs. Hence there should be a State of the Art Pharma Research Laboratory to carry out sophisticated analysis of drugs to detect such substances. For the setting up of such Laboratory, the financial outlay would be **Rs 50 Crore (Table-9).**
11. Globalization has fundamentally changed the environment for regulating drug products and created unique regulatory challenges for CDSCO for the following reasons:
    i. More foreign manufacturing facilities supplying bulk Drugs, Medical Devices, Blood Products, Diagnostics, Anti Cancer drugs to India.
    ii. Increasing volume of imported Medicinal Products
    iii. Greater complexity in supply chain
    iv. Imports coming from countries with less developed regulatory system

v. Export of Medical Products from outside India with the label "Made in India"

It is therefore important that the CDSCO should have India Country Offices, at least one each in 5 countries. Initially, such offices could be set up in China and South Africa to inspect foreign manufacturing facilities and address other regulatory issues. The offices in the other three countries could be set up o a need analysis basis.The financial outlay for each office would be Rs 35 Crore and total is **Rs 175 Crore** (Rs 35 X 5 locations). **(Table-10)**

12. There is a need for increased transparency in CDSCO and a need a to increase and maintain credibility with the public. This can be achieved by having proper E-Governance system in place. With this, all offices of Zonal/Sub-Zonal/Port offices/Laboratories of CDSCO and offices of State Drugs Controllers will be interlinked for fast communication and effective monitoring of quality of Drugs. It includes IT enabled services, National Registry, Video Conferencing facilities, archiving of all files etc. This will cost around **Rs - 250 Crore-**

13. A Pharmacovigillance Program of India (PVPI) has been launched on 14th July 2010 to capture Adverse Drug Reaction (ADR) data in Indian population in a systematic way. The main objective of the Program is to monitor ADR in Indian population. The data would be captured through the Medical Colleges in the country which would be provided necessary administrative and logistic support.

It is envisaged that through this Program, India will be able to generate independent, evidence based ADR data which would help in taking regulatory decisions on safety aspects of drugs marketed in India.

To implement effective Pharmacovigillance program in India, the financial outlay would be Rs 50 Crore per year. For 5 years, it would be **Rs 250 Crore.**

14. There is a felt need to educate and sensitise both the medical care providers and recipients on promotion of generic drugs, antibiotic resistance, spurious drugs. It is therefore proposed to earmark funds for IEC activities for the Plan period at **Rs. 150 crore**

15. Various APIs are imported into India for manufacturing drug formulations. Recently, the CDSCO has carried out overseas inspections of the manufacturing units in China to verify the GMP compliance. The results have been encouraging. It is proposed to increase such overseas inspections in the Plan period. It is therefore proposed to earmark **Rs. 25 crore** for this activity.

16. With increased globalisation of the regulatory mechanism apart from the changing profile of the pharma industry, it is important to impart **continuous training** to the drug regulators. It is, therefore proposed to have an earmarked fund of Rs. 50 cr for this activity and Rs 20 Cr for travel expenses. Total would be Rs 20 cr for the Plan Period

17. The Central Government should create new Central Drugs Testing Laboratories for testing of Cosmetics. It is proposed that having regard to expanding Cosmetics Industry in the country the Central Govt should set up 5 new laboratories at the cost of Rs 40 Crore each amounting to **total Rs 200 Crore (Table-11)**
18. The Central Government should create new Central Drugs Testing Laboratories for testing of Diagnostics kits/reagents and Blood samples. It is proposed that having regard to expanding Diagnostics Industry and blood banks in the country the Central Govt should set up 3 new laboratories at the cost of Rs 20Crore each amounting to **total Rs 60 Crore (Table-12)**

B. <u>Strengthening of State Drugs Regulatory Systems:</u>

Drugs and Cosmetics Act is a Central Act implemented by both Centre and States. Major responsibilities of States are to grant/renew the drugs manufacturing licenses and sale licenses. They are also involved in enforcement of various provisions of Drugs and Cosmetics Act and Rules including drawing of samples for analysis, prosecutions etc. At present, States have grossly inadequate infrastructure and manpower. There is a crying need to strengthen State Drugs Control organisations.

Considering the sensitivity of the Pharma Sector and lack of resources available with State Governments, it is important to have a Centrally Sponsored Scheme to strengthen their infrastructure, both physical and human resources. The Scheme would be funded by the Centre and the States in a ratio of 60:40. However, it has to be ensured, by way of a MoU that States bring in their share upfront and also sanction required number of Posts, in order to be eligible to receive funds from the Central Government.

The following components along with cost estimates would be covered in the Scheme :-

Item	**Cost for each (Cr)**	**Total number**	**Total cost(Cr)**
Upgradation of State labs	15	26	390
Manpower (Regulators) cost (2500 personnel @ Rs 40000/Person/month)	120/annum	5 yrs	600
Maintenance and Running cost of State labs	6/annum/lab	26 for 5 yrs	780
Construction/expansion/up gradation of State Drugs Control offices	10	35	350

Creation of more State labs	30	20	600
Manpower for labs (2000 personnel@Rs 40000/person/month)	96/annum	5 yrs	480
* Proposed share of expenditure between the States and the Centre in the ratio of 60:40			
Total			3,200 crore

For strengthening of State Drugs Regulatory and Control mechanisms, **Rs 3200 Crore** will be required. The States would bear 40% of the cost ie **Rs 1280 Crore** and the Central Government's share @ 60% would be **Rs 1920 Crore.**

Strengthening of Medical Devices Regulations:

Import, manufacturing, sale and distribution of Medical devices is regulated under the Drugs and Cosmetics Act 1940 and Rules 1945. At present, only those Medical Devices that are notified by Central Government are regulated under the said Act as drugs. These medical devices include Disposable Hypodermic Syringes, Disposable Hypodermic Needles, Disposable Perfusion Set, In vitro Diagnostic Devices for HIV, HbsAg and HCV, Cardiac Stents, Drug Eluting Stents, Catheters, Intra Ocular Lenses, I.V. Cannulas, Bone Cements, Heart Valves, Scalp Vein Set, Orthopaedic Implants and Internal Prosthetic Replacements which have been notified by the Govt. of India from time to time.

At present, there are many concerns/ gaps in the existing regulations applicable for Medical Devices, as these are considered as Drugs and all provisions of Drugs are applicable to Medical Devices also.

The Working Group had requested comments from various experts and stakeholders. Most of them have suggested :

- Independent authority for regulation of Medical Devices
- Inter-departmental expert committee
- Ample funds for international travel for participation in technical committees
- Testing laboratories
- Training Academy
- Dedicated regulatory personnel

In view of the above, the Govt of India has already initiated steps to amend the Drugs and Cosmetics Act to have separate provisions for Medical Devices. The salient features of the proposed bill would be to provide a separate definition of Medical Devices, their risk based classification for regulatory control, Clinical Trials on Medical Devices, Conformity Assessment Procedures, Penal provisions, etc.

The proposed amendments are under active consideration of the Ministry of Health and Family Welfare for putting forth a Drugs and Cosmetics (Amendment) Bill in the Parliament.

The CDSCO has to be strengthened in terms of manpower and other infrastructure to take up additional responsibilities in the growing area of medical devices.

C. <u>Recommendations for Medical Devices:</u>

a. Dedicated Regulatory personnel for Medical Devices (300 personnel) . As proposed in the Drugs and Cosmetics (Amendment) Bill, all categories of Medical Devices would be regulated.

b. Experts in the field of Medical devices (10 experts). The regulation of Medical Devices requires multi disciplinary experts like Bio technologist, Bio materialist, Electronic Engineer etc.

c. Set up of National Medical Devices Testing Laboratories (Category wise 5 labs) Rs 40 Cr each. (Rs 40 cr X 5 labs = **200 Crore)** (Justification is same as CDTL lab)

d. Funds for international travel. (**Rs 5 Crore**)

D. <u>Recommendations for Clinical Trials:</u>

Clinical trials are regulated by Central Drugs Standard Control Organisation (CDSCO), Directorate General Health Services, Ministry of Health & Family Welfare. Clinical trials are required to be carried out in accordance with requirements and guidelines specified in Rule 122DA, 122DAA, 122DB, 122E and Schedule Y of Drugs & Cosmetic Rules.

The Working Group discussed various issues on regulation of clinical trials including its monitoring. The Group took note of various steps already taken to streamline the regulation of clinical trials in the country. Constitution of 12 New Drug Advisory Committees for evaluation of proposals of clinical trials and approval of new drugs & mandatory registration of clinical trials in ICMR clinical trial registry www.ctri.in were appreciated by the Group.

The Group after discussion recommended the following:

- Issues of consent, ethical review, monitoring of adverse events etc. need to be specifically reviewed and regulations strengthened wherever required.
- Accountability and liability of multiple stakeholders particularly, ethics committees, principal investigators and sponsors, CROs need to be clearly mentioned.
- To streamline reporting of adverse events their analysis , issues of payment of medical expenses and compensation in study/trial related injury or death, awareness & training of stakeholders, advocacy to participants' rights, categorization of injuries etc. .
- To consider regulations for demonstration projects, and observation studies, non-interventional studies etc.
    - CDSCO should take immediate steps to finalise current draft on regulation of clinical trials and CROs.Review and amend schedule Y to strengthen clinical trial regulations and examine whether ICMR guidelines for research could be merged into Schedule Y.

- The infrastructure & manpower at CDSCO needs to be increased manifold to cope with challenging tasks of reviewing the increasingly mounds of data that are submitted for clinical trials and drug approvals.
- CDSCO should provide all the relevant and necessary information on the web site to make the decision making transparent.

TOTAL FINANCIAL OUTLAY FOR 12TH FIVE YEAR PLAN FOR DRUGS SECTOR:

S.no	Item	Cost (Crore)
A	**For CDSCO**	
1	Manpower	Rs 630
2	New offices	Rs 35
3	Up gradation of existing offices	Rs 60
4	Mini labs at Port offices	Rs 160
5	New CDTL labs	Rs 320
6	Up gradation of existing labs	Rs 90
7	Running/Maintenance of labs	Rs 92
8	National Training Academy	Rs 50
9	Mobile labs	Rs 250
10	Pharma Research lab	Rs 50
11	CDSCO Overseas Country offices	Rs 175
12	E-governance/Archiving	Rs250
13	Pharmacovigillance	Rs 250
14	IEC	Rs150
15	Overseas Inspections	Rs 25
16	Man power for S.no 4, 5,6,8,9,10,12, 17,18 and Medical devices lab. (4300 personnel)	Rs 964

17	Training to Regulators	Rs 50
18	Travel Expenditure	Rs 20
19	Cosmetics labs	Rs 200
20	Diagnostic labs/Blood testing labs	Rs 60
21	Spurious drug survey and Samples cost for testing of Drugs, Cosmetics, Medical Devices etc	Rs 20
B	**For Strengthening of State Drug Regulatory System**	
1	Central Govt Share(60%) for Strengthening States Drugs Regulatory Systems	Rs 1920
C	**Medical Devices**	
1	National Labs	Rs 200
2	Funds for International Travel	Rs 25
	IPC	
1	Manpower/other expenses	Rs 100
	NIB	
1	Manpower/other expenses	Rs 100
	CDL Kasauli	
1	Manpower, Infrastructure, Training etc	RS 10
	Total	**Rs 6256 cr**

Total financial outlay for Strengthening of Drugs Regulatory System Rs 6256 crore during the Plan period.

Table-1

S. No.	Name of the Post	No. of Posts	Pay band + Grade Pay (Rs.)	Monthly expenditure
1	JDC(I)	015	PB-4+8700	12,79,725
2	DDC(I)	032	PB-3+7600	18,00,480
3	ADC(I)	055	PB-3+6600	26,95,275
4	DI	431	PB-2+4800	1,46,90,635
5	Medical Device Officer (New Cadre)	300	PB-2+4800	1,02,25,500
6	ADI	269	PB-4200	69,79,205
7	Senior Account Officer	002	PB-3+7600	1,12,530
8	Account Officer	009	PB-3+6600	4.41,045
9	Director (Admn and Vig.)	001	PB-4+8700	83,315
10	Dy. Director (Admn)	009	PB-3+6600	4,41,045
11	Dy. Director (Budget and Accounts)	001	PB-3+6600	49,005
12	Section Officer	003	PB-2+4800	1,02,255
13	Specialists I. Clinical Pharmacologist 10 II. Biochemist 02 III. Immunologist 02 IV. Biotechnologist 02 V. Biostatistician 02 VI. Bio Medical Technologist 05 VII. Bio Materialist 01 VIII. Electronic Engineer 01 IX. Chemical Engineer 01 X. Plastic Engineer 01 XI. Cosmetologist 02 XII. Veterinarian 02 XIII. Molecular Biologist 01 XIV. IT Specialist 02 XV. Toxicologist 02 XVI. Oncologist 01 XVII. Heamatologist 01 VIII. Endocrinologist 01 XIX. Urologist 01 XX. Gastroenterologist 01 XXI. Dermatologist	064	PB-3+6600	31,36,320

	01 XXII. Pulmonologist 01 XXIII. Neurologist 01 XXIV. Psychiatrist 01 XXV. Ophthalmologist 01 XXVI. Cardiologist 01 XXVII. Gynecologist 01 XXVIII. Anesthetist 01 XXIX. Orthopedist 01 XXX. Data Processing Manager (Including Zonal/Sub-Zonal Officers) 14			
14	Legal Officers	04	PB-3+6600	1,96,020
Total		**1195**		**4,22,34,355**
Annual Expenditure 4,22,34,355 X 12 =Rs. 50,68,12,260, Say Rs 51 Crore				

Table-2

Creation of New CDSCO offices:

S.No	Item	Cost	Total Cost
1	Civil Construction	Rs 1500/Sft 20,000 sft 1500X20000=3,00,00,000	Rs 3 Cr
2	Furniture and IT Services/Library	Rs 2 Cr	Rs 2 Cr
		Total (for each office)	Rs 5 Cr*

Note: * Excluding land cost.

Total cost for creation of all new 7 CDSCO Offices would be Rs 5 Cr X 7 =Rs 35 Cr

Table- 3
Up gradation of existing CDSCO offices:

S.No	Item	Cost	Total Cost
1	Civil Construction	Rs 1500/Sft	Rs 1.5 Cr

		10,000 sft 1500X10000=1,50,00,000	
2	Furniture and IT Services/Library	Rs 1.5 Cr	Rs 1.5 Cr
		Total (for each office)	Rs 3 Cr*

Note: * Excluding land cost.

Total cost for up gradation of 20 CDSCO Offices would be Rs 3 Cr X 20 =Rs 60 Cr

Table- 4
Creation of Mini Labs at Port offices of CDSCO

S.No	Item	Cost	Total Cost
1	Civil Construction	**Rs 1500/Sft 4,000 sft 1500X4000=60,00,000**	**Rs 0.6 Cr**
2	Equipment/Instruments	**Rs 5 cr**	**Rs 5 Cr**
3	Furniture and IT Services/Library	**Rs 1.5 Cr**	**Rs 1.5 Cr**
4	Reagents/chemicals		**Rs 0.9 Cr**
		Total (for each office)	**Rs 8 Cr***

Note: * Excluding land cost.

Total cost for creation of all new 20 Mini labs at Port office of CDSCO would be Rs 8 Cr X 20 =Rs 160 Cr

Table-5
Creation of New Central Drugs Testing Laboratories:

Expected Testing Capacity: 10,000 Drug samples per annum per lab

S.No	Item	Cost	Total Cost
1	Civil Construction	**Rs 1500/Sft 40,000 sft 1500X40000=6,00,00,000**	**Rs 6 Cr**
2.	Equipments/Instruments	**Rs 22 Cr**	**Rs 22 Cr**
3	Reagents/Chemicals	**Rs 1 Cr per annum For 5 years**	**Rs 5 Cr**
4	Furniture and laboratory furniture/IT Services/Library	**Rs 6 Cr**	**Rs 6 Cr**
5	Miscellaneous	**Rs 1 Cr**	**Rs 1 Cr**
		Total (for each Laboratory	**Rs 40 Cr***

Note: * Excluding land cost.

Total cost for creation of all new 8 CDTL laboratories would be Rs 40 Cr X 8 =Rs 320 Cr

Table- 6
Up gradation of existing CDSCO Labs

Expected Testing Capacity: 5,000 Drug samples per annum per lab

S.No	Item	Cost	Total Cost
1	Civil Construction	Rs 1500/Sft 20,000 sft 1500X20000=3,00,00,000	Rs 3 Cr
2.	Equipments/Instruments	Rs 1.20 Cr	Rs 6 Cr
3	Reagents/Chemicals	Rs 0.5 Cr per annum For 5 years	Rs 2.5 Cr
4	Furniture and laboratory furniture/IT Services/Library	Rs 3 Cr	Rs 3 Cr
5	Miscellaneous	Rs 0.5 Cr	Rs 0.5 Cr
		Total (for each Laboratory	**Rs 15 Cr***

Note: * Excluding land cost.

Total cost for up gradation of 6 CDSCO laboratories would be Rs 15 Cr X 6 =Rs 90 Cr

Table-7
Creation of CDSCO Training Academy

Expected to train 50000 Regulatory Personnel (State & Centre) every year

S.No	Item	Cost	Total Cost
1	Civil Construction (Auditorium, Rooms, Canteen, Resident Director house, Case study rooms, etc)	Rs 1500/Sft 40,000 sft 1500X40000=6,00,00,000	Rs 6 Cr
2.	Equipments/Projector/Air-conditioning/Generator etc	Rs 15 Cr	Rs 15 Cr
3	Maintenance/Running cost/ Electricity	Rs 2 Cr per annum For 5 years	Rs 10 Cr
4	Furniture and Auditorium furniture/IT Services/Library	Rs 15 Cr	Rs 15 Cr
5	Boundary Wall/Lawn/ Miscll.	Rs 4 cr	Rs 4 Cr
		Total	**Rs 50 Cr***

Note: * Excluding land and Manpower cost.

Table-8
Mobile testing Laboratories.

S.No	Item	Cost	Total Cost
1	Mobile Van	Rs 1 Cr	Rs 1 Cr
2.	Equipments/Instruments	Rs 3 Cr	Rs 3 Cr
3	Reagents/Chemicals/Fuel	Rs 0.2 Cr per annum For 5 years	Rs 1 Cr
		Total (for each Mobile Van)	**Rs 5 Cr***

Note: * Excluding Manpower cost.

Total cost for 50 mobile testing labs Rs 5 Cr X 50 =Rs 250 Cr

Table-9
Pharmaceutical Research Laboratories

S.No	Item	Cost	Total Cost
1	Civil Construction	**Rs 1500/Sft** **30,000 sft** **1500X30000=4,50,00,000**	**Rs 4.5 Cr**
2.	Equipments/Instruments	**Rs 30 Cr**	**Rs 30 Cr**
3	Reagents/Chemicals	**Rs 1 Cr per annum** **For 5 years**	**Rs 5 Cr**
4	Furniture and laboratory furniture/IT Services/Library	**Rs 5 Cr**	**Rs 5 Cr**
5	Air-conditioning, Lawn, Boundary wall, Generator etc	**Rs 5.5 cr**	**Rs 5.5 Cr**
		Total	**Rs 50 Cr***

Note: * Excluding land cost and Man power

Table-10
CDSCO Country Offices in 5 Countries (to start with in China and South Africa)

S.No	Item	Cost	Total Cost
1	Rented Accommodation	Around 2000 Sft Rent Rs 0.6 Cr per annum For 5 Years	Rs 3 Cr
2.	Furniture/ IT Services/ Library	Rs 6 Cr	Rs 6Cr
3	Manpower Minimum of 6-8 officials	Rs 2 Cr per annum For 5 years	Rs 10 Cr
4	Travel Cost	Rs 3 Cr per annum For 5 years	Rs 15 cr
5	Miscellaneous (Electricity, Telephone bill, etc)	Rs 0.2 Cr per annum For 5 years	Rs 1 Cr

		Total (for each country)	**Rs 35 Cr**

Note: For 5 country offices Rs 35 X 5 = Rs 175 Cr.

Table-11

Creation of New Central Cosmetics Testing Laboratories:

Expected Testing Capacity: 10,000 Cosmetics samples per annum per lab

S.No	Item	Cost	Total Cost
1	Civil Construction	**Rs 1500/Sft** **40,000 sft** **1500X40000=6,00,00,000**	**Rs 6 Cr**
2.	Equipments/Instruments	**Rs 22 Cr**	**Rs 22 Cr**
3	Reagents/Chemicals	**Rs 1 Cr per annum** **For 5 years**	**Rs 5 Cr**
4	Furniture and laboratory furniture/IT Services/Library	**Rs 6 Cr**	**Rs 6 Cr**
5	Miscellaneous	**Rs 1 Cr**	**Rs 1 Cr**
		Total (for each Laboratory	**Rs 40 Cr***

Note: * Excluding land cost.

Total cost for creation of all new 5 laboratories would be Rs 40 Cr X 5 =Rs 200 Cr

Table -12

Creation of New Central Diagnostic kits/Blood Samples Testing Laboratories:

Expected Testing Capacity: 5000 Diagnostic Kits/Blood samples per annum per lab

S.No	Item	Cost	Total Cost
1	Civil Construction	**Rs 1500/Sft** **20,000 sft** **1500X20000=3,00,00,000**	**Rs 3 Cr**
2.	Equipments/Instruments	**Rs 11 Cr**	**Rs 11 Cr**
3	Reagents/Chemicals	**Rs 0.5 Cr per annum** **For 5 years**	**Rs 2.5Cr**
4	Furniture and laboratory furniture/IT Services/Library	**Rs 3 Cr**	**Rs 3 Cr**
5	Miscellaneous	**Rs 0.5Cr**	**Rs 0.5Cr**
		Total (for each Laboratory	**Rs 20 Cr***

Note: * Excluding land cost.

Total cost for creation of all new 3 laboratories would be Rs 20 Cr X 3=Rs 60 Cr

(II) PROVISION OF "FREE MEDICINES FOR ALL" IN PUBLIC HEALTH FACILITIES UNDER NRHM / NUHM

Provision of 'Free Medicines for All' in Public Health Facilities under NRHM/NUHM

Summary

During the 12th Five Year Plan, a provision will be made ***for 'free medicines for all' in Public Health Facilities*** under the National Rural Health Mission(NRHM) for facilities upto the District Hospital in those districts which are/ would not be covered under the National Urban Health Mission(NUHM) and in the District Hospitals and other tertiary care centres under the NUHM. As part of the provisions all State Governments will be encouraged to set up medical supplies corporations on the lines of Tamil Nadu Medical Supplies Corporation (TNMSC) to supply free, quality generic medicines - essential medicines to both indoor and outdoor patients who seek care in Public Health Facilities (about - 52% of the total number of patients, including the erstwhile 20% of unreached, very poor people). The total cost on this account during the plan period would be Rs 28675 crores for running costs and an additional Rs 1293 crores as one-time capital costs. The Centre's contribution at 85 % would be Rs 25667 crores for the entire Plan period. Through this provision it shall be ensured that 52% patients begin to seek medical care from public health institutions and out of pocket expenditure in health care is reduced significantly by the end of 12th Five Year Plan. This provision would not only meet the social objective of providing care to the poor and the vulnerable but would also bring in efficiency gains by bulk procurement of drugs. Allocation for this provision under the National Rural Health Mission (NRHM)/ National Urban Health Mission (NUHM) would be over and above the normal allocation for the 12th Plan Period.

Background

Health care costs are the second most frequent reason for rural indebtedness. A major component of health care costs is medicines.[1] Studies show that in India the cost of medicines is anything between 50 to 80 percent of the total cost of treatment. Currently, many of the patients seeking care in Public Health Facilities have to buy medicines from retail shops and these medicines are very costly for a variety of reasons. However, in Tamil Nadu, since 1995 all patients visiting Public Health Facilities (which in Tamil Nadu, constitute 40% of the total number of patientsper as NSSO 60th round figures) get all medicines free. This has been possible because of setting up of an autonomous corporation in the Public Sector, the Tamil Nadu Medical Services Corporation (TNMSC), which procures in bulk directly from manufacturers, ***quality generic medicines*** through a transparent bidding process. TNMSC then supplies these to the Public Health Facilities (PHFs) through a demand sensitive passbook system instead of the traditional 'supply driven' inflexible system of distribution. It supplies about 260 drugs to Public Health Facilities as per its Essential Drug List and 192 'specialty' drugs for secondary and tertiary care as per need. The TNMSC procurement prices of quality generic medicines are very low; for many medicines they are one tenth and sometimes even one fiftieth of the retail prices (see also table in Annexure). Hence even at a budget of Rs. 29 per capita, (Budget of Rs. 210 crore for a population of 7.2 crore) plus medicines supplied by the Central Government (about Rs 20 per capita), Tamil Nadu is able to provide free medicines to all indoor and outdoor patients in all PHFs - (from all PHCs to all secondary and tertiary care hospitals under the State Government). The Government of Kerala has adapted the TNMSC model. The governments of Bihar and Rajasthan are in the process of doing so.

RECOMMENDATIONS

Adaptation of TNMSC model of 'Free Medicines for All' in Public Health Facilities (PHF) During the 12th FYP, significant advance towards the goal of 'Free Medicines for All' in Public Health Facilities (PHF) under the NRHM/NUHM would be made. For this purpose, all State Governments would be encouraged to adopt and adapt

[1] See: Sakthivel, Selvaraj and Anup K Karan (2009): "Deepening Health Insecurity in India: Evidence from National Sample Surveys since 1980s", *Economic & Political Weekly*, October 3, XLIV: 40.

(taking into account specific features, if any, of different states), the Tamil Nadu model to reach the goal of free medicines for all in the PHFs.

Out of 100 patients needing care, currently only 80 use public or private facilities; 20 are unreached. Amongst those who access health care, currently utilization of public health services is on an average around 20-25 %. Based on the Tamil Nadu experience, it is hoped that it will increase to 40% when free medicines and quality care will be provided in the PHFs. Infrastructure strengthening for delivery of the scheme is being separately provided for under the NRHM which will also carry out IEC activities for creating awareness about this Scheme. Secondly, the erstwhile 20% unreached very poor people would also now access services in PHFs. It is therefore estimated that by the end of the 12th Plan, in different states, on an average, 52% of all patients would receive care from the PHFs. The budgetary outlay required for quality generic medicines for these patients has been estimated in the table below by extrapolating from the experience of Tamil Nadu. Ideally of course these estimates need to be calculated from the disease burden. This will help the target population (including the hitherto unreached) access free medicines.

Budgetary Outlay for 'Medicines for All' Scheme for Public Health Facilities

	Subject Head	Amount in Rs	Remarks
1.	TN's budget for medicines at 40 % – access of PHFs	210 crores	Rs 210 crores[2] for TN *population* of 7.2 crores as per 2011 census provisional figures. (In TN, out of *patients* seeking treatment, 40% go to PHFs, that is 40 % utilization)
2.	All India requirement at TNMSC procurement prices	3530 crores	Extrapolated to patients seeking treatment from 121 crores population of India: Rs 210 crores x (121/7.2)
3.	**All India requirement inclusive of** additional requirement for the very poor 20 % patients who are currently totally deprived	5735 crores	This translates to 62.5 % increase in patients attending PHFs*: 1.625 x Rs 3530 crores . See footnote.
4.	**Total All-India Requirement for 5 year Plan Period for medicines for PHFs**	**28675 crores**	At Rs 5735 crores x 5
5.	**a) At 85 % central contribution of running costs (NRHM formula)**	**Rs. 24374 crores**	**(85% of Rs 28675 crores)/5 = Rs 24374 crores/5 = Rs 4875 crores per year.**
6.	**b) Capital Costs**		
7.	IT enabled Supply Chain system @Rs 5 lakhs per district for all India	31.55 crores	631 districts @ Rs 5 lakhs
8	Warehouses and related infrastructure like cold storage, storage racks @ Rs 2 crores per district for 631 districts	1262 crores	At 10-12000 sq. feet per warehouse; and 631 districts @ Rs 2 crores.
9.	**c) Total Capital Costs all-India**	**1293 crores**	
10.	**d) Center's Contribution at 85% of (a) plus 100 % of (c)**	**Rs. 25667 crores**	**Rs 24374 crores plus Rs 1293 crores**

*Out of per 100 patients, currently only 80 seek treatment; 20 are out of the reach of both private and public health services. Out of these 80 patients, 32 (40%) go to the PHFs; rest 48 go to private practitioners. Due to the 'Free Medicines for All' scheme, it is assumed that all over India, like in TN, now 40% of patients will take treatment at PHFs. Secondly, now the 20 patients who were hitherto unserved, will also take treatment from PHFs. Thus out of 100 patients, now 52 instead 32 patients will take treatment at PHFs. Thus under this

[2] Source: TNMSC, July 2011. This does not include Centre's contribution for National Programme etc.

assumption that all these 20 hitherto unserved patients will also take treatment in PHFs, number of patients reaching PHFs will increase by 62.5% (52/32 x100). See Annexure 2 for more details.

The above estimate is to be seen in the light of the current Government expenses on medicines. Rough figures from the budget estimates of 2010-11 show that Government (Centre and States put together) had spent about Rs. 6,000 crores with the Central Government alone spending around Rs. 2,500 crores. Hence the additional annual expense is only Rs 4875 crores during the plan period for the Centre for this Scheme for 85% contribution for the recurring costs. It is expected that during the 12th FYP, the health care expense would increase quite substantially from current 1.1% of GDP to 2.5% of GDP. Hence It would be possible to get the above estimated funds for this provision under NRHM/NUHM.

Summary of Costs

The total cost during the 5-year Plan Period to the Center for 'Free medicines for all in PHFs' would be –

At 85 % contribution from the Centre for recurring costs: Rs 24374 crore (Rs 4875 crores per year) plus Rs 1293 crores for 100 % of the capital costs will be equal to a Total of Rs 25667 crores for the 5-year Plan Period.

Note:

- - Inflation has been ignored because the estimated outlay - has some cushion; full amount will not be utilized from the first year. Secondly bulk medicine prices have not increased during last 5 years and in fact in TNMSC procurement, they have decreased in many cases.
- - Only TNMSC prices have been considered for estimation.-
- - Financial outlay required for AYUSH have not been taken into account in these calculations.
- It is expected that in 5 years, if not earlier, the system would be self-sustaining by charging (as is being done in Tamil Nadu) the Government health facilities a percentage of (~ 5 to 10%) on the drugs procured by the State level procurement agency.

Important Features and essential Conditions for the Scheme -

It may be noted that in TNMSC, bulk procurement is directly from Schedule M certified manufacturers, of quality generic medicines through a transparent bidding process. A list of selected medicines including mainly the essential medicines is used for procurement. However, this is not the only reason for the success of the TNMSC model. Autonomy for the professionally run Public Sector procurement agency working in a transparent manner and a demand sensitive passbook-based supply system instead of the traditional 'supply driven' inflexible supply system are the two other essential elements of the success of the TNMSC model. Hence while adopting the system in other states following steps would be considered essential -

1) Bulk procurement of generic medicines directly from the manufacturers will be done from a list of mainly essential medicines and some others, drawn up taking into account state-wise variations in morbidity. For this purpose the NLEM 2011 would be used a guide. -. The procurement of drugs need to be made under International Non-proprietary Names (INN) only
2) Only TNMSC prices have been taken for estimation, though a similar system is in operation in Kerala since 2007-08 because the TN system has been in place for the last 15 years and has been studied, evaluated in detail. Initially, some small States may not be able to bargain for prices as low as TNMSC prices. However there is enough cushion in the budget as all the budgeted amount will not be utilized fully from the first year in all States.
3) While working within the framework given by the State Government, the procurement agency would function as an autonomous and transparent set up. Requirement of technical support to States for setting up such procurement systems and mechanisms will be met out of funds under NRHM/NUHM
4) A demand sensitive passbook-based supply system, online supply chain monitoring, strict quality control, black listing of defaulting suppliers, complete transparency and systems of public accountability would be ensured. Institutionalized prescription audits and standard treatment guidelines will be put in place to ensure rational use of medicines.

Annexure 1

Table: A Comparison of Chittorgarh, TNMSC Procurement Prices and Retail Market MRPs

Generic Name of Drug (1)	**Unit** (2)	**Chittorgarh Tender Rate (Rs.)** (3)	**MRP Printed on pack/strip (Rs.)** (4)	**TNMSC Prices 2010-11 (Rs)*** **(5)**
Albendazole Tab IP 400 mg	10 tablets	11.00	250.00	4.62
Alprazolam Tab IP 0.5 mg	10 tablets	1.40	14.00	0.45
Arteether 2 ml Inj	1 injection	9.39	99.00	9.71 for 80 mg per vial
Amylodipine Tab 5 mg	10 tablets	2.50	22.00	0.42 for 10 tabs of 2.5 mg
Cetrizine 10 mg	10 tablets	1.20	35.00	0.50
Ceftazidime 1000 mg	1 injection	52.00	370.00	8.77 for 250 mg injection
Atorvastatin Tab 20 mg	10 tablets	18.10	170.00	2.30 for 10 tabs of 10 mg
Diclofenac Tab IP 50 mg	10 tablets	2.20	25.00	0.63
Diazepam Tab IP 5 mg	10 tablets	1.90	29.40	0.47
Amikacin 500 mg	1 injection	6.95	70.00	6.78

Source: Prices in Columns (3) and (4) from then Collector Samit Sharma's presentation, July 2009, and websites cited, op.cit. Source for TNMSC prices: http://www.tnmsc.com/tnmsc/new/html/pdf/drug.pdf and http://www.tnmsc.com/tnmsc/new/html/pdf/spldrug.pdf

*For similar strengths and pack sizes unless indicated otherwise. Accessed, April 29, 2011.

Annexure 2

A Detailed Explanation of How the All-India Estimate of Rs 5735 crores was arrived at

Under Key Assumption that out of 100 patients needing tt, 20 patients (20%) who are very poor and deprived are not reached at all. And of the rest 80 patients (80%), 32 (40%) seek treatment (tt hereafter) in government /Public Health Facilities (PHFs); and 48 (60%) seek tt in the private sector. The calculations remain same if we had assumed 20% of the population (say of TN or India) was unserved.

1. Total population of TN = 7.2 cr. *And let the fraction of patients needing tt to total population be y.* Therefore Total No of Patients needing tt in TN = 7.2 y crores.

2. Out of 7.2y crores, 20% are not reached in TN. That is 20% of 7.2y crores are not reached (or 0.2 x 7.2y crores). Therefore those who are able to access tt is 80% of 7.2y crores (or 0.8 x 7.2y crores).

3. Utilisation of the PHFs in TN is 40%. That is 40 % of (0.8 x 7.2y crores) = 32 % of 7.2y cr = 0.32 x 7.2y cr = 2.304y cr.

4. Total Outlay of TN = Rs 210 cr

5. Therefore per patient cost is = Rs 210 cr /2.304y cr = Rs. 91.145/y.

6. Total population of India = 121 cr.

7. And therefore assuming same y factor, there are 121y crore patients in India

9. Out of this No of patients seeking tt from PHFs = 32% of 121y cr = 38.72y cr patients (as in 3 above).

10. Cost of free supply for above = 38.72y cr x (Rs 91.145/y) = Rs 3530 cr approx. (A)

11. 20% of patients in India = 20% of 121y cr = 24.2y cr patients.

12. Cost of free supply of medicines for (11) above = 24.2y crores x (Rs 91.145/y) = Rs 2205.70 crores. (B)

13. Total of (A) + (B) = Rs 3529.13 cr + Rs 2205.70 cr = Rs. 5734.83 cr say Rs 5735 cr. This amount will reach through PFIs, (32 +20) % x 121y cr or 52% x 121y cr patients.

(III) ESSENTIAL DRUGS LIST (EDLS), DRUG RESISTANCE, IRRATIONAL DRUGS AND PRESCRIPTION, PRICING AND IP

Essential Drugs List (EDL), drug resistance, irrational drugs and prescription, pricing and IP

Summary India has the largest number of people who do not have access to all essential drugs that they need – an estimated 680 million. Expenditure on medicines is also a leading cause of rural indebtedness. India therefore, in the coming decade, would be faced with not only the task of increasing access (availability and affordability) to essential medicines in its public and private health system, but would also be faced with the difficult challenge of safeguarding domestic production of medicines and regulating prescription and dispensation of medicines in the private sector to address public health challenges such as drug resistance.

This chapter captures the background of discussions on irrational drugs and prescriptions, drug resistance particularly anti-biotics, access and promotion of generic drugs and pharmacovigilance and provides detailed policy recommendations for the 12th five year plan.

RECOMMENDATIONS:

National List of Essential Medicines (NLEM): - Having a national list of essential drugs (NLEM) makes it easier both to quantify needs and to procure and manage drugs more efficiently. An essential drugs list provides a firm foundation on which to introduce standard treatment guidelines which play a crucial role in rational prescription and use of medicines.

1. NLEM implementation should be strengthened with the introduction of *Standard Treatment Guidelines*. Implementation of Standard Treatment Guidelines in the private sector is a priority to address drug resistance, promote rational prescription and rational use of drugs.
2. While the NLEM should guide the choice of medicines for treatment guidelines, it must be reviewed at least once in two years , with inputs from not only experts, but also from health groups and communities of people living with cancer, HIV, mental health, hepatitis, etc. -
3. The drugs in the list should be finalized keeping in mind treatment guidelines, their safety and therapeutic efficacy and requirement even if price of the drugs are too expensive. Inclusion of a drug in the NLEM makes it easier for the Government to use measures such as -price control, compulsory licensing to reduce prices.

IRRATIONAL DRUGS AND FIXED DOSE COMBINATIONS (FDCs): Irrational FDCs, non-essential vitamins/tonics, cough syrups feature in the top selling pharmaceuticals in terms of value and volume but they harm public health and patients by increasing adverse effects, imposing higher financial burden on patients and facilitating - emergence of drug resistance (in the case of FDCs of antibiotics). Therefore, stricter criteria for registration and - regulatory review of medicines by CDCSO should be a priority. - This helps weed- out substandard, toxic, irrational medicines from the market. It is therefore necessary that:-

1. CDSCO implements a much stricter registration regime for FDCs. Products should be selected and approved only when the combination has a proven advantage in therapeutic effect, safety, adherence or in decreasing the emergence of drug resistance in malaria, tuberculosis and HIV/AIDS.
2. Except FDCs included in the WHO's essential Drug List, all FDCs registered in India are reviewed in terms of their therapeutic effect and legally sustainable action taken for phased out weedingof all irrational FDCs, DTAB should set up a suitable mechanism for the purpose.

IRRATIONAL PRESCRIPTION AND A CORRESPONDING RISE IN DRUG RESISTANCE: - With hardly any new antibiotics, anti-TB, anti-malarial being developed, the control of drug resistance to currently available medicines has become crucial. It is therefore necessary that:-

1. There is a well evidenced and compelling need for public and patient education in the appropriate use of drugs particularly antibiotics/antimicrobials, with potential benefits to the individual patient and public health.

2. Treatment guidelines of the HIV, TB, malaria programme should be formulated for the public and the private sector. These prescription guidelines can then be made applicable not only in government ART and DOTs centres but also to private health facilities and providers.
3. Use of generic names or the international nonproprietary name (INN) should be encouraged at all stages of procurement, distribution, prescribtion and use as it contributes to a sound system of procurement and distribution, drug information and rational use at every level of the health care system. -
4. Pharmaceutical marketing and aggressive promotion also contributes to irrational use. There is a need for a mandatory code for identifying and penalizing unethical promotion on the part of Pharma companies.
5. The Ministry of Health and Family Welfare will set up a Committee to review and suggest measures for the effective implementation of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (DMRA).
6. The Health Ministry in collaboration with MCI should incorporate into the medical, pharmacy and nursing syllabus rational use antibiotic policies, and promotion of generic medicines.
7. A comprehensive law is required to mandate prescription audits, a measure necessary to curb drug resistance.
8. The DCGI and FSSAI will jointly examine the neutraceuticals having multivitamins, minerals etc for prophylactic and therapeutic purpose

AFFORDABILITY (PRICE CONTROL, TRADE MARGINS & IP): Besides linking the National List of Essential Medicines to the Drug Price Control Order, a number of policy and legal measures by the Health Ministry can address the issue of making medicines available and affordable in India. It is necessary that :-

1. All drug pricing related matters should be under one Ministry and not be divided between MOHFW and MOCF. Particularly the Health Ministry should be the nodal Ministry for NPPA.
2. Review of the DPCO to determine which loopholes are used by companies to escape price control.
3. Prescriptions must be made in INN name which could play a crucial role in removing incentives for doctors to prescribe the most expensive brands of generic drugs.
4. Linking the drug regulatory authority (CDCSO) to IP delays generic competition. Patent matters must continue to be firmly delinked from the drug licensing process for clinical research, manufacture and marketing approval.
5. Ministry of Health shall identify and issue compulsory licenses for patented expensive drugs required for public health programmes and take steps to make them affordable.
6. There is a need to ensure that foreign direct investment in existing Indian drug companies is shifted from the automatic route to the FIPB route so that the Government could get a chance to scrutinize such proposals from the public health perspective.

PHARMACOVIGILANCE OF ADVERSE DRUG REACTIONS: The Health Ministry has started a pharmacovigilance programme to allow physicians and patients in India to report toxicities and adverse drug reactions tol assist drug regulators in limiting the use or even phasing out approved drugs with high toxicities. There is therefore a need to :-

1 Ensure that the process of reporting adverse reactions is simple and accessible.
2 To encourage patients and consumer protection groups - to report drug reactions as it has been observed that consumers do a better job in reporting drug reaction than doctors.
3 Develop and maintain a national (computerised) pharmacovigilance database consisting of all suspected adverse drug reactions to medicines observed in India.
4 Mandate that the report of any suspected adverse drug reaction should be filed with the national pharmacovigilance database and not with the manufacturer.
5 Sensitise the overworked physicians to the why and how of pharmacovigilance. -

CDSCO: The implementation and effective enforcement of all the recommendations listed above is dependent on a strong drug regulatory mechanism. Conflict of interest declaration (especially with respect to the medicine/medical device industry, clinical trials) be made mandatory for all individuals, official and non-official, involved in policy making and those who are part of committees related to policies and laws.

CHAPTER – 2

FOOD REGULATION

Report of the Sub- Group on Food Regulation

1. The first meeting of the Working Group on Food and Drugs Regulation, constituted by the Planning Commission was held on 13.06.2011 and it was decided to form two separate sub-groups on Food and Drugs. The items of the TOR of the Working Group relevant for the Sub-Group on Food are:

- To review the food regulatory mechanism in the country to ensure providing quality, safe and wholesome food in the country.
- To review the existing manpower in FSSAI and suggest measures for further strengthening.
- To review the food testing laboratories under the Central Government and suggest measures for further strengthening.
- To review the existing manpower in respect of food regulation in States and suggest measures for further strengthening including financial assistance.
- To review the food testing laboratories in States and suggest measures for further strengthening including financial assistance.
- To suggest modifications in policies and priorities under the food regulatory framework during the Twelfth Five Year Plan.
- To indicate the financial outlay required for the implementation of the initiatives stated above during the Twelfth Five Year Plan.
- To give recommendations on any other matter relating to the topic.

2. The Sub-group on Food, chaired by CEO, FSSAI comprised Ms. Sunita Narain, Director, Centre for Science and Environment, Dr Mira Shiva, Director, Initiative for Health Equity & Society, All India Drug Action Network, Dr. Arun K. Panda, Joint Secretary, MoHFW, Shri Sanjay Prasad, Director, MoHFW and Dr. Dhir Singh, ADG (PFA), FSSAI. The Sub-Group held 3 meetings on 22-06-11, 28-06-11and 21-07-11.

Background

3. The Sub-Group noted that the Food Safety and Standards Act, 2006 came into force from 5.08.2011 and replaced multiple food laws, standard setting bodies and enforcement agencies with one integrated food law. The FSS Rules and Regulations also came into force with effect from 5.8.11. The Acts and Orders that were repealed when the FSS Act came into force are the Prevention of Food Adulteration Act, 1954, the Fruit Products Order, 1955, the Meat Food Products Order, 1973, the Vegetable Oil Products (Control) Order, 1947, the Edible Oils Packaging (Regulation) Order, 1998, the Solvent Extracted Oil, De oiled Meal and Edible Flour (Control) Order, 1967, the Milk and Milk Products Order, 1992. The objective of the FSS Act is to consolidate the laws relating to food and establish the

Food Safety and Standards Authority of India for laying down science based standards for articles of food and regulating manufacture, storage, distribution, sale and import of food articles to ensure availability of safe and wholesome food for human consumption.

4. The challenges that the Act seeks to address include movement from multilevel and multi-department control to a single line of command, with FSSAI being a single reference point for all matters related to food safety throughout the entire food chain, a unified licensing system, encourage self-compliance, provision of graded penalties based on severity of offence together with a mechanism of speedy disposal of cases, focus on food safety, and harmonization between domestic and international food policy issues without compromising on public health and national interest.

5. The Sub-Group further observed that several activities have already been initiated towards implementation of the Act. This includes setting up the Food Authority in September, 2008, the establishment of the Scientific Committee and Panels in May, 2009 and the Central Advisory Committee in October, 2009, integration of staff from different concerned ministries and departments, notification of all sections of the Act, taking over the imported food clearance process at major seaports and airports, organising training programmes, and holding national and regional consultations/ conferences.

Recommendations of the Sub-Group

6. The Sub-group noted that the FSSAI is in the process of setting up its structure to implement its vast mandate. Now in the wake of the FSS Act coming into force, the process needs to be accelerated supported by adequate funds and faster decisions.

7. On the issue of transparency the Sub-group was informed that the FSS Act contains provisions [sections 16 (4) (a) to (d) and section 18 (2) (d)] with regard to the transparency and disclosure/ confidentiality of information which guides the functioning of the FSSAI. Accordingly the Food Safety and Standards Authority of India (Procedure of Scientific Committee and Scientific Panels) Regulations, 2010, stipulates that the minutes of the meetings of the Scientific Committee, Scientific Panels and Working Groups are posted on the FSSAI's website after their adoption. The Regulations also state that the members of the Committee, Panels and Working groups and external experts shall undertake to act independently of any external influence and have to make a Declaration of Commitment and an Annual Declaration of Interest, and for each meeting a Specific Declaration of Interest. The Regulations also provide for uploading of the agenda and minutes of meetings of Scientific Panels and Committee on FSSAI's website. In this context the provisions of Clause 16(6) of the Act were noted by the Sub-Committee:

"The Food Authority shall not disclose or cause to be disclosed to third parties confidential information that it receives for which confidential treatment has been requested and has been acceded, except for information which must be made public if circumstances so require, in order to protect public health."

8. The Act lays down a transparent procedure to be followed for standard setting and the Food Authority has laid down a detailed procedure that will be followed for drawing up/revision of standards. FSSAI is also developing an online transparent licensing system that would integrate in phases the licensing and registration process throughout the country as a part of e-governance initiative. The Sub-group recommended that being in the nascent stage the FSSAI may continue to focus on evolving appropriate organisational culture and practices to ensure transparency in its functioning and decision making. Further the interest of public health and safety should guide the processes of new product approvals and standard setting, including review of current standards. In the context of laboratories to be established/ upgraded in the States, the sub-group observed that the labs could be fully functional only when adequate manpower is provided. Therefore, the Sub-group recommended 100% central funding for these laboratories.

9. The Sub-group recommended that bio-safety should be an integral part of any risk assessment being undertaken by FSSAI.

10. The Sub-group further recommended that a proper surveillance system needs to set up which should be directed to build public information on current and new threats. Food surveys may be carried out regularly and results be made public. An annual report on state of food safety may also be published, and food safety policies that are preventive and promote healthy food may be developed.

11. The Sub-Group was of the view that sufficient focus on food safety issues is lacking in the curriculum of MBBS and an appropriate module on food safety and bio-safety needs to be introduced at the earliest.

12. The Sub-group further recommended that since the actual working of FSSAI will commence in the 12th Plan Period, a mid-term appraisal may be carried out in the 3rd year of the Plan for any course correction that may be required.

13. With regard to housing for the employees of the FSSAI the Sub-Group recommended that FSSAI should take houses on lease for the entitled employees rather than constructing houses as it would be difficult for a small organisation to maintain assets at so many places in the country.

14. The Sub-Group emphasised that with a view to put necessary infrastructure along with manpower at State level which has been a short coming in some of the earlier schemes, it is recommended that minimum required manpower that is essential to make statutory FSS structure including laboratories should be fully funded for the 12th Plan period with the understanding that the expenditure would be borne by the States in next plan. Approximately Rs 2620 crore has been assessed for next five years in this regard. All releases of funds to State Governments should be linked to tight guarantees regarding fulfilling of the States' obligations through an MOU. It was also recommended that the scheme should explore innovative ideas for successful implementation of the projects envisaged under the Scheme.

15. The Sub-Group agreed that for effective implementation of the Act and achieving the goals envisaged, it is imperative that sufficient resources are made available to the Food Authority, both at the Central and State levels. The Sub-group recommends a total outlay of Rs.6548 crore (including Rs. 2246 crore for manpower related grant to States) for FSSAI for the 12th Plan period. This includes manpower

for FSSAI headquarters and Regional Offices, adequate laboratory infrastructure at Central and State levels, putting in place a strong food safety surveillance system along with establishment of E-governance system, establishment of a state of the art risk assessment and food safety research centre, adequate training of personnel and stakeholders and generation of awareness about food safety issues among consumers and other stakeholders. The details are given below.

16. The Sub-Group examined in detail the various components of the Proposed Scheme and recommended the following (further details can be seen in the scheme document appended to this report) :

A. CREATING SYSTEMS AND INFRASTRUCTURE FOR SCIENCE BASED STANDARDS

(i) National Food Science and Risk Assessment Centre(NFSRAC) - Total Outlay Rs.155 crore

It is proposed to set up a dedicated institution under the direct control of FSSAI for regulatory research and risk assessment, as well as to oversee surveillance in the lines of international institutions like the Centre for Disease Control (CDC) and Centre for Food Safety and Applied Nutrition in USA and other countries. The institute is also envisaged to carry out a food safety risk analysis training programmes.

Total fund requirement of Rs.155 crore has been projected for manpower, purchase of advanced equipment, training of staff, surveillance, research and development and recurring and miscellaneous expenses.

Implementation Schedule:

The Centre will become functional within one year of sanction of the project.

Deliverables:

The Centre will be the repository of all food standards and will carry out all risk assessment related work and analyse food surveillance data received from labs and other surveillance organisations.

(ii) Upgradation of Central Food Laboratories (CFL) (NABL /GM testing)-Total Outlay Rs.40 crore

It is proposed to upgrade and develop the existing Central Food Laboratories at Kolkata and Mumbai (being set up) as control laboratories for development of testing methods, standardise practices, exercise technical supervision over nearly 100 referral and basic testing laboratories each. The estimated cost is Rs.10crore for CFL,Kolkata and Rs.30 crore for CFL,Mumbai (a new lab already sanctioned).

(iii) Nationwide Food Safety Surveillance network and data collection on regular basis-Total OutlayRs.50crore.

It is proposed to carry out periodic surveys for surveillance purposes with built in mechanism for emergency warning and linked with rapid action machinery.

This will publish annual state of food safety reports. The cost of sampling and testing and implementation through outsourcing has been assessed at Rs.50 crore for the 12th Plan period.

Implementation Schedule:

Implementation will be through an agency which will be engaged within 6 months of the sanction of the project.

Deliverables:

Generation of data regarding food hazards, possible outbreaks of food borne diseases etc which will help establish public health priorities for prevention, intervention and control.

(iv) Strengthening Of Food Safety And Standards Authority Of India

(Manpower/Administrative and Establishment Expenses at FSSAI Headquarters and Regional/Field Offices (Existing/Proposed)-Total Outlay Rs. 525 crore)

- Existing sanctioned establishment

  The total expenditure towards administrative expenses of FSSAI during the 12th Plan period is estimated at **Rs.175crore (**approximately Rs.35cr per year.). This includes rent, electricity, publicity, procurements, office expenses etc.

- Expansion of scientific wing, imported food testing/screening, additional regional offices, Codex wing etc.

  As regards establishment expenses, apart from the expenditure on the existing establishment (@Rs.10cr per year), FSSAI requires additional posts for its new Regional offices at 7 locations (210 posts), for smooth operation of the imported food clearance process (372 posts), upgradation or strengthening of laboratories (42 posts), international coordination and functioning of the National Codex Contact Point (33 posts), strengthening of the existing sub-regional offices (35 posts) and emergency response centre and media/ public relation cell (13 posts). FSSAI had proposed 531 posts in its original proposal for manpower against which sanction was received only for 355 posts, which includes 31 posts for a new scientific division. Thus in effect, FSSAI has been sanctioned only 324 posts which is even less than the 328 posts transferred to FSSAI from various ministries and departments. There is thus a gap of 176 posts between proposed and sanctioned posts. These posts are essential for the smooth functioning of FSSAI. Thus, additional requirement of manpower is of 881 posts. The financial implication of the establishment is assessed at Rs.350crore for the Plan period.

  Implementation Schedule:

Once approved, the proposal will be processed within 2-3 months for sanction and FSSAI will fill up the posts within 6 months of receipt of the sanction order.

Deliverables:
Establishment of a well organised structure in FSSAI having personnel / manpower with appropriate set of skills and experience to achieve the mandated role of FSSAI**.**

- Office accommodation (construction of new office building, including NFSTI)

Presently, FSSAI headquarters is functioning from the 3rd & 4th Floors of FDA Bhavan which is also the office of the CDSCO. As the organisation is expanding and with the increased manpower component, a new office building is required. It is proposed to have a multi-storey modern complex which will also house the proposed National Food Safety Training Institute. The estimated expenditure is Rs.300crore.

Implementation Schedule:

The design and plan have already been prepared for the site adjacent to the FDA Bhavan from where the FSSAI is presently functioning. The construction work will be awarded within 6 months from the date of approval of the proposal and the building will be ready within approximately 2 ½ years from the date of award of the work. The land is already with the Ministry of Health and Family Welfare.

Deliverables:

Independent premises for FSSAI Headquarters along with establishment of the National Food Safety Training Institute would be completed within the 12th Five Year Plan.

- Housing (to be taken on lease)

Since FSSAI employees will not be eligible for general pool accommodation and also as the Department of Expenditure has agreed to provide leased accommodation only to CP and CEO, it will be difficult to attract experienced and qualified personnel unless residential accommodation is provided by the organisation. It is, therefore, proposed to that provision would be made for leasing at least 200flats in the NCR region and at least 10 flats each (total 100) at the location of Regional offices. The total estimated expenditure is Rs.60crore.

Implementation Schedule:

FSSAI will start leasing accommodation immediately after the proposal sanctioned. However, progress of leasing will be staggered over the next 2 years in keeping with the progress of sanction and filling up of posts.

Deliverables:

The housing satisfaction level that is expected to be reached during the 12th Plan is around 25%.

B. FOOD SAFETY MANAGEMENT SYSTEM

Under the FSS Act, all food testing has to be done in accredited laboratories and prosecutions based on testing in non-accredited laboratories will fail in the courts on this ground alone. Presently almost all the public sector food laboratories are not accredited. FSSAI commissioned a gap analysis study for up-gradation of 50 food laboratories under the Central and State Governments. The study has indicated that there is an urgent need to upgrade the infrastructure, strengthen staffing and training inputs and put in place more reliable laboratory management and operational procedure.

The Sub-group observed that a network of efficient laboratories is the backbone of any credible food safety initiative. Most existing PFA laboratories lack facilities for testing of microbiological parameters, heavy metals and residues. Further, adequate number of food testing laboratories is essential for effective enforcement with greater rate of conviction of violators, citizen empowerment and voluntary testing by food establishments to comply with the law. The hierarchy of laboratories proposed is: Cluster Food Testing Laboratories (1 in 5districts) doing basic tests, Zonal Food Laboratories (1 in 10districts) performing all tests including residues and heavy metals, 10 Referral Laboratories and two control labs under FSSAI. In addition, mobile laboratory facilities are also required in the country to cater to festivals, natural calamities and inaccessible areas. Some of the members of the Sub-Group expressed concern that the State governments may not provide adequate manpower for running the laboratories, as a result of which the equipment provided by the Central Government would lie unutilised and the laboratories may not become functional. Therefore, it was agreed that there should be 100% funding of the laboratories by the centre for the States strictly on the basis of State Guarantees through an MOU.

(i) Cluster laboratories of accredited standards for every 4-5 districts (one time cost for setting up of 125 laboratories for 625 districts and recurring expenditure for Plan period (@ 6.5 crore per lab)

Food testing facilities need to be available closer to the place of collection of samples for successful implementation of the FSS Act. Access to food testing facilities is also essential for the empowerment of citizens who may keep an eye on the quality of food available in the area as also provided in the law. It is, therefore, proposed that there should be at least one primary food testing laboratory for a cluster of 5 districts on the average in the country which will be able to perform the basic physical, chemical and microbiological tests. Cost of establishment and operation of each such laboratory is assessed at Rs.6.5 crore. As 125 such laboratories are proposed to be established, total fund implication during the Twelfth Plan is Rs.812 crore.

(ii) Up-gradation of existing 62 Public Food Labs to accredited standards for comprehensive testing facilities as Zonal Labs- one laboratory for every 10 districts (@ Rs 5 crore / lab)

From the Gap Analysis Study conducted by FSSAI, it was brought out that there is an urgent need to upgrade infrastructure of the existing laboratories in the States. Equipment proposed to be procured are HPLC, GC-MS, LC-MS, AES and microbiology unit. It is proposed to allocate Rs.5crore for up-gradation of each laboratory. To ensure successful operation of the scheme procurement of equipment with operation and maintenance clause for 5 years will be explored.

(iii) Up-gradation of existing 10 Public Labs to accredited Referral Laboratories (@ Rs 10 crore per lab)

It is proposed that 10 of the existing 72 public laboratories may be upgraded to referral laboratories with fund allotment to the respective States @ Rs.10 crore for each laboratory. These laboratories will receive referral or appellate samples from Designated Officers and also have other specialised testing facilities. In this case also, to ensure successful operation of the scheme procurement of equipment with operation and maintenance clause for 5 years will be explored.

(iv) 35 Mobile Food Labs for remote area, large public congregations, disease outbreaks etc (@ Rs. 7.5 crore per lab per State)

It is proposed to allot Rs.7.5 crore to each State for setting up mobile food laboratories during the Five year Period. These will carry out screening and analysis of samples to provide rapid results, provide additional sampling and testing capacity and also reduce time period between sample collection, analysis and reporting. The mobile laboratories will work in close coordination with the local laboratories and samples requiring more extensive testing would be sent to the fixed-site local laboratory. Such mobile laboratories will be highly useful during festivals and large public gatherings, remote areas, natural calamities and other emergencies.

(v) Networking of all food testing labs working under FSS Act

The laboratories under administrative control of FSSAI and States shall in normal functioning and under special circumstances while conducting surveillance shall be undertaking testing/analysis of food samples/food

additives etc. which after analysis may prove to be unsafe /hazardous to health. Networking of all the laboratories would be essential for sharing of information about hazardous food material detected while testing for emergency response/alerts whenever necessary. The networking shall also ensure collation of sampling/analysis data for risk management. As per estimates, it is proposed to have an outlay of Rs 9 crore for networking and maintenance of data bank/software.

C. ENFORCEMENT

(i) Setting up of enforcement structure in States/UTs (Manpower)

It is proposed to provide financial assistance towards cost of manpower to State Governments for establishing new district level food safety offices being created for the first time under the Act. The total estimated cost of manpower is Rs 2246 crore in the 12th Plan period. FSSAI will sign MoUs with States/ UTs to specify their responsibilities for availing the assistance.

Implementation Schedule:

Subject to the signing of MoU, funds will be released to the State Governments.

Deliverables:

Timely issuance of license and registration of FBOs, more sampling and inspections, enhanced conviction rates through proper handling of samples, proper maintenance of records and timely submission of reports for taking further decision, increased awareness amongst stakeholders and better coordination in emergency situations.

(ii) One time assistance for infrastructure/operational equipment/facilities for strengthening District Level Food Safety Office for 626 districts

Availability of critical infrastructure and operational equipment/facilities at field level is essential for smooth functioning and timely action for enforcement of provisions under FSS Act and discharge of duties/responsibilities by the cutting edge level functionaries. It is proposed to provide onetime financial assistance to the State Governments/UTs to meet the cost of infrastructure/operational equipment/ facilities for setting up of new district level food safety offices being created under FSS Act. The total financial implication would be Rs.374 crore. FSSAI will sign MoUs with States/ UTs to specify their responsibilities for availing the assistance.

Implementation Schedule:

Subject to the signing of MoU, this fund will be released to the State Governments.

Deliverables:

Timely issuance of license and registration of FBOs, more sampling and inspections, enhanced conviction rates through proper handling of samples, proper maintenance of records and timely submission of reports for taking further decision, increased awareness amongst stakeholders and better coordination in emergency situations.

D. TRANSPARENCY AND OVERSIGHT

(i) National Food Safety Helpline

It is proposed to establish a National Food Safety Helpline for direct communication with all stakeholders in an interactive manner, centred at FSSAI Headquarters. It will be linked to the emergency response centres in the States. Expected expenditure is about Rs.1 crore per year in the 12th Plan Period.

Implementation Schedule:

A small cell has already been established for the operation of the National Helpline. The Helpline will be fully functional within a period of 6 months from date of approval.

Deliverables:

Establishment of direct and interactive communication channels with all stakeholders in food safety matters.

(ii) Emergency Response and Rapid Alert Centre (@ Rs 1 crore per States/UTs)

It is proposed to have in place an emergency response system in each Food Safety Commissioner's office at an average cost of Rs.1 crore each for responding to food alerts/ threats to public health etc. These response centres are proposed to be finally linked with all district headquarters, panchayats and other local bodies for collection/ dissemination of information through networking under e-governance plan. Total expenditure for 35 States/UTs would be Rs.35crore.

Implementation Schedule:

The State Governments will be establishing the emergency response centres and it is expected they will be operational within 1 year from the date of approval.

Deliverables:

Establishment of direct and interactive communication channels with all stakeholders in food safety matters.

(iii) Whistle Blower Scheme

A draft reward scheme for information on unsafe/adulterated food has been prepared for encouraging general public and employees to furnish information regarding unsafe food and malpractices within or outside the system. Funds are proposed to be allocated to the States/UTs during the 12th Plan on the basis of their population. Actual disbursement will, however, depend upon the response to the scheme.

Implementation Schedule:

The scheme is expected to be approved within 6 months and fund utilization after that would depend on the response of the State Governments.

Deliverables:

Better surveillance of food safety issues due to availability of information regarding adulterated/ unsafe food from all stakeholders.

(iv) E-Governance

Inter-connecting all licensing & registration offices and laboratories and introduction of GPS based sample collection system, online licensing

It is proposed to establish a computerised system to integrate all the food safety systems from district level upwards for an integrated online licensing and registration system, maintenance of a database on food safety issues and provision of GPS based sample collection system for transparency. It will enable a transparent licensing and registration system and aid in food safety surveillance and rapid response to any emergency. Funds are proposed to be given to the offices of the Designated Officers and the State Food Safety Commissioners for hardware and manpower. Total fund requirement is envisaged at Rs.175crore during the 12th Plan period.

Implementation Schedule:

Implementation will be through a competent agency who will carry out the work on all India basis. The agency will be engaged within 6 months of receipt of sanction and the work will be completed within 2-3 years thereafter.

Deliverables:

All District headquarters and laboratories will come under E-Governance and get connected to the National grid to enable all information to be available on one system.

E. CAPACITY BUILDING

(i) National Food Safety Training Institute (NFSTI) (apex institute to do human resource planning for whole country and prepare trainers)

(ii) Training at NFSTI

As a part of the strategy to build a motivated and technically uptodate cadre of food safety personnel in the country, the Regulations have made it compulsory for every officer to undergo refresher courses besides intensive entry level course. This will require a large number of trainers throughout the country. At present, there is no training institute in the country which imparts training on food safety issues. It is proposed to establish a National Food Safety Training Institute at the FSSAI Headquarter which will provide regular training programmes for trainers of food safety personnel and also other stakeholders. Courses would include induction training, upgradation of knowledge, refresher courses and training on specialised subjects. An outlay of Rs.15 crore is proposed during the Twelfth Five Year Plan for conducting training programmes, including payment of honorarium etc. to resource persons. The cost of construction of the centre is included in the projections for the building for FSSAI Headquarter.

Implementation Schedule:
The Institute will start functioning within 6 months of approval.

Deliverables:
Establishment of the first of its kind nodal centre for training on food safety related issues in the country.

(iii) Trainings by States/UTs

Implementation of FSS Act would largely depend on the training of the officials/officers who shall be engaged in regulation and enforcement of FSS Act at State level. State Governments will therefore be required to hold training programmes for food safety personnel at the State and District levels. It is proposed to provide token assistance to the States for conducting such trainings for ensuring capacity building of personnel engaged in enforcement/implementation of the Act for which it is proposed that a provision of Rs.30 crore may be made for the Twelfth Five Year Plan Period. Disbursal would be on the basis of training plans developed by the States/ UTs.

Implementation Schedule:

Disbursal would be on the basis of training plans developed by the States/ UTs.

Deliverables:

Capacity building of personnel /stakeholders on implementation/ food safety related issues at State/district levels.

F. AWARENESS GENERATION/ IEC

The success on the food safety front substantially depends on awareness of all the stakeholders about the food safety issues and rights and obligations under the law. Also, it is imperative that food safety messages percolate down to all levels for which a strong communication campaign is required. Some preliminary work in this direction has already been done through advertisements and TV programmes. At the same time, training, and capacity building of food safety personnel is essential for enforcement of the Rules and Regulations and proper training infrastructure and institutions need to be in place.

(i) Awareness Activities and Educational Programmes by FSSAI

For generating awareness amongst consumers and all other stakeholders, FSSAI proposes a vigorous awareness campaign through media- print & electronic- and non-media – distribution of IEC material - approaches, dedicated programmes like Doordarshan's Kalyani programme, distribution of food testing kits, special events at National and State levels, printing of handbooks on food safety, implementation of a specific Action Plan on food safety, audio- visual shows in villages, schools, municipal areas etc. and general advertisements in public places, journals, national dailies etc. It is proposed that for awareness activities through media Rs.350 crore may be allotted and for non-media Rs.319 crore may be allotted during the Twelfth Plan.

Implementation Schedule:

The work will be executed by engaging a reputed agency for managing media related activities.. The work related to selecting the agency will start shortly so that actual work can begin within 6 months of approval.

Deliverables:

Increased awareness of food safety related issues at all levels.

(ii) Grant to States for IEC Activities (@ Rs 2 crore per State per year)

It is proposed that Rs. 2 crore per State/ UT per year may be provided to the State/ UT for awareness generation campaigns on food safety at the State/ UT level on issues specific to that region in local dialects for deeper penetration of the food safety messages and provisions of the FSS Rules and Regulations right down to the village level.

Implementation Schedule:

Release of grants to the States/UTs will be on the basis of the response received from them to the scheme.

Deliverables:

Better trained food safety personnel at State and District levels and increased awareness about food safety issues right down to the village level.

17. Details of Proposed Financial Outlay

	Component/ Scheme	Fund required in 12th Plan Period (Rs. in crore)	
		FSSAI	**States**
A	**CREATING SYSTEMS AND INFRASTRUCTURE FOR SCIENCE BASED STANDARDS**		
(i)	National Food Science and Risk Assessment Centre • Manpower – Rs. 12.25 crore • Equipment – Rs. 25 crore • R&D – Rs.20 crore • Workshops/Seminar/Training – Rs.15 crore • Infrastructure and recurring expenses – Rs. 82.75 crore	155.00	
(ii)	Up-gradation of Central Food Laboratories (CFL) (NABL /GM testing)- Control Laboratories • CFL, Mumbai (Rs. 30.00 Cr. – new set-up) • CFL, Kolkata (Rs. 10.00 Cr. – up-gradation)	40.00	

(iii)	Nation-wide Food Safety Surveillance network and data collection on regular basis	50.00	
(iv)	Strengthening of Food Safety and Standards Authority of India • Existing sanctioned establishment • Expansion of scientific wing, imported food testing/screening, additional regional offices, Codex wing etc. • Office accommodation (construction of new office building, including NFSTI) • Housing (to be taken on lease)	175.00 350.00 300.00 60.00	
B	FOOD SAFETY MANAGEMENT SYSTEM		
(i)	Cluster laboratories of accredited standards for every 4-5 districts (one time cost for setting up of 125 laboratories for 625 districts and recurring expenditure for Plan period (@ 6.5 crore per lab)		812.00
(ii)	Up-gradation of existing 62 Public Food Labs to accredited standards for comprehensive testing facilities as Zonal Labs- one laboratory for every 10 districts (@ Rs 5 crore / lab)		310.00
(iii)	Up-gradation of existing 10 Public Labs to accredited Referral Laboratories (@ Rs 10 crore per lab)		100.00
(iv)	35 Mobile Food Labs for remote area, large public congregations, disease outbreaks etc (@ Rs. 7.5 crore per lab per State)		263.00
(v)	Networking of all food testing labs working under FSS Act	9.00	
C	ENFORCEMENT		
(i)	Setting up of enforcement structure in States/UTs (Manpower)		2246.00
(ii)	One time assistance for infrastructure/operational equipment/facilities for establishing new District Level Food Safety Office for 626 districts		374.00
D	TRANSPARENCY AND OVERSIGHT		
(i)	Whistle Blower Scheme	25.00	
(ii)	National Food Safety Helpline	5.00	
(iii)	Emergency Response and Rapid Alert Centre (State level control room) (@ Rs 1 crore per States/UTs)		35.00

(iv)	E-Governance Inter-connecting all licensing & registration offices and laboratories, introduction of GPS based sample collection system, online licensing		175.00
E	CAPACITY BUILDING		
(i)	National Food Safety Training Institute (NFSTI) (apex institute to do human resource planning for whole country and prepare trainers)	7.00	
(ii)	Training at NFSTI	8.00	
(iii)	Trainings by States/UTs		30.00
F.	AWARENESS GENERATION/ IEC		
(i)	Awareness Activities and Educational Programmes by FSSAI Media: Rs. 350 Crore Non-media (production of educational material, targeted activities for women, youth, children, food manufacturers, processors, handlers, exhibitions etc): Rs 319 Crore	669.00	
(ii)	Grant to States for IEC Activities (State specific Schemes with emphasis on local language) (@ Rs 2 crore per State per year)		350.00
	Total	1853	4695
	Grand Total (FSSAI + States)	6548	

Summary of Financial Outlay

	Component/ Scheme	Fund required in 12th Plan Period (Rs. in crore)	
		FSSAI	**States**
A	**CREATING SYSTEMS AND INFRASTRUCTURE FOR SCIENCE BASED STANDARDS**		
		1130.00	
B	**FOOD SAFETY MANAGEMENT SYSTEM**		

		9.00	**1485.00**
C	**ENFORCEMENT**		
			2620.00
D	**TRANSPARENCY AND OVERSIGHT**		
		30.00	**210.00**
E	**CAPACITY BUILDING**		
		15.00	**30.00**
F.	**AWARENESS GENERATION/ IEC**		
		669.00	**350.00**
	Sub-total	**1853.00**	**4695.00**
	Grand Total (FSSAI + States)	**6548.00**	