

**SEVENTH REPORT**

**STANDING COMMITTEE ON  
CHEMICALS & FERTILIZERS  
(2005-06)**

**(FOURTEENTH LOK SABHA)**

**MINISTRY OF CHEMICALS & FERTILIZERS  
(DEPARTMENT OF CHEMICALS & PETROCHEMICALS)**

**AVAILABILITY AND PRICE MANAGEMENT OF  
DRUGS AND PHARMACEUTICALS**

*Presented to Hon'ble Speaker 28.09.2005*

*Presented to Lok Sabha on 25.11.2005.*

*Laid in Rajya Sabha on 24.11.2005*



**LOK SABHA SECRETARIAT  
NEW DELHI**

*September, 2005/Asvina, 1927 (Saka)*

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**COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS**  
**(2005-06)**

**Shri Anant Gangaram Geete - Chairman**

***Members  
Lok Sabha***

- 2 Shri Afzal Ansari
- 3 Shri Prahlad Joshi
- 4 Sardar Sukhdev Singh Libra
- 5 Shri Tek Lal Mahato
- 6 Shri Punnu Lal Mohale
- 7 Shri A.K. Moorthy
- 8 Shri P. Rajendran
- 9 Shri Anantha Venkata Rami Reddy
- 10 Shri Madhusudan Takkala Reddy
- 11 Shri Akshyay Pratap Singh
- 12 Shri Narsingrao H. Suryawanshi
- 13 Shri V.K. Thummar
- 14 Shri Bhanu Pratap Singh Verma
- 15 Shri Mansukhbhai Dhanjibhai Vasava
- 16 Shri A.K.S.Vijayan
- 17 Shri Bhal Chandra Yadav
- 18 Vacant
- 19 Vacant
- 20 Vacant
- 21 Vacant

***Rajya Sabha***

22. Shri Gireesh Kumar Sanghi
- 23 Shri Raju Parmar
24. Shri B.S.Gnanadesikan
25. Shri Ajay Maroo
26. Dr. Chhatrapal Singh Lodha
27. Shri Vasant Chavan
28. Shri R. Shunmugasundaram
29. Shri Raj Mohinder Singh Majitha
30. Shri T.R. Zeliang
31. Vacant

***Secretariat***

1. Shri John Joseph - *Secretary*
2. Shri P. Sreedharan - *Joint Secretary*
3. Shri Brahm Dutt - *Director*
4. Shri S.C. Kaliraman - *Under Secretary*
5. Shri Santosh Kumar - *Committee Officer*

## **INTRODUCTION**

I, the Chairman, Standing Committee on Chemicals & Fertilizers (2005-06) having been authorised by the Committee to submit the Report on their behalf present this Seventh Report on 'Availability and Price Management of Drugs and Pharmaceuticals'.

2. The subject was selected for examination by the Standing Committee on Chemicals & Fertilizers (2004-05). The Committee considered the information sought from the Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals), the Ministry of Health & Family Welfare, Ministry of Science & Technology and Ministry of Commerce & Industry on the subject. The Committee took evidence of the representatives of the Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) at their sittings held on 14<sup>th</sup> September, 2004, 23<sup>rd</sup> November, 2004 and 20<sup>th</sup> July, 2005. At the sitting of the Committee held on 20<sup>th</sup> July, 2005 representatives of the Ministry of Health & Family Welfare, Ministry of Science & Technology and Ministry of Commerce & Industry also accompanied the representatives of the Department of Chemicals & Petrochemicals.

3. The Committee also heard the views of the representatives of All India Organisation of Chemicals & Druggists (AIOCD) and Low Cost Standard Therapeutics (LOCOST) at their sitting held on 10<sup>th</sup> June, 2005 and representatives of All India Drug Action Network (AIDAN), Indian Drug Manufacturers Association (IDMA) and Consumer Unity & Trust Society (CUTS) at their sitting held on 1<sup>st</sup> July, 2005.

4. The Committee considered and adopted this Report at their sitting held on 27<sup>th</sup> September, 2005.

5. The Committee wish to express their thanks to the representatives of the Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals), Ministry of Health & Family Welfare, Ministry of Science & Technology, Ministry of Commerce & Industry and Non-Government Organisations for placing their views before them and furnishing the information desired in connection with the examination of the subject.

6. The Committee place on record their deep appreciation for the work done by the Standing Committee on Chemicals & Fertilizers (2004-05) on the subject.

7. The Committee also place on record their appreciation for the invaluable assistance rendered to them by the Officials of the Lok Sabha Secretariat attached to the Committee.

**New Delhi;**  
**September 27, 2005**  
**Asvina 5, 1927 (Saka)**

**ANANT GANGARAM GEETE**  
*Chairman,*  
**Standing Committee on**  
**Chemicals & Fertilizers.**

# **REPORT**

## **PART – I**

### **CHAPTER – I**

#### **BACKGROUND ANALYSIS**

##### **INTRODUCTORY**

With the growth in population, the need for making drugs and pharmaceuticals available at affordable prices to the masses, has become a challenge before the nation, more particularly when about 26.03 crore of the population is living below poverty line. The prevalent healthcare system in the country caters only to the need of about 20 per cent of the population and the remaining 80 per cent depend on the extremely expensive and unaffordable private sector.

1.2 During the last two decades, the Indian pharmaceutical industry has grown considerably and presently it manufactures drugs and other products valued at about Rs. 35,000 crore annually. Apart from meeting indigenous requirements, the export of drugs and pharmaceuticals were Rs. 16,681 crore as against import of Rs. 2,956 crore during the year 2004-05. India accounts for 8% of world's production by volume (4<sup>th</sup> rank) and 1.5% by value (13<sup>th</sup> rank). The industry has 300 large and medium companies and also about 6000 small scale units. However, the availability of quality products at affordable prices to the poor masses is still an objective of the Government which is yet to be achieved fully. The Department of Chemicals & Petrochemicals (C&PC) under the Ministry of Chemicals & Fertilizers is responsible for planning, development and control of the Pharmaceutical industry alongwith ensuring availability and pricing of drugs and formulations. Apart from the Department of Chemicals & Petrochemicals, the Ministry of Health & Family Welfare has responsibility of approval of new drugs,

import permission, quality control and clinical trials under the Drugs & Cosmetics Act, 1940. Besides, State Drug Controllers have responsibility for licensing, inspection and enforcement under the Drugs & Cosmetics Act, 1940.

1.3 To regulate the drugs and pharmaceuticals industry, the Government have announced and updated the 'National Drug Policy' from time to time, the main mile-stones being as under :-

- (i) On the basis of recommendations of Hathi Committee Report (1975), the Government formulated Comprehensive Drug Policy in 1978.
- (ii) Drug Policy, 1986.
- (iii) Modified Drug Policy, 1994.
- (iv) A new Pharma Policy was formulated by the Government in 2002. However, due to the stay order passed by the Karnataka High Court, it could not be implemented. The Department of C&PC has filed a SLP before the Hon'ble Supreme Court against this order.

1.4 The Committee are informed by the Department of Chemicals & Petrochemicals that a Task Force under the Chairmanship of the Principal Advisor, Planning Commission has been constituted *inter-alia* to examine the following aspects:-

- (i) To explore various options other than price control for achieving the objective of making available life-saving drugs at reasonable prices and alternately for imposing the price control, if need be.
- (ii) To examine the issue of monitoring of prices and bulk/pooled procurement issues of medicines.
- (iii) To deliberate on the concept of negotiated prices of patented drugs.
- (iv) To explore the issue of debranding of drugs on selective basis.
- (v) Promotion of low cost generic drugs in the country.
- (vi) Exemption/reduction in taxes on life saving/essential drugs.

- (vii) Issue of bringing the medicines included in the National List of Essential Medicines, 2003, under price control.
- (viii) Strengthening of the regulatory mechanism both at the Centre and in the States.
- (ix) Establishment of a Central Drug Authority.

After examining the recommendations of the Task Force, a new Pharmaceutical Policy will be formulated.

1.5 The Committee (erstwhile Standing Committee on Petroleum & Chemicals) had earlier examined the Drug Policy related issues and made their recommendations in their 2<sup>nd</sup> Report (10<sup>th</sup> Lok Sabha- 1993) and 15<sup>th</sup> Report (13<sup>th</sup> Lok Sabha-2001). The Committee's examination of the subject 'Availability and Price Management of Drugs and Pharmaceuticals', as detailed in succeeding Chapters, is aimed to further emphasise the need and importance of making quality medicines available to the masses at affordable prices. The Committee's examination mainly covers;

- (i) Implementation of Drugs (Prices Control) Order, 1995 - Pricing of Scheduled Drugs.
- (ii) Pricing of non-Scheduled drugs.
- (iii) Role and responsibility of NPPA.
- (iv) Availability of drugs/medicines.
- (v) Drugs for public health.
- (vi) Spurious drugs.
- (vii) Revival of sick PSUs.
- (viii) Indian system of medicines.
- (ix) Setting up of National Drug Authority.
- (x) Research & Development in the Pharma Sector.

## **CHAPTER – II**

### **PRICING AND AVAILABILITY OF DRUGS**

#### **(A) Implementation of Drugs (Prices Control) Order, 1995- Pricing of Scheduled Drugs**

2.1 During the course of examination the Committee were informed that although the Government had some kind of control immediately after the 1962 war with China, price-control of drugs through the Drugs (Prices Control) Order, (DPCO) under the Essential Commodities Act 1955 came in 1970. Thereafter in 1970 the Government had price control over all drugs. The Hathi Committee appointed by the Government of India and its report submitted in April, 1975 also recommended price control and production control. Thereafter, gradual reduction in span of price control in line with economic policies of the country started in the drug industry also. Accordingly, the successive policies of drugs control since 1978 have resulted in decontrol of more and more drugs. In DPCO, 1979, 347 drugs were under price control which were reduced to 142 in DPCO, 1987. DPCO, 1995 initially kept control on 76 drugs which were further reduced to 74.

2.2. The DPCO, 1995 was promulgated by the Government on the 6<sup>th</sup> January, 1995 under section 3 of the Essential Commodities Act, 1955. The 74 bulk drugs specified in the First Schedule (**Annexure**) of DPCO, 95 as on date and the formulations based thereon are under price control and their prices are fixed/revised by the Government/National Pharmaceutical Pricing Authority (NPPA) in accordance with the provisions of DPCO, 95. These drugs have been identified for inclusion under price control in the DPCO, 95, on the basis of the criteria mentioned in the 'Modifications in Drug Policy, 1986,' announced in September, 1994, as under:-

- (i) The criterion of including drugs under price control will be the minimum annual turnover of Rs. 400 lakhs.
- (ii) Drugs of popular use, in which there is a monopoly situation will be kept under price control. For this purpose, if for any bulk drug, having an annual turnover of Rs. 100 lakhs or more there is a single formulator having 90 per cent or more market share in the Retail Trade (as per ORG) a monopoly situation would be considered as existing.



- (iii) Drugs in which there is sufficient market competition viz. at least 5 bulk drug producers and at least 10 formulators and none having more than the 40 per cent market share in the Retail Trade (as per ORG) may be kept outside the price control. However, a strict watch would be kept on the movement of prices as it is expected that their prices would be kept in check by the forces of market competition. The Government may determine the ceiling levels beyond which increase in prices would not be permissible.
- (iv) Government will keep a close watch on the prices of medicines which are taken out of price control. In case, the prices of these medicines rise unreasonably, the Government would take appropriate measures, including re-clamping of price control.
- (v) For applying the above criteria, to start with, the basis would be the data upto 31<sup>st</sup> March, 1990 collected for the exercise of the Review of the Drug Policy. The updating of the data will be done by the National Pharmaceutical Pricing Authority.
- (vi) Genetically engineered drugs produced by recombinant DNA technology and specific cell/tissue targeted drug formulations will not be under price control for 5 years from the date of manufacture in India.

2.3 On being enquired by the Committee about the working of the Drugs (Prices Control) Order 1995, the Department, in a note submitted that the Order has been issued under section 3 of the Essential Commodities Act, 1955. Under the DPCO 1995, the Central Government is empowered to fix/revise the prices of Scheduled bulk drugs and formulations based on them. The Government have constituted National Pharmaceutical Pricing Authority (NPPA) and delegated these powers to it. NPPA fixes/revises the prices of the Scheduled bulk drugs and Scheduled formulations and it also monitors the prices of non-Scheduled formulations in accordance with the provisions of DPCO 1995. The State Drugs Controllers help NPPA in monitoring the prices and enforcing the provisions of DPCO. The State Governments are also authorized to take action under the Essential Commodities Act for violation of the provisions of the DPCO 1995. However, it is generally observed that the stringent action of prosecution under the Essential Commodities Act sometimes does not lead to desired results. Since there are no provisions for compounding of offences and no provisions of fine or penalties for the violation of the DPCO in accordance with the Essential Commodities Act and the only provisions available are for prosecution and recovery of the overcharged amount, the State Governments find the process cumbersome for initiating any action. The Ministry have informed that the prices of drugs are therefore not being monitored very effectively at the State level.

2.4 When the Committee asked whether at times NPPA is late in revision of prices of formulations in case of price reduction of bulk drug/controlled formulation and the drug company is benefited due to delay, the Department in their post evidence reply submitted as under:-

“The fixation /revision of prices of bulk drugs is a continuing process and is done based on comprehensive Cost Price Study. Prices are fixed/revised under para 3 of DPCO, 1995. In case of non-submission of relevant data by manufacturers of Scheduled bulk drug, the prices are fixed under para 11 of the DPCO, 1995 based on available data. In case of reduction in the peak rate of customs duty, the prices of Scheduled bulk drugs and derivatives are reduced on suo-motu basis. Similarly the formulation prices are fixed/ revised as and when there is a reduction in the notified price of a Scheduled bulk drug. The DPCO, 1995 has a provision that manufacturer /formulators would apply for price fixation/revision as and when there is a change in the price of a bulk drug within a period of 30 days. However, in the case of downward revision in the bulk drug price seldom a formulator applies for price revision, hence NPPA has to revise prices in such cases on suo-moto basis under para 11 of DPCO, 1995.

Keeping in view the large number of Scheduled formulations, non-cooperation of the drug manufacturers and limited staff available with NPPA and the other procedural requirements, it does take some time in fixing/revising the drug prices, although all efforts are made by NPPA in this regard.”

2.5 Asked about the action taken to solve the problems being faced in implementation of DPCO at State Level and whether there should be special cells of DPCO in each State, the Department in their written reply stated as under:-

“The Government constituted a Committee, on 19<sup>th</sup> August, 2004, under the Chairmanship of Joint Secretary (PI) to examine the span of price control (including trade margin) in the light of National Common Minimum Programme. This Committee has submitted its interim report to the Government. The Committee has recommended, inter-alia, establishment of DPCO cells in all States on the model of Karnataka for greater/frequent interaction/reporting between the NPPA and the State Drug Controllers. The DPCO Cell in Karnataka was created in 1998. This Cell is dedicated to the work related to DPCO”.

**(B) Pricing of Non-Scheduled Drugs**

2.6 The Department of Chemicals & Petrochemicals have informed that the prices of non-Scheduled drugs and formulations are fixed by the manufacturers themselves keeping in view the various factors like cost of production, marketing/selling expenses, R&D expenses, trade commission, market competition, product innovation, product quality etc. The Government takes corrective measures when the public interest is found to be adversely affected.

2.7 The Committee have also been informed that in respect of non-Scheduled formulations where the price increase was found very high by the NPPA, manufacturers concerned were impressed upon by the latter to reduce prices of those formulations. When the Committee asked about the monitoring of prices of non-Scheduled drugs and formulations, the Department in a note, have submitted as under:-

“As part of its price monitoring activity, NPPA has been monitoring the prices of non-Scheduled formulations for quite a long time based on market data available in monthly Retail Store Audit Reports of ORG-IMS. There are certain internal guidelines (approved by NPPA/Authority) set for monitoring the prices of non-Scheduled formulations. These guidelines are uniformly followed by the NPPA for the whole pharma industry. The guidelines are suitably modified from time to time based on experience. The guidelines which are being presently followed are as under:-

- (i) The monitoring of prices of non-Scheduled formulations is currently on the basis of data from ORG-IMS.
- (ii) Companies are short listed where there is an increase in price of a non-Scheduled formulation by more than 20% in one year and the annual turnover of the formulation pack exceeds Rs. 1 crore. Further, the share of the formulator in that segment of the formulation is required to be at least 20% of the market or the medicine is one of the first 3 top medicines of that group. The criteria, namely, high turnover and 20% price increase are designed to identify cases of mass consumption and to meet the requirement of ‘public interest’ referred to in para 10 (b) of the DPCO, 1995.
- (iii) The NPPA then initiates action and letters are sent to the manufacturers of such formulations to furnish reasons for

such price increases and also, wherever required, invites them to the NPPA for personal hearing and representation before the Member Secretary/Chairman.

- (iv) The matter is then examined and submitted to the full meeting of the Authority.”

2.8 On being enquired by the Committee as to whether any problem was being faced in fixation/revision of prices of drugs under price control regime, the Department replied that it has been observed that wherever there is price reduction in case of bulk drugs, no application for price fixation/revision of its formulations is submitted as required under the provisions of DPCO'95. NPPA after waiting for 30 days initiates suo-moto price revision. With regard to Bulk Drugs pricing, companies are reluctant to allow the officers of the NPPA to visit and inspect their manufacturing facilities. In the area of monitoring, there is no cooperation in sharing of company data with NPPA required from time to time.

2.9 In this connection when the Committee asked when a drug is brought under price control the company makes a slightly different formulation for different presentation and enquired as to what should be the mechanism to overcome such a situation, the Department in their post evidence reply furnished as under:

“In some cases, it has been noticed that whenever Government/NPPA fixes/revises ceiling or non-ceiling price of medicines/formulations some drug companies change the composition of the medicines/formulations and obtain new license from respective State Drug Controller/Licensing Authority. The State Drug Control/Licensing Authority should not allow change in composition without any valid ground and without consulting DCG (I) & NPPA.”

2.10 On being pointed out by the Committee that sometimes price control increases production of decontrolled, non-essential drugs and decreases production of single ingredient essential drugs, the Department in their written reply stated as under :-

“ A Committee on Drugs and Pharmaceuticals Industry under the Chairmanship of Shri Jaisukhlal Hathi was constituted on 8-12-1974 to examine various facts of the Drug Industry in India with a view to promote growth of the Drug Industry. The Committee submitted its report in April 1975 and recommended, inter-alia, abolition of brand names in a phased

manner and procurement of single ingredient drugs and drugs included in Indian Pharmacopoeia for Central and State Government Institutions and local bodies under generic names. “

**(C) Role and Responsibilities of National Pharmaceutical Pricing Authority (NPPA)**

2.11 The NPPA has been constituted as an attached office of the Department of Chemicals & Petrochemicals. The NPPA is an independent body of experts entrusted, inter-alia, with the task of fixation-revision of prices of drugs and pharmaceuticals and other related matters such as updating the list of drugs under price control by inclusion and exclusion on the basis of established criteria/guidelines and also to monitor the prices of decontrolled drugs and formulations.

2.12 The functions of the National Pharmaceutical Pricing Authority are:-

- (i) To implement and enforce the provisions of the Drugs (Prices Control) Order, 1995 in accordance with the powers delegated to it.
- (ii) To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.
- (iii) To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
- (iv) To collect/maintain data on production, exports and imports, market share of individual bulk drugs and formulations.
- (v) To deal with all legal matters arising out of the decisions of the Authority.
- (vi) To render advice to the Central Government of changes/revisions in the drug policy.
- (vii) To render assistance to the Central Government in parliamentary matters relating to drug pricing.

2.13 The Department of Chemicals & Petrochemicals informed that the prices of the bulk drugs are fixed/revised by the NPPA as per the provisions of para 3 of the Drugs (Prices Control) Order 95. Since inception, NPPA has fixed/revised prices of 184 bulk drugs (including derivations) and 2658

formulations. Further para 11 of the DPCO 95 stipulates that where any manufacturer or importer of bulk drug or formulation fails to submit the application for price fixation/revision, as the case may be, or to furnish information as required under this Order, within the time specified therein, the Government may, on the basis of such information as may be available with it, by order fix a price in respect of such bulk drug or formulation, as the case may be. In case the required information/data is not furnished by the Manufacturers, NPPA fixes the prices of the bulk drugs under para 11 of DPCO'95 based on available information. Since inception of NPPA in 1997, in about 34 cases of bulk drugs and 1988 cases of formulations, prices have been fixed invoking para 11 of DPCO 95.

2.14 Further when the Committee asked whether some companies are charging prices of drugs more than notified by NPPA, the Department in their post evidence reply stated that whenever it comes to notice of NPPA, that drug companies are charging prices higher than the notified prices of NPPA, necessary action under para 13 of DPCO' 95, to recover the overcharged amount is taken. From inception of NPPA till June 2005, an amount of around Rs 89 crores has been recovered as overcharged amount.

2.15 On being enquired further whether NPPA was facing any difficulty in implementation of the Drugs (Prices Control) Order along with suggestions for improvement, the Department in a written reply, stated the following difficulties in implementation of the Drugs (Prices Control) Order:-

- “(i) Non-submission of regular returns like price lists in Form V, yearly information on turnover in Form VI etc. by manufacturers/importers.
- (ii) Non-submission of Form III/Form IV for revision of prices wherever there is reduction in price of drugs.
- (iii) Non-cooperation of the Industry to provide information for cost cum technical studies in case of bulk drugs.
- (iv) The high incidence of litigation when companies are asked to pay overcharged amounts, which are often in crores.

As soon as demand notice for recovery of overcharged amount is issued, the affected companies/firms immediately approach the Court and obtain interim stay order against the recovery of the overcharged amount. In certain cases, the companies do not respond to the demand notice, in spite of repeated reminders.

Non-submission of requisite information/data is a major problem under DPCO, 1995. It would be appropriate to consider incorporation of some penalties for minor offences such as non-submission of data, price list etc. to ensure better implementation of various provisions of DPCO, 1995. These penalties may be expressly mentioned in DPCO, 1995 to ensure the proper implementation of various provisions of DPCO, 1995.

In certain cases, it is observed that pharma companies choose to change the composition of the formulation manufactured by them to avoid the implementation of the ceiling prices fixed by NPPA for the particular formulation. The above practice can be effectively checked, in case, a penalty such as cancellation of drug licence is considered. For this purpose, DPCO, 1995 should have some power as provided in Drugs and Cosmetics Act, 1940.”

2.16 Asked about the suggestions to strengthen the NPPA, the Department stated as under:-

- (i) NPPA monitors prices of formulations based on ORG/IMS data which cover about 30000 formulations packs manufactured and marketed by about 300 Companies. During the course of monitoring, problem of authenticity and inadequacy of data and also lack of computerization has been noticed. NPPA does not have adequate infrastructure/machinery/staff (technical/professional) for dealing with such big industry. There are only 18 officers in the NPPA based in Delhi.
- (ii) To improve the system of monitoring, it is proposed to develop a suitable computer software programme for NPPA, so that more accurate and effective monitoring of Scheduled and non-Scheduled drugs could be carried out. Also, the present system of price monitoring is being reviewed by the Task Force and based on its recommendations, further steps would be taken in this regard. In addition, the following hurdles are being faced in way of working of NPPA:-
  - (a) DPCO' 95 has been issued under the powers conferred by the Essential Commodities Act' 1955. The action for penal provisions as per para 24 of DPCO' 95 are also as per the Essential Commodities Act'1955. In the absence of specific provision in DPCO'95 regarding

- penalties, prosecution etc., implementation of various provisions of DPCO'95 are affected.
- (b) Drug companies fail to furnish information as prescribed under DPCO'95, but no specific provision for punitive actions are there in DPCO'95 to take action against errant companies/units.
  - (c) There is no provision in DPCO'95 itself to impose fine/compound the offence of errant unit.

2.17 When the Committee asked about the proposal to set up Cell of NPPA in each State for effective monitoring of prices of drugs and pharmaceuticals, the Department in their written reply stated that an exercise to strengthen the NPPA has been started and a scheme for computerization of the NPPA has been approved. The Task Force constituted under the Chairmanship of the Principal Adviser (PP), Planning Commission is also considering the issue of intensive monitoring of prices of drugs by the NPPA. There is a proposal to establish DPCO cells in all States on the model of Karnataka, which will report to NPPA.

**(D) Availability of Drugs at affordable prices and use of generic drugs.**

2.18 Making a presentation about availability of essential drugs under price control and necessity of bringing more drugs under it, the representative of Low Cost Standard Therapeutics (LOCOST) submitted before the Committee as under :-

“ We have pointed out that major fallacies that the drugs which should have been included were not included in the list. The most striking example is anemia preparation. Iron deficiency anemia affects 74 per cent of our children and more than half of our women. There is not a single drug for anemia under price control. Even a drug like ORS for diarrhea, which is killing millions of children, is not under price control. All vaccines for any infectious disease were put outside price control. My colleague said about HIV disease, coronary heart disease and cancer. These diseases are totally excluded. There is not a single drug for these diseases. On the other hand, many of the important diseases like TB, malaria, leprosy, hypertension, psychiatric disorders, really one or two drugs are under price control. So, by adopting economic criteria rather than public health and need based criteria, we got a very funny list. Not only that, the drugs which should not have been included got included in this list. There were certain outdated drugs which no Doctor uses, and hazardous drugs like Analgin in the price control list. Essential drugs like Vitamin E do not figure. So, what



we are saying is now that the Government has prepared a list of essential medicines in 1996 and 2003 and when it is deciding which drugs to be put under price control, this should be a reference list .....

2.19 On being enquired by the Committee as to whether the Government have prepared a list of essential medicines and the number of drugs included therein are under price control, the Department of Chemicals and Petro-Chemicals in a post evidence reply submitted as under:-

“The Ministry of Health and Family Welfare issued a National List of Essential Medicines in July, 2003. The List contains 354 drugs out of which about 50 drugs are under price control.”

2.20 When the Committee desired to know as to whether these drugs listed in National List of Essential Medicines can be brought under price control, the Department in a post evidence written note stated as follows:-

“A Task Force under the Chairmanship of Principal Adviser, Planning Commission has been constituted by the Government to suggest options other than price control in case of essential/life saving medicines. A decision in this issue would be taken after receipt of the report of the Task Force.”

2.21 When the Committee asked about the policy of monitoring of drug prices in developed countries particularly where more inventions are being made, the Department, in their written reply, stated that some kind of monitoring strategies like price negotiations, bulk purchase under National Health Schemes, Health Insurance Schemes are there in developed countries like Canada, France, UK, Japan, Germany, etc. Such countries have their own monitoring/controlling bodies as per their requirements. For example, Canada's Patented Medicines Prices Review Board through negotiations sets a maximum allowable price that Pharmaceutical Manufacturers may charge for patented medicines and any attempt to impose higher prices can result in significant fine for the manufacturer. In U.K. local healthcare services are provided to the citizens under the National Health Service.

2.22 In this regard, during the oral evidence, the representative of the Department of Chemicals and Petro-Chemicals submitted before the Committee as under:-

“Also, to take care of any future situation, we are contemplating that there should be a price negotiation mechanism for the new patented drugs as is being followed in some countries like Canada where even before approving their marketing they negotiate the price. A similar system is contemplated here.”

2.23 As per the provisions of the modified Drug Policy, 1986, drugs in which there is sufficient market competition viz. at least 5 bulk drug producers and at least 10 formulators and none having more than the 40 per cent market share in the Retail Trade (as per ORG) may be kept outside the price control. The representative of LOCOST stated that there is no free market operating in the area of medicines in pharmaceutical industry and in health and hospital service sectors. The buyer/end user namely, the patient has no choice as the Doctor makes the choice and for patient sometime it is a question of life or death. Further, for most of the products, around 30-40 per cent of market share is cornered by the leading 3-4 products. The top selling brand of a particular category often is also the higher priced or highest priced one. The brand leader in most of the cases is also the price leader

2.24 On being pointed out by the Committee that the brand leader being the price leader in most cases, there may not be real competition in the market, the Department of C&PC in a post evidence reply stated that generally the brand leader is also the price leader in case of non-Scheduled drugs.

2.25 While suggesting the ways to come out of this problem, the representative of All India Drug Action Network (AIDAN) stated during their submission before the Committee that pressure of sales representatives on Doctors is tremendous to prescribe their branded drugs. However, if they

prescribe the generic names, the alternative cheaper medicines can be taken which are equally effective.

2.26 Some of the NGO's working in drugs and pharmaceutical sector/ public health submitted before the committee that there is huge variation between the prices of various branded medicines. A few examples being as under :-

S.No.	Medicine	Price Range
1	Amlodipine 5 mg.	From Rs. 0.50 to Rs. 4.81
2.	Inj Ceftriaxone	From Rs. 50 to Rs. 213
3.	Ciprofloxacin	From Rs. 26.81 to Rs. 85.34

2.27 Branded drugs are drugs which are promoted by using a proprietary name given by the company producing it, in addition to the chemical name of the compound, for example Paracetamol in Indian market is marketed as Calpol, Metacin, Crocin, Paracip, etc. In the developed countries only companies which have discovered the particular molecule can give it a brand name. The others can sell the molecule (after the patent expires) only under its chemical name. Because the branded drug promoted by the company carries the cost of drug development, the innovator brand is the costliest.

2.28 A representative of one NGO stated that in India, however, any company, which is involved in manufacturing/marketing of drugs can give the drugs its own brand name. With the thousands of companies in the Indian market, there are hundred and thousands of brands of individual drugs which sometimes create confusion. The representative informed that recently, the press highlighted about LONA drug which is the brand name for both clonazepam and a low sodium salt preparation. In India, there has been virtually no new drug development but there have been numerous successful attempts for manufacture of new molecules

developed in the West through other processes. Branded drugs are costlier in India because of the higher profit margins for the companies and because of the high cost of drug promotion.

2.29 Generic Drugs are drugs which are marketed only under their chemical name i.e. Paracetamol marketed only as Paracetamol I.P. There is otherwise no difference in composition, effect and quality standards requirement in generics compared to branded drugs. In other countries the companies other than the innovator company have to market their drug as a generic preparation. The annual exports of thousands of crores by Indian companies to both developed and developing countries is mainly in the form of low-cost generics. The same companies which export low-cost generic drugs abroad promote aggressively the same drugs as highly priced branded drugs in the domestic market. Very few companies manufacture and market their drugs in generic form. This phenomenon has prevented the Indian patients or consumers from benefiting from access to low cost medicines.

2.30 When the Committee asked about promotion of generic drugs by All India Organisation of Chemists and Druggists (AIOCD), their representative during the evidence stated that, if any prescription came to his shop, he was not supposed to substitute the medicine, if he did so, he could be prosecuted under the Drugs and Cosmetics Act. When the Doctor writes a particular medicine like Ciploflexin, Cipla, then he has to give only Cipla. If he does not write specifically, then the chemist has the right to substitute. The chemists have a big chart for this wherein they can give different prices for them. But if they substitute, they would be prosecuted. This is also a hurdle.

2.31 The Committee informed by the representative of LOCOST that in India, there is a unique anomaly created by the Indian Drug Industry known as branded generics. These are generics as far as the trade is concerned, but branded as far as the patient is concerned. To the pharmaceuticals trade and institution they are sold at low prices in high volumes as generics, but to the customers they are made to appear as branded drugs and sold at prices which approximate or even exceed the prices of branded drugs. Branded generics

occupy the space in Indian drugs market that should have been occupied by true generic drugs. The drug industry markets and promotes them only to the pharmaceutical trade and institutions as generics and profits by making high volume sales. In order to give the trade huge margins at the cost of consumer, which otherwise be difficult to justify, the company appends a brand name to the drug, making it appear like any other branded preparation in the market. The Committee were apprised of few examples where trade margin ranged from 203 per cent to 714 per cent.

2.32 When the Committee pointed out that there was huge trade margin on essential drugs, the representative of the Department of Chemicals & Petrochemicals while admitting this during oral evidence stated that the branded products might give a margin of 20 to 30 percent only, but the margin for some of the generic products might be 500 or 1,000 percent.

2.33 In this regard, the representative of All India Organisation of Chemists and Druggists(AIOCD), suggested that for controlled as well as decontrolled medicines, the minimum margin given to wholesaler and retailer should be 20 percent including the excise duty.

2.34 When the Committee asked whether there is rationality between the cost of production and selling price, the representative of AIOCD stated as under:-

“Today, the NPPA is controlling the controlled category drugs. In decontrolled category, the Government has no control over the prices. It was said that the prices were too high. Under the decontrolled category, the prices are printed by the manufacturers and their margins on these products goes up from 100 per cent to 500 per cent. The Government cannot control it. We told the Government that we would take up this matter with manufacturers and we would ask them to reduce the prices of medicines like Ciproflaxin, nimesulide, etc. We are ready to support the Government in its effort to bring down the prices. Even in respect of generic medicines, we are ready to lower our margin.”

2.35 In this connection, the Department of Chemicals & Petrochemicals has informed that a Committee was constituted under the Chairmanship of the

Joint Secretary (PI) on 19<sup>th</sup> August, 2004, to examine the issue of span of price control (including trade margin) on drugs and pharmaceuticals in view of the National Common Minimum Programme and the observations of the Supreme Court. The Committee has submitted its interim Report to the Government. The proposal of controlling trade margin on drugs was also examined. However, it was felt that it might adversely affect drugs manufactured by a large number of small scale manufacturers. Hence, it was not implemented.

2.36 Further, supplementing the information on the matter, in a written note the Tamil Nadu Government has informed that to get rid of pocketing of huge margin by retailers and to supply essential drugs on reasonable prices, the State has a Tamil Nadu Medical Association Corporation (TNMAC). As per the system, bids for tender prices are called by the Corporation and the lowest tender is awarded for supply of medicines. TNMAC has a good quality check and they are not only in drugs but also in CT scans. In all the district hospitals, they are running CT scan very well.

2.37 It was informed that Delhi Government is also doing some pooled procurement on very reasonable price. In Rajasthan, there is a lifeline fluid stores. They have intervened in the issue of IV fluids and are selling them through Government dispensaries. It has been very successful.

2.38 On being asked by the Committee that in order to ensure the availability of drugs at reasonable prices whether the Government should step in to open fair price shops at different places after pooled procurement on the lines of Tamil Nadu Government, the Department of C&PC in a written reply stated as under:-

“The Drug Policy as amended from time to time is directed towards making available the quality drugs at reasonable prices. A Task Force has also been constituted under the Chairmanship of the Principal Advisor (PP), Planning Commission to explore various options other than price control for achieving the objective of making available life saving drugs at reasonable

prices. The Task Force is also examining the issue of monitoring of prices and bulk/pooled procurement issues of medicines. “

2.39 The Committee asked what Indian Drugs Manufacturers Association (IDMA) could do for ensuring availability of medicines in hospitals for poor people. The representative of the IDMA stated as follows:-

“if Government has some policy for distribution of life saving drugs in hospitals and Government have a list, our Association will provide 10 or 20 per cent free medicines, we will not charge any money”.

2.40 Presently the Government supervision/control over non-Scheduled drugs is based on ORG-MARG survey. Explaining the lacuna in the system one NGO's stated that this survey does not reflect the field level realities in the country. It takes about one per cent sample of the sales of the retail outlets. In May 2005, out of total 237318 Chemists, it collected data from 2236 Chemists. It is an extrapolation from 280 companies of about Rs. 19000 crore annual sales to retailers. A significant number of regional companies are not covered.

2.41 The ORG-IMS does not reflect figures of bulk institutional sales by industry. The Department of C&PC in a post-evidence reply has stated that ORG-IMS is a private MNC in the business of collecting/compiling data for the last several years. NPPA is depending on their data as no other suitable data is available.

2.42 On being enquired by the Committee as to whether there was any agency with the Government for collection and compilation of data, the representative of the Department of C&PC during the course of oral evidence admitted before the Committee that unfortunately there was no system with them for collection and compilation of data for pharma sector except the ORG-IMS. The NPPA has been directed to explore the possibility of setting up of an independent agency in this regard.

2.43 The Committee also enquired about the system to deal with shortage of a particular drug and whether any foolproof mechanism for reporting shortages has been developed. The Department in their reply furnished as under :-

“NPPA is carrying out this responsibility mainly through monthly reports received from the State Drugs Controllers. As and when the reports for shortage for any particular drug, in any part of the country are received, the concerned company is asked to rush the stock and make the drug available. In case of temporary shortage for any specific reason, the matter is also taken up with the concerned company. The response of the companies has generally been prompt.

In addition to above, NPPA also takes note of the shortage of any formulation in any part of the country brought to its notice by individuals, NGOs, print media and Hon'ble Members of Parliament and suitable action is taken. It may be mentioned that normally shortages are of temporary nature and therapeutic substitutes are available in respect of most of the medicines.”



## **CHAPTER - III**

### **DRUGS FOR PUBLIC HEALTH**

#### **(A) Availability of Essential Drugs**

It came out during examination that the healthcare expenditure by the Central Government is only about 0.9 percent of the total GDP. The Secretary (Chemicals & Petrochemicals), in this regard, informed during evidence that the Government contemplate to raise this expenditure to about 2 to 3 percent of GDP over the next five years.

3.2 The representative of LOCOST informed the Committee that there has been divergence between the priorities of public health and drugs covered under DPCO. The policy is based on market share of a drug company and not on whether a particular drug is essential for the disease pattern in the country. Only drugs with annual turnover greater than Rs. 4.00 crore, where there is insufficient competition (i.e. one formulator having more than 40 per cent share of market share despite having at least 5 bulk producers and 10 formulators) are to be considered under price control. Monopoly situation in which any formulator with annual turnover greater than Rs. 1.00 crore in which a single formulator has more than 90 per cent share is also to be covered under price control. All other drugs & formulations were to be exempted from price control.

3.3 On being pointed out by the Committee that the poor people are unable to get the essential drugs and desired to know that whether there should be any policy for drug manufacturers to produce at least a certain percentage of essential drugs, the Department of C&PC in a written reply stated that the Indian Drug Industry has developed to such a level that the availability of drugs was not a problem and there was no shortage of drugs. A manufacturer was free to produce as medicines as per his corporate policy and prevailing market forces. However,

at present, no manufacturer can be compelled to produce at least a certain percentage of essential drugs.

3.4 The representative of LOCOST further added that some of really essential drugs have gone out of price control, majority of the drugs related to public health problem are either under-represented or unrepresented in DPCO 95. The anti-cancer and, anti-AIDS drugs are not under price control. ORS, instrumental in preventing dehydration in diarrhoea, is not covered under price control. The following table shows the public health problems and the absence of their drugs in the Drug Price Control Basket:-

Public Health Problem	Drugs Required for the disease	Drug Listed in DPCO for the purpose	Remarks
1. Iron Deficiency anemia	Ferrous sulphate Folic acid	NONE	Anemia is a major public health problem in women and children with a prevalence of 74.3 in children of 6-35 months and a prevalence of 49-56% in women (NFHS 1998/99). Anemia contributes to 1/3 of maternal mortality Exclusion is against interests of public health.
2. Tuberculosis	INH, Rifampicin, Ethambutol, Pyrazinamide. Also in view of the increasing prevalence of drug resistant TB, drugs like Ofloxacin, Ethionamide, Cycloserine, which are required but are exorbitantly priced should be included.	Rifampicin	TB is the single largest killer disease in India with 5 lakh deaths per year. According to WHO estimates TB patients spend Rs. 645 crore on private TB care in 1997. Rural patients have to spend Rs. 1000 per month on diagnosis and treatment which invariably results in mortgaging of assets and valuables.
3. Malaria including chloroquine resistant falciparum malaria which has become prevalent in many parts of India.	Chloroquine, Primaquine, Quinine	Chloroquine	Quinine is essential in treatment of chloroquine resistant falciparum malaria which can otherwise be fatal and which is increasing in its prevalence in India.
4. HIV disease/AIDS	Zidovudine, Lamivudine, Nevirapine, Indinavir	NONE	India had the second highest number of HIV disease patients in the world (3-4 million). Yet no drug under price controls to make them more affordable.
5. Agents to prevent dehydration in diarrheal diseases. Dehydration due to diarrheal diseases kills	Oral Rehydration Salts	NONE	1 lakh children under 5 years of age die due to diarrhea and dehydration. There are more than 1 crore diarrheal episodes/year thousands of children every year in India. Why is ORS then not represented?
6. Leprosy	Dapsone, Clofazimine, Rifampicin	Rifampicin	The exclusion of the other two drugs which are used in greater quantities is inexplicable.
7. Filariasis	Diethylcarbamazine citrate	NONE	Six million Indians develop acute filaria and 45 million have chronic filarial lesions.

8. Hypertension	Atenolol, Enalapril, Hydrochlorothiazide, Amlodipine	Captopril, Methyeldopa	Hypertension is an increasingly common problem in rural and urban areas. Different kinds of antihypertensives are required depending on the patient's associated conditions.
9. Coronary artery disease:	Glyceryl trinitrate, Isosorbide dinitrate, Beta blocker, Calcium blocker	NONE	Coronary artery disease has prevalence of 80-120/1000 in urban areas and 30-60/1000 persons. Drugs for such a problem should be there in such a list.
10. Vaccines (new) for Rabies, Hepatitis B: Rabies kills thousands of people every year in India. Hepatitis B is an important public health problem which causes acute, chronic hepatitis and liver cancer.	Cell culture derived rabies vaccine. The current vaccines for rabies are very expensive. The old vaccine based on sheep brain is outdated and occasionally hazardous.	NONE	Nearly 1.1-1.5 million people are administered rabies vaccine every year. The reported mortality with rabies is 30000-40000 per year, which is an underestimation. A single dose of cell culture derived costs Rs. 300 in the market. In the immunization of a single patient 5 doses are required, the cost per patient turns out to be Rs. 1500, which is beyond the reach of the poor.
11. Cancer: Over 7 lakh patients develop cancer every year	Many drugs are available which are however prohibitively expensive which can play a curative or palliative role in different types of cancer.	NONE	Many forms of cancer especially in children and many in adults are completely curable with effective chemotherapy. However, anti-cancer drugs are mainly still sourced from abroad, and are prohibitively expensive. They can cost thousands of rupees per dose.
12. Sera for use in tetanus, diphtheria, Rh isoimmunization.	Anti-tetanus serum Anti-diphtheria antitoxin Anti-D immunoglobulin	NONE	Its exclusion is inexplicable.
13. Analgesic-antipyretic: Fever and pain are the most common of symptoms which need to be relieved.	Paracetamol is the drug of choice for relief of fever and is a safe analgesic.	Paracetamol is excluded from the list.	The exclusion of this drug, which is essential and of mass consumption defies logic.
14. Anticonvulsants	Phenytoin, Carbamazepine, Valproic acid	NONE	Seizure disorders are common and require prolonged even lifelong therapy and should have been included.

3.5 In regard to sale of irrational drugs, the Department of C&PC in a written note informed that the combination of drugs are considered irrational, illogical or haphazard, if it does not conform to anyone or more criteria mentioned below:-

- (a) There is a synergetic or corrective action of the combination.
- (b) The drugs are required to be taken simultaneously.
- (c) For better compliance and convenience to the patient.
- (d) These are not-toxic specially for prolonged use.
- (e) There is no adverse interaction between the drugs.
- (f) Doses of each drug is not required to be individualized.

3.6 The Committee have been further informed by the Department of C&PC that there exists a system in the country for examining the rationality of drug formulations marketed in the country through the Drugs Technical Advisory Board (DTAB) and its Expert Committee, statutory body under section (5) of Drugs and Cosmetics Act 1940, under the Chairmanship of DG, Health Services, to advise the Central and State Governments. Reportedly, some of drugs included in the list of Scheduled Drugs are irrational.

3.7 In reply to question about steps taken to ensure low price drugs for diseases like HIV/AIDS, the Secretary, Chemicals & Petrochemicals stated during evidence as under :-

“For HIV/AIDS recently some of the drugs are being produced as generic as a result the Indian manufacturers have come into the scene and the prices have lowered sharply. For instance, one drug used to cost 10,000 dollars per person per annum for HIV/AIDS. Since the Indian manufacturer has started manufacturing these, it has been brought down to 240 dollars per person per annum, which means about 9,600 dollars saving per year.

Similarly, the Government’s effort through NACO is also contributing towards lowering these prices. For this HIV/AIDS, bulk purchases are made by NACO and the same one which was available for Rs. 9,600, because of bulk purchased by NACO, some of these drugs are available now for only Rs. 5,000.”

3.8 In reply to a question about ensuring the availability of generic drugs on long term basis in the country, the Department in their written reply submitted that in India most of the drugs are generic in nature. However, brand names are used by the companies to popularise drugs made by them. Since drugs are prescribed by doctors, confidence in the quality of every generic drug is an important factor in promoting acceptance of generic drugs among Medical Community. This, to a great extent, depends upon a confidence in the robustness of the drug regulatory system operating in the country which is substantially being addressed by the Capacity Building Project and implementation of the Mashelkar Committee Report.

3.9 The Committee also asked whether the drugs for public health problem like anemia, tuberculosis, Malaria, Leprosy, filariasis, hypertension,

cancer, coronary artery disease and drugs like ORS, Paracetamol alongwith vaccines for killer diseases are outside DPCO, 1995, the Ministry in their Post Evidence reply stated as under :-

“The following bulk drugs which are used for treatment of TB, Malaria and Hypertension are under price control.

<b>Disease</b>	<b>Name of the Bulk Drug</b>
Tuberculosis	Rifampicin, Streptomycin
Malaria	Chloroquine
Hypertension	Pentoxifylline, Captopril, Methyldopa, Verapamil

The bulk drugs used for the remaining disorders/diseases are outside price control”.

### **(B) Role of State Governments**

3.10 The State Drug Controllers have been entrusted to ensure availability of quality drugs at reasonable prices to the public by implementing the provisions of the Drugs and Cosmetics Act, 1940, the Rules made thereunder and also under Drugs (Price Control) Order, 1995. During the course of the examination of the subject, with a view to strengthening the system, the Committee sought the views of State Governments in the matter. Important views/suggestions received from States/UTs. of Andhra Pradesh, Daman & Diu, Delhi, Goa, Gujarat, Haryana, Himachal Pradesh, Kerala, Rajasthan, Madhya Pradesh, Orissa, Pondichery, Tamil Nadu etc. and their State Drug Control Authorities have been summarized as under:-

- (1) Special funds should be released by the Government of India to strengthen the manpower and other facilities in the State Drugs Control Administration.

- (2) Trade margin on drugs should be reviewed so as to bring down the prices.
- (3) An official updated booklet on the latest price approval on drugs may be brought out by the National Pharmaceutical Pricing Authority (NPPA) as a reference book on annual basis.
- (4) Major chunks of medicines are away from control of prices. Anti-Cancer Drugs, Anti-HIV Drugs, Neutraceuticals, cetrisen and many antibiotics are highly priced. Wherever such instances have been referred to NPPA, they have expressed their helplessness in the matter. The issue of heavy price difference in generic drugs should be immediately resolved and ceiling prices for non-scheduled formulations be fixed.
- (5) A special cell should be created in each State Drugs Control Department to take up appropriate action to monitor the prices of drugs and to take legal action against the defaulters.
- (6) The Government of India may issue an order to have Maximum Retail Price (MRP) including of all taxes on the label of all drugs so that public may be protected from the over pricing by the chemists.
- (7) Periodic training programme should be imparted to train all the officers of the Drugs Control Administration for better implementation of the Acts relating to drugs and pharmaceuticals.
- (8) More drugs should be brought under the ambit of DPCO, 1995 and uniform tax structure may be adopted throughout the country to encourage R & D.
- (9) The companies doing R&D in new molecules should be identified and such companies be allowed to charge reasonable extra R & D charge while fixing the ceiling prices by NPPA. They should also be

exempted from the DPCO 1995 for at least five years to meet the expenditure incurred on the invention of new molecules.

- (10) The Government should curb menace of spurious drugs.
- (11) All life saving drugs should be kept under the price control.
- (12) The drugs should be manufactured and sold in generic names instead of brand names.
- (13) The drugs which are not in use or have become obsolete should be removed from the controlled list of DPCO, 1995.
- (14) There should be some provisions in DPCO, 1995 to enable the Drugs Control Department to impose penalty on chemists for minor offences/irregularities instead of prosecution.
- (15) The recommendations of the Mashelkar Committee in regard to strengthening of State Drug Control Organization should be implemented.
- (16) Excess amount charged by the manufacturers should be recovered from them and deposited in Drug Prices Equalization Account (DPEA). Out of this, some percentage of amount should be allocated to those State Drug Controllers who have unearthed the cases of overcharging.
- (17) NPPA should expedite revision/fixation due to change in cost of material by revising the ceiling price of drugs and formulations.
- (18) All imported drugs and formulations should be brought under the purview of price control.
- (19) Need for better coordination between the Ministry of Chemicals & Fertilizers and Ministry of Health & Family Welfare.

- (20) There should be amendment in the Essential Commodity Act so as to impose a fine of suitable amount for violations of Drug Prices Control Order 1995. This will pave way for departmental action against defaulters instead of prosecution.
- (21) Some more Central Drugs Testing Laboratories should be set up in various parts of the country.
- (22) No taxes should be levied on the life saving drugs.
- (23) There should be ceiling beyond which the increase in prices of medicines would not be permissible.
- (24) There should be pooled procurement of medicines required for public health care like Government hospitals, dispensaries etc.

**(C) Spurious Drugs**

3.11 The Committee have been informed that the provisions for quality, licensing, storage, sales, distribution of drugs are governed by the provisions of the Drugs and Cosmetics Act, 1940 administered by the Ministry of Health and Family Welfare. Reported there are cases of fake/ counterfeit/ substandard/ spurious drugs.

3.12 A drug shall be deemed to be spurious:-

- If it is manufactured under a name which belongs to another drug.
- If it is an imitation of or is a substitute for, another drug or resembles another drug in a manner likely to deceive, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character.



- If the label or container bears the name of an individual or company purporting to be the manufacturer of drugs; which individual or company is fictitious or does not exist; or
- If it has been substituted wholly or in part by another drug or substance or.
- If it purports to be the product of a manufacturer of whom it is not truly a product.

3.13 The Department of Chemicals & Petrochemicals has informed that the Ministry of Health and Family Welfare had constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelkar. The Committee submitted its report in November, 2003. It has inter-alia recommended for stringent penal provisions especially in regards to spurious drugs and other measures to help in investigation and prosecution. The Drugs and Cosmetics (Amendment) Bill, 2005 has been introduced in Rajya Sabha to enhance penalties, to declare the offences cognizable and non-bailable, to enable police personnel to file prosecution, to provide for special courts for drug related offences and also to compound offences under the Act.

3.14 There are 27 States and Central Laboratories functioning throughout the country to test the quality of drugs. The Government analysts after testing declares a particular drug as spurious or not of standard quality on the basis of identification and other tests. The investigating agency may also detect spurious drug on the basis of investigation. Under Capacity Building Project, the Central Government have undertaken various measures to upgrade the existing facilities of various testing laboratories. Three new drug-testing laboratories are being established in the newly created States and one new Regional Drug Testing laboratory has been set up at Chandigarh.

3.15 On being enquired by the Committee as to whether the Drug Inspectors are collecting samples regularly in each month from each shop, the Department of

C&PC, in a written note, stated that there is no set policy to collect samples each month from each shop in the country. It depends upon the testing capacity available in a particular State as well as the funds available to pay the cost of samples collected by Drugs Inspectors. Usually the samples are collected at random and on suspicion.

3.16 The All India Organisation of Chemists and Druggists (AIOCD) in a written note furnished to the Committee stated that the problem of spurious medicines is not restricted to India alone and it is a worldwide phenomenon. No study report or authentic record is available in this regard. The World Health Organisation had made a statement that 15 percent of all drugs in circulation in the world are counterfeit or sub standard. These medicines give a grave health problem sometime leading to death. It has been further stated in the information provided by the WHO that 5 per cent of medicines exported to developed countries including USA and as much as 40 per cent exported to the Third World Countries are spurious in nature.

3.17 When the Committee enquired as to what were the observations of WHO in regard to spurious drugs in India, the Department of C&PC, in its reply has stated that there was a media report alleging that as per WHO report about 35 per cent of spurious drugs emanated from India. However, on a specific enquiry by the Government of India, WHO has denied having issued such a report.

3.18 The manufacturers of spurious and adulterated drugs can be punished with a maximum penalty or life imprisonment and heavy fine upto Rs.10 lakh. However, they are being convicted/punished in rare cases. In this connection, when the Committee desired to know as to what should be the modalities to deal with such menace, the Department of C&PC, in its written reply, stated that as the normal procedures of courts take a long time to finish the trial, the proposed special courts might solve the problem. The Drugs and Cosmetics (Amendment) Bill 2005 has also proposed compounding of offences which may help in faster disposal of cases.

3.19 The representative of the Ministry of Health & Family Welfare while agreeing that the prevalence of spurious drugs was a menace, stated during evidence that unfortunately, the regulatory system in the country was rather fragmented and the manufacturing of these drugs was being done by criminal elements in a very clandestine kind of activity.

**(D) Revival of Sick PSUs.**

3.20 The Committee pointed out that public sector units like Indian Drugs & Pharmaceuticals Ltd. (IDPL) and Hindustan Antibiotics Ltd. (HAL) laid the foundation of the drug industry in the country and also supplied basic drugs for public health for long. Asked about the steps taken to revive the sick PSUs under the Department of Chemicals & Petrochemicals, the Department in a note stated that the progress for revival of PSUs under their administrative control is as under:-

SI.No.	Name of PSU	Status
1.	Indian Drugs and Pharmaceutical Ltd. (IDPL)	BIFR had recommended for winding up of the company and the company is before the High Court for appointment of a Liquidator. The Department has filed an appeal in AAIFR against the BIFR's winding up order. Besides this, the Deptt. also constituted an Expert Committee to undertake the study of techno-economic feasibility of rehabilitating the IDPL. The Committee has submitted its report on 20.04.2005 which is under examination in the Department.
2.	Hindustan Antibiotics Ltd. (HAL)	It is a BIFR company. In the Budget 2004-05, the Finance Minister announced financial support for restructuring HAL. The Draft Revised Rehabilitation Scheme of HAL was sent for consideration of BRPSE in March, 2005. In the meeting held on 22.7.2005, BRPSE considered the draft rehabilitation scheme. Follow up action thereon is being taken by the Department.
3.	Bengal Chemical and Pharmaceutical Ltd. (BCPL)	BIFR has sanctioned a Modified Rehabilitation Scheme for the company of 14.01.2004. Follow up action thereon is being taken by the Department.
4.	Bengal Immunity Ltd. (BIL)	BIFR had recommended for winding up of the company. All the employees have been relieved

		under VSS. The company is closed and is before the High Court for appointing a Liquidator.
5.	Smith Stanistreet Pharmaceutical Ltd. (SSPL)	BIFR had recommended for winding up of the company. All the employees have been relieved under VSS. The company is closed and is before the High Court for appointing a Liquidator.

### **(E) Indian Systems of Medicines**

3.21 The Committee pointed out that the many people prefer traditional systems of health and medicines like Homeopathy, Ayurveda, Siddha. Asked about the steps to strengthen these to supplement the National Health Care system, the Department in a note stated that the Department of Ayurvedic, Unani, Siddha and Homeopathy (AYUSH) in collaboration with Council for Scientific and Industrial Research (CSIR) have undertaken Traditional Knowledge Digital Library (TKDL) project to evolve a digitized data base of traditional medical knowledge embodied in the classical literature of Ayurveda, Siddha, Unani and Yoga systems which are codified and well documented but available in public domain in languages not accessible to patent examiners. The objective of TKDL is to provide an instrument to the patent officers for examining patent claims on the uses of medicinal plants and to prevent wrong patenting on Indian medical knowledge. So far about 60,000 formulations from classical Ayurvedic and Unani texts have been digitized in Patent Compatible Format in 5 international languages. Further work of TKDL is underway covering Yoga practices & asanas apart from Ayurveda, Unani and Siddha formulations described in classical literature. Access policy under non-disclosure agreement is in the process of necessary approval before making the TKDL available to international patent offices. The TKDL tool would prove an important instrument against bio-piracy on indigenous medical knowledge. Framing of national law on protection of Intellectual Property Rights related to traditional knowledge has also been taken up by HRD Ministry. Bio-diversity Act and Rules thereunder administered by the Ministry of Environment & Forests also provide for safeguard measures against bio-piracy.

3.22 The strategies outlined in the National Policy on AYUSH, are as under :-

- a) To promote good health and expand the outreach of health care to people, particularly those not provided health cover, through preventive, promotive, mitigating and curative intervention through Indian Systems of Medicine & Homeopathy;
- b) To improve the quality of teachers and clinicians by revising curricula to contemporary relevance and research by creating model institutions and Centers of Excellence and extending assistance for creating infrastructure facilities;
- c) To ensure affordable AYUSH services & drugs which are safe and efficacious;
- d) To facilitate availability of raw drugs which are authentic and contain essential components as required under pharmacopoeial standards to help improve quality of drugs, for domestic consumption and export;
- e) Integrate AYUSH in health care delivery system and National Programmes and ensure optimal use of the vast infrastructure of hospitals, dispensaries and physicians;
- f) Re-orient and prioritise research in AYUSH to gradually validate therapy and drugs to address in particular the chronic and new life style related emerging diseases;
- g) Create awareness about the strengths of these systems in Indian and abroad and sensitize other stakeholders and providers of health;
- h) To provide full opportunity for the growth and development of AYUSH systems and utilization of the potentiality, strength and revival of their glory.

3.23 Asked about steps taken for quality control and monitoring of Indian system of medicines, the Department of Chemicals & Petrochemicals stated :-

Department of AYUSH have undertaken following initiatives for augmenting the quality control and monitoring of Ayurveda, Siddha, Unani (Asu) and Homeopathy medicines in the country :-

- (i) 9<sup>th</sup> Ayurvedic Pharmaceutical Committee (APC) has been constituted which is made up of multi discipline experts. The APC evaluates and approves Pharmacopoeial work assigned to 13 laboratories. On the recommendations of APC, Standard Operating Procedures (SOPs) for the manufacturing of ASU drugs and shelflife studies have been started on project basis in 13 identified laboratories.
- (ii) The Pharmacopoeial Laboratories of Indian Medicine and Homeopathy are the Central Laboratories established as per the legal requirements prescribed in the Drugs and Cosmetic Act in the context of quality control of Ayurveda, Siddha, Unani and Homeopathy medicines. These laboratories undertake pharmacopoeial as well as quality pharmacopoeial as well as quality testing work of ASU & H drugs. These laboratories are being strengthened to augment their functional capacity.
- (iii) Ayurveda, Sidda, Unani Drug Technical Advisory Board (ASUDTAB) has been reconstituted. In its recent meeting the Board has considered the issues of re-classification of Ayurveda, Siddha and Unani drugs with a view to streamline regulation of different kinds of proprietary /patented products and enforcement of provisions of Chapter IV-A of the Drugs & Cosmetics Act, 1940 in respect of labelling/shelf-life/expiry date of ASU drugs, creation of central licensing authority of ASU drugs etc.
- (iv) Department of AYUSH has implemented schemes to strengthen State pharmacies and Drug Testing Laboratories for improving their functional capacity and productivity. So far 40 State pharmacies and 21 Drug Testing Laboratories have been supported under the central scheme.
- (v) Good Manufacturing Practices (GMP) are implemented since 2000 as Schedule 'T' of Drugs and Cosmetic Act with the objective of ensuring manufacturing of quality ASU medicines. GMP seek possession of in house quality control laboratory or suitable arrangement with recognized laboratory for quality testing of drugs.
- (vi) A central scheme has been implemented to support State Drug Licensing Authorities for strengthening the enforcement mechanism of quality assurance of ASU drugs.
- (vii) Ayurveda, Siddha and Unani Drugs Consultative Committee (ASUDCC) comprising of State Licensing Authorities and central representatives, is being reconstituted as per the provisions of Drugs

and Cosmetic Act. The responsibility assigned to DCC is to recommend modes and modalities for uniform implementation of Drugs and Cosmetics Act in the context of Ayurveda, Siddha and Unani Drugs. The ensuing meeting of DCC is scheduled in the first week of August 2005 to, *inter-alia*, discuss constitution of a Central Licensing Authority for approval of ASU Patent and Propriety medicines and for dealing with matters referred from States.

## **CHAPTER – IV**

### **SETTING UP OF NATIONAL DRUG AUTHORITY**

The issues relating to drugs and pharmaceuticals are being dealt with by more than one Ministry/Department of the Central Government. The pricing policy of drugs and pharmaceutical comes under the purview of the Ministry of Chemicals & Fertilizers, the Health Policy is framed by the Ministry of Health & Family Welfare. The patent aspect is looked after by the Ministry of Commerce. Again the quality aspects of drugs are dealt by the Drug Controller General of India under the Ministry of Health. The Ministry of Science and Technology are handling the funds for pharmaceutical incentives for Research & Development for developing new drugs.

4.2 For dealing all related issues in a coordinated manner, it was envisaged to make modification in Drug Policy, 1986, as announced in September, 1994 by setting up a National Drug Authority to perform the following functions:-

- “(i) Develop and define basic appropriate standards relating to the manufacture, import, supply, promotion and use of drugs.
- (ii) To approve and register pharmaceutical products for use in the country only, if
  - (a) It meets real medical need,
  - (b) It is therapeutically effective, and
  - (c) It is acceptably safe.
- (iii) To enforce effectively appropriate quality standards of medicines and Good Manufacturing Practices, throughout the country, having full regard to the needs of public health and standardise dosage strength and pack sizes of formulations with a view to check proliferation.
- (iv) To monitor standard practices in drug promotion and use and to clearly identify those which are acceptable and prohibit those which are unethical and against the consumers’ interest.
- (v) To monitor the prescribing practices and to evaluate their appropriateness for the purpose of guiding the medical profession and for achieving the aim of rational prescribing.



- (vi) To ensure that appropriate information about registered pharmaceuticals is made available for the guidance of consumers having regard to:
  - (a) The adverse consequences of non-compliance by patients particularly in the case of antibiotics, steroids etc.,
  - (b) Dangers of self-medication, and
  - (c) The need to involve consumers as full partners in the health care system.
- (vii) To prepare and publish a national formulary and formularies relevant to various levels (like district hospital, community centre, primary health centre) for the guidance of consumers as well as Doctors.”

4.3 The functions mentioned above involve new responsibilities which will include:-

“Special focus on examining the technology of bulk drugs; capacity validation of machinery; assessing suitability of manpower for bulk drug production; undertaking scientific scrutiny of master formulae for manufacture of formulations; developing testing labs for cosmetics, diagnostics and devices; laying down standards for veterinary drugs; examination of labels and promotional claims and prescribing procedures for public hearing under the Drugs and Cosmetics Act; monitoring of clinical trials for the protection of human rights; quality control of herbal medicines; updating new drug approval process; weeding out of irrational combination formulations; and formation of expert committees for examination of new drugs.”

4.4 The Committee pointed out that the setting up of proposed National Drug Authority was over due and enquired about the reasons for undue delay in setting up the authority, the Department of Chemicals & Petrochemicals in their written reply, furnished as under:-

“A Committee on Drugs and Pharmaceuticals Industry under the Chairmanship of Shri Jaisukhlal Hathi was constituted on 8-2-1974 to examine various facets of the Drug Industry in India with a view to promoting growth of the Drug Industry. The Committee submitted its report in April 1975 and recommended, inter-alia, abolition of brand names in a phased manner and procurement of single ingredient drugs and drugs included in Indian Pharmacopoeia for Central and State Government

Institutions and local bodies under generic names. The Government laid a Statement on the Table of the Lok Sabha on 29<sup>th</sup> March, 1978 containing its decisions on the recommendations of the Committee. Later this came to be known as Drug Policy, 1978.

The Government reviewed the Drug Policy, 1978 and restructured it in 1986 by announcing 'Measures for Rationalisation, Quality Control and Growth of Drugs and Pharmaceuticals Industry in India' which, inter alia, envisaged setting up of a machinery to be called the National Drug and Pharmaceuticals Authority to look after the rational use of drugs. The importance of quality control and rational use of drugs was reiterated in the 'Modifications in Drug Policy, 1986', announced in September, 1994 and it was envisaged therein that a National Drug Authority be set up to undertake the regulatory functions performed by the Central Drugs Standard Control Organisation (CDSCO) in addition to assuming many new responsibilities. This, inter alia required major structural changes in the existing regulatory system, where licensing of manufacturers etc. as well as enforcement of the Drugs and Cosmetics Act, 1940 and Rules made thereunder, are primarily done by the state authorities. Efforts are being made to strengthen the existing capacity of the Central Drugs Standard Control Organisation (CDSCO) which would be necessary before undertaking the new responsibilities and conversion of CDSCO into a full fledged Central Drug Authority (CDA).

Creation of a CDA is under active consideration of the Ministry of Health and Family Welfare."

4.5 The Department have also informed that the Ministry of Health and Family Welfare constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelkar. This Committee submitted its report in November, 2003. In the report, the Mashelkar Committee made various recommendations for strengthening of drug regulation including creation of Central Drug Administration (CDA), having ten separate divisions to look after multi disciplinary demands on the regulatory system and also taking over drug manufacturing licensing activities in the country by the Centre.

## **CHAPTER – V**

### **RESEARCH AND DEVELOPMENT IN THE PHARMA SECTOR**

The Indian Pharmaceuticals Industry has achieved global recognition. Leading Indian companies have established marketing and manufacturing activities in over 60 countries including USA and Europe. But to remain globally viable and to produce cheaper drugs for the masses, Research and Development (R&D) is a must and more particularly after introduction of product patent regime. High caliber experts and modern facilities are required in various areas of drug development. In the Indian Pharmaceutical Industry, the average R&D expenditure is stated to be around 2 percent of the turnover contributed by around 50 companies against the 15-20 percent in Western countries.

5.2 The Drug Industry is a highly R&D oriented sector in which there is a very high rate of obsolescence. This sector has also been identified as one of the thrust areas for export. Therefore, there is a need to ensure that the technologies used in the country are cost effective and efficient in tune with disease pattern in the country.

5.3 On being enquired by the Committee as to what are the difficulties being faced by drug manufacturers due to introduction of patent regime, the Department of Chemicals & Petrochemicals, submitted in a written reply, as under:-

“With the ushering in of the product Patent regime w.e.f. 1<sup>st</sup> January, 2005, India and the Indian Pharmaceutical Sector will have to face new challenges that would accompany such a change. This will signal the beginning of a new chapter as Patent on products also, in addition to patent on processes, in the Pharmaceutical Sector would be granted. This necessitates the Industry to innovate and invent and shift focus from mere reverse engineering. R&D will have to become the cornerstone for existence. Researchers will have to apply their creative skills in producing new drugs. Large investments on R&D has to be taken up in right earnest.

Recognizing the imperativeness of taking proactive measures to give the necessary fillip to R&D in the Pharmaceutical Sector in the country, the

Government is also taking steps to strengthen the R & D initiatives through various Programmes/incentives to the manufacturers.”

5.4 The Pharmaceutical Research and Development Committee (PRDC) was set up under the Chairmanship of Dr. R.A. Mashelkar, Director General, CSIR to study and identify the measures needed to strengthen R&D base of the Indian Pharmaceutical Industry and to identify the support required by Indian pharmaceutical companies to undertake domestic R&D. The Committee submitted their report in November, 2003.

5.5 When the Committee wanted to know about the steps taken by the Government in regard to encourage the R&D in the Drug sector, the Department of Chemicals & Petrochemicals informed that a Pharmaceutical Research and Development Support Fund (PRDSF) with a corpus of Rs. 150 crore was set up under the Department of Science and Technology. Annual grant of Rs. 150 crore has been approved from this year. Under Income Tax Act, 150 percent of R&D expenditure in drug industry is exempted upto the year 2007.

5.6 On being enquired by the Committee about the effect of recent amendments in Patent Act on prices and availability of drugs, particularly life saving drugs and pharmaceuticals, the Department of C&PC submitted in a written note, as under:-

“The existing patent law in the country provides for a strong and comprehensive set of safeguards, and inter-alia, has effective provisions to ensure availability of pharmaceutical products at reasonable price through compulsory licensing. Many of the drugs already in the Indian market, including those in the National List of Essential Medicines 2003, are off-patent and their prices would not get affected by the new patent regime. This also would not have an immediate impact on the availability and prices of medicines.

The existing patent law in the country, which provides for a strong and comprehensive set of safeguards, is fully equipped to deal with issues relating to non availability of drugs and/or exploitative pricing. The

protective/public interest provisions of the patents law were comprehensively reviewed by the Joint Committee of Parliament, which examined the provisions of the Patents (Second Amendment) Bill, 1999. The Committee primarily focused on the efficacy of safeguards of public interest and public health concerns. Taking note of the Doha Ministerial Conference of WTO in 2001, the Committee restructured the provisions relating to public interest, compulsory licensing, Government use, national security and public health and nutrition with a view to enabling an appropriate timely and efficient response to national and public interest concerns. The existing law has effective provisions:

- a) To ensure availability of products at reasonable price through compulsory licence. {Section 84}.
- b) To deal with emergent situation or cases of public non-commercial use {Section 92}.
- c) The provision relating to parallel import of patented product for ensuring availability of patented products at cheaper price to the consumers {section 107A(b)}.
- d) To ensure import of medicines by Government {section 47(4)}.
- e) The Bolar provision pertaining to act of making, constructing, using or selling a patented invention merely for the purpose of submission of information to the regulatory authorities before the expiry of term of patent so as to allow swift transition of the patented products into the public domain immediately after the expiry of the term of the patent. This provision specially safeguards the interest of generic manufacturers {section 107 A(a)}.
- f) For acquisition of patent right by Government {section 102}.
- g) To enable use of patent for research, experiment and education purpose{Section 47(3)}.
- h) To enable use of invention for the purposes of Government {section 100}.
- i) For revocation of patent for non-working in India {section 85}.
- j) For revocation of patent in public interest {section 66}.
- k) For summary revocation of patent on security consideration {section 157A}.”

5.7 When the Committee desired to know as to how much amount has been spent on R&D by Indian pharma industry during the last five years, the Department of Chemicals & Petrochemicals stated in their post-evidence, reply as under:-

“The R&D expenditure of major R&D companies for the last five years as obtained from their published Annual Reports is tabulated below:

(Rs. in lakh)

Sl. No.	Name	1999-2000	2000-2001	2001-2002	2002-2003	2003-2004
1	Ranbaxy Laboratories Ltd.*	6744	6687	7705	19217	27612
2	Dr. Reddy's Lab Ltd. *	1327	4154	11076	16349	22604
3	Sun Pharmaceuticals Industries Ltd.	2010	2500	3360	6577	10768
4	Cadila Health Care Limited	2130	3507	4155	3830	8820
5	Wockhardt Limited *	NA	4025	3021	3362	6041
6	Cipla Limited	1192	1981	2249	5171	5650
7	Nicolas Piramal	864	916	975	1200	5586
8	Lupin Ltd.		4220	5356	3600	4599
9	Aurobindo Pharma Ltd.	1433	859	1294	2205	4558
10	Torrent Pharmaceuticals Ltd.	1616	2174	2247	3122	3967
11	Glenmark Phrmaceuticals Ltd.	105	2310	1218	3058	3716
12	Biocon India Limited	609	387	710	1100	2333
13	USV Limited	1504	1359	1192	1498	2078
14	Alembic Limited	692	741	1441	1967	1958
15	IPCA Labs Limited	644	579	826	1298	1703
16	Sushan	235	632	889	854	1084
17	Candila Pharma	494	927	889	854	1042
18	Unichem Limited	361	1097	1007	864	843
	<b>Total</b>	<b>21960</b>	<b>39055</b>	<b>49610</b>	<b>76126</b>	<b>114962</b>

\* Figures are from Annual Report, which is for the Calendar Year.

5.8 Asked about the major achievements on the Indian Drug Industry in developing new drugs, the Department of Chemicals & Petrochemicals informed in a note that the following drugs were discovered and approved for marketing in the country :-

S.No	Name of the Drug	Pharmacological Classification	Name of the Discoverer
1	Hamycin	Topical Anti – fungal	M/s Hindustan Antibiotics, Pune.
2	Centimizone	Anti-thyroid	Central Drug Research Institute, Lucknow
3	Enfenamic Acid	Anti-inflammatory Agent	Regional Research Laboratory, Hyderabad.
4	Nitroxazepine Hydrochloride	Anti-depressant	M/s Hindustan Ciba-Geigy, Mumbai.
5za	Azabiperidol	Neuroleptic Agent	M/s Hindustan Ciba-Geigy, Mumbai.
6	Tinazoline	Nasal decongestant	M/s Hindustan Ciba-Geigy, Mumbai.
7	Centbucridine	Local Anaesthetic agent	Central Drug Research Institute, Lucknow
8	Satranidazole	Anti-amoebic	M/s Hindustan Ciba-Geigy, Mumbai.
9	Amoscanate	Anthelminitic	M/s Hindustan Ciba-Geigy, Mumbai.
10	Kyasavur Forest Disease (KFD) Vaccine	Vaccine	Virus Diagnostic Laboratory, Shimoga (Karnataka)
11	Gugulipid	Lipid Lowering Agent	Central Drug Research Institute, Lucknow.
12	Centchroman	Post –Coital Contraceptive	Central Drug Research Institute, Lucknow.
13.	Centpropozon	Anti-depressant	CDRI, Lucknow
14.	Bulaquin	Anti-Malaria	CDRI, Lucknow.

## **PART – II**

### **RECOMMENDATIONS/OBSERVATIONS OF THE COMMITTEE**

1. The Department of Chemicals & Petrochemicals under the Ministry of Chemicals & Fertilizers is responsible for planning, development, regulation and control of the pharmaceuticals industry along with ensuring availability and pricing of drugs and pharmaceuticals. With the quantum increase in population over a period of time, the need for making drugs and pharmaceuticals available at affordable prices to the masses has become a challenge before the nation. From the early 1970s, there have been efforts by the Government to implement a 'National Drug Policy' to regulate the industry. For this purpose, the Government had set up a Committee in 1974, popularly known as the 'Hathi Committee'. On the basis of the Report prepared by this Committee in 1975, the first Comprehensive Drug Policy was formulated in 1978. Subsequently, keeping in view the need, the Drug Policy was revised in 1986. In the context of liberalization of the economy and growth of the industry, the Drug Policy was modified in 1994. Subsequently a new Pharma Policy was announced by the Government in 2002. However, due to the stay order passed by the High Court of Karnataka on a Public Interest Litigation, this new policy has not been enforced.

2. Recently, the Government constituted a Task Force under the Chairmanship of the Principal Adviser, Planning Commission *inter-alia* to explore various options other than price control for achieving the objective of making available life saving drugs at reasonable prices

and issues related to price control, patenting of drugs, promotion of use of generic drugs, bringing items in the 'National List of Essential Medicines, 2003,' under price control etc. This Task Force has submitted its draft recommendations to the Government and a new Pharma Policy will be formulated by the Government after considering the recommendations of the Task Force along with other inputs on the subject.

3. The Committee (the erstwhile Standing Committee on Petroleum & Chemicals) examined the 'Draft National Drug Policy' and submitted their Second report to Parliament on 6<sup>th</sup> August, 1993. The Committee had made several recommendations about availability of essential and life saving drugs of good quality at reasonable prices, to increase health budget from 1 per cent of GDP to WHO guidelines of 5%, reservation of drugs for PSUs and revival of PSUs, safeguards in patent regime, enhancing R&D expenditure and to encourage Indian systems of medicine. The Committee (13<sup>th</sup> Lok Sabha) again examined 'Pricing and Availability of Drugs /Pharmaceuticals ' and presented their 15<sup>th</sup> Report to Parliament on 29<sup>th</sup> August, 2001. The Committee's present examination of 'Availability and Price Management of Drugs and Pharmaceuticals' is once again with the objective of making available quality medicines at affordable prices to the masses. The findings of the Committee as detailed in the succeeding paragraphs relate to the need for amendment of the Drugs (Prices Control) Order, 1995, bringing more essential and life saving drugs under price control, promotion of use of generic medicines, increase in National health budget, emphasis on more R&D and strengthening of drug



control offices throughout the country to have proper control over the production and availability of essential drugs and pharmaceuticals. The Committee desire that their recommendations are considered in the formulation of the new Drug/Pharma Policy, which is being prepared on the basis of the recommendations of the Task Force constituted by the Government. The Committee's recommendations/ observations are detailed in the succeeding paragraphs.

4. The Committee note that presently the Government fix the prices of limited drugs viz. Scheduled drugs under the Drugs (Prices Control) Order, 1995. Over the years the number of such drugs have been reduced considerably. The extent of reduction in the span of price control can be gauged from the fact that while all drugs were subject to control in 1970, 347 drugs were under price control in 1979. Subsequently, these were reduced to 142 in 1987 and as of now only 74 drugs are under price control. Curiously enough, the present criteria of inclusion of a drug in the list of Scheduled Drugs under the price control is limited to factors like production monopoly and turnover. Surprisingly, considerations like the essential requirement of drugs for public health, the concept of life saving drugs etc. are not taken into account in the process of enlisting of drugs in the Schedule. Even though the 'Hathi Committee' Report recommended preparation of a 'List of Essential Drugs' as far back as 1975, it was only in July, 2003 and that too on the directive of the Supreme Court that the Government prepared a 'National List of Essential Medicines' (NLEM) consisting of 354 drugs. Intriguingly, out of this NLEM, only 50 drugs are under price control. All these clearly show that there is an

**imperative need to have a re-look into the entire process of inclusion of drugs in the Schedule for price control. The Committee, therefore, strongly recommend that the Government should consider bringing more NLEM Drugs under price control for the benefit of the poor sections of the society, particularly when several advanced countries like Canada, Japan, UK, etc. are stated to be having some system of price control over essential and life saving drugs. Needless to emphasize, the Government should take due note of essential drugs meant for diseases like Cancer, T.B, HIV/AIDS and new set of diseases like encephalitis and leptospirosis which are increasingly affecting the urban and rural poor masses.**

**5. The prices of non-Scheduled drugs and formulations are fixed by the manufacturers based on factors like cost of production, marketing expenses, R&D expenses, market competition, quality of product etc. Even though one of the main objectives of the National Pharmaceutical Pricing Authority (NPPA) is to monitor prices of non-Scheduled drugs, it has no machinery for collection of price related basic data across the country. The Committee are distressed to note that NPPA depends entirely on a private organisation's Survey reports for price related data in the country. The Committee would like the Government to strengthen the wings of NPPA to make it self-sufficient to carry out its activities independently and effectively.**

**6. The Committee note that the State Drugs Controllers help the National Pharmaceutical Pricing Authority (NPPA) in monitoring the**

prices and enforcing the provisions of Drugs (Prices Control) Order (DPCO), 1995. The State Governments are authorised to take action under Essential Commodities (EC) Act, 1955 for violation of the provisions of the DPCO,1995. However, prosecution under EC Act, 1955 sometimes does not lead to stringent action against defaulters. At present, there are no provisions of fine or penalties for the violation of the DPCO'95 for non-submission of requisite data, price list and for not allowing officers of NPPA to visit and inspect manufacturing premises. The Committee, therefore, desire that DPCO,'95 should be amended suitably to incorporate provisions for compounding offences by stringent fines or penalties therein.

7. The Committee also find that at present the prices of drugs are not being monitored effectively at the State level. In this regard, they have been apprised by the Department of Chemicals and Petrochemicals that except in Karnataka where a DPCO Cell has been constituted for monitoring the prices of drugs, which is working well, there is no effective mechanism in other States. There is a proposal by the Department to establish DPCO Cells in all the States on the model of Karnataka, which will report to NPPA. The Committee, therefore, desire that the process of creation of DPCO Cells should be expedited in all States on the lines of Karnataka for proper monitoring of prices of drugs and pharmaceuticals in a time bound schedule.

8. The Committee's examination has clearly revealed that there is an urgent need to revamp and strengthen the National Pharmaceutical Pricing Authority (NPPA) and the Drug Regulatory Mechanism in the States in order to make the regulatory role exercised by them more effectively. NPPA depends on the State Drug Administration for feedback in fixing/regulating the prices of drugs and pharmaceuticals. However, the Committee find that there is lack of sufficient staff and infrastructure with the State Drug Controllers to cope with the growth of the pharma sector, the complex nature of the industry and the demand and availability of medicines across the country. As per the information made available by the Department of Chemicals & Petrochemicals to the Committee, an exercise to strengthen the NPPA has been started and a scheme for its computerization has been approved. The Committee feel that without an effective NPPA and Drug Regulatory Mechanism in the States, the desired objective of monitoring the prices of drugs to safeguard the interest of patients/consumers cannot be achieved fully. They, therefore, recommend that the Government should ensure that the NPPA and the Drug Regulatory Mechanism in the States must be strengthened expeditiously and the Committee be informed about the conclusive action taken in this regard.

9. The Committee note that presently not all patented drugs are under price control in the country. They feel that after the amendments in the Patent Act and the coming of the product patent era, the availability and prices of drugs might be affected. Apprehensions have been expressed about its possible impact on prices, in particular. In this regard, the Department of Chemicals and Petrochemicals has informed that some kind of monitoring strategies, price negotiations etc. are prevalent in developed countries like Canada, France, U.K. etc. As per the information furnished to the Committee, in Canada, the Patented Medicines Prices Review Board, through negotiation, fixes a maximum chargeable price for patented medicines by the pharmaceutical manufactures and any attempt to impose higher prices than the fixed ones attracts stringent fine. During the course of evidence, the Committee were also apprised by the representative of the Department that to take care of such a situation in future, they are contemplating that there should be a price negotiation mechanism for the new patented drugs prior to the grant of marketing approval. The Committee desire that the proposal should be concretized and enforced in the country expeditiously.

10. The Committee note that as per the present policy, drugs in which there is sufficient market competition are kept outside price control. The criteria for deciding sufficient market competition is that

there are at least 5 bulk producers and 10 formulators and none of them has more than 40 per cent market share in the retail trade. It has been stated by the representatives of non-official organisations during their evidence before the Committee that in actual practice, a fair competitive situation does not exist in the market. According to them, the brand leader is the price leader in most of the cases and hence, the market forces do not tend to appear to determine the prices of the drugs. Specific cases were also quoted to substantiate the point. The Committee's examination revealed that though, there is a provision that a strict watch will be kept on the movement of the prices and the Government may determine the ceiling levels beyond which increase in prices would not be permissible, this provision has seldom been applied. In this context, some of the State Governments have also informed that when the cases of high prices of Anti-cancer drugs, Antibiotics, Neutraceuticals and Cetrizine were referred to the National Pharmaceutical Pricing Authority (NPPA), the latter conveyed its helplessness in curtailing the high prices. The Committee are unhappy over this unsatisfactory state of affairs and desire that the situation should be remedied forthwith. They therefore, recommend that for the category of drugs for the same therapeutic use, the Government should determine a reasonable ceiling beyond which increase in prices may not be allowed.

**11. It came out during examination that Indian Drug Companies export generic drugs worth thousands of crores of rupees to various developed and developing countries. However, these very companies promote aggressively the same drugs as highly priced branded drugs/formulations in the domestic market. Reportedly medical representatives influence the professionals to prescribe branded drugs. This phenomenon has prevented the masses from access to the low cost generic medicines manufactured by the Indian Drug Industry. The Committee are of the considered view that in order to overcome this situation, there is an urgent need for promotion of generic drugs in a big way. They, therefore, desire that the Department of Chemicals & Petrochemicals, in coordination with the Ministry of Health and Family Welfare, should devise ways to ensure use of generic drugs in a massive way, so that the people are able to get quality drugs at reasonable prices.**

**12. The Committee find that for non-Scheduled drugs, the Maximum Retail Price (MRP) printed by the manufacturers is very high. While the drug is available to retailers at a substantially low price, the benefit does not percolate to the consumer. When the Committee drew the attention of the Department to the information made available by an NGO that there were huge trade margins on essential drugs to the extent of even 240, 714 percents in certain cases, the representative**

of the Department of Chemicals and Petrochemicals while admitting this during the evidence stated that the branded products might give a margin of 20 to 30 per cent only, but the margin for generic products might be 500 or 1000 per cent due to market factors. The Committee further observe that the proposal of controlling the trade margin on drugs was examined by a Departmental Committee constituted by the Department of Chemicals & Petrochemicals, but it was felt by the Department that it might adversely affect the drugs produced by a large number of small manufacturers and hence, was not implemented. The Committee are not convinced of the reasons advanced by the Department. They, therefore, strongly recommend that the Department of Chemicals and Petrochemicals should take concrete steps to reduce the trade margins, particularly on essential and life saving drugs.

13. The Committee note that there exists a system for examining the rationality of drugs and formulations marketed in the country through the Drugs Technical Advisory Board (DTAB) and its Expert Committee, a statutory body under section (5) of the Drugs and Cosmetics Act, 1940, under the chairmanship of DG, Health Services to advise the Central and State Governments. The Committee have been informed that some drugs like Vitamin E, Analgin, Diosmine, etc. which are hazardous, unscientific and irrational and abundantly available in the



market, still come under the First Schedule of the Drugs (Prices Control) Order (DPCO), 1995. The Committee feel that such unscientific and irrational drugs are manufactured and promoted only with the profit motive. They, therefore, desire that while reviewing the list of Scheduled Drugs as recommended by the Committee elsewhere in the Report, hazardous and obsolete drugs should be dropped therefrom. Besides, the Committee also recommend that the Government should discourage promotion of unscientific and irrational drugs.

14. The Committee are concerned to note that a number of spurious/fake/counterfeit/sub-standard drugs are available in the market which is becoming a health hazard for the common people. The representative of the Ministry of Health and Family Welfare admitted candidly during oral evidence before the Committee that unfortunately, the monitoring and regulatory system was rather fragmented in the country and that spurious drug manufacturing was done mostly by the criminal elements in a very clandestine manner. In the Committee's view such a situation exists due to unregulated pharmaceutical manufacturing units being run by some unscrupulous drug manufacturers. The Committee, therefore, recommend that the Government should strengthen the drug regulatory authorities to ensure proper checking at production/ distribution level. Steps should

also be taken to modernize the existing laboratories to check cases of spurious drugs.

15. The Committee further find that the provisions for quality, licensing, storage, sales and distribution of drugs are governed by the provisions of the Drugs and Cosmetics Act, 1940, administered by the Ministry of Health and Family Welfare. The Committee desire that the Department of Chemicals and Petrochemicals should impress upon the Ministry of Health and Family Welfare that the drug distribution and delivery system should be made more effective and all the drugs produced indigenously as well as imported should be assessed for safety, efficacy and quality before they are made available to the consumers. In this connection, the Committee would also like the Ministry of Health and Family Welfare to implement various measures in letter and spirit as recommended in the Mashelkar Committee Report to check the prevalence of spurious/fake drugs in the country.

16. The Committee are of the firm opinion that public sector enterprises engaged in the manufacture of drugs have an important role not only in relation to availability, but also with reference to pricing. They, however, regret to note that the public sector units like Indian Drugs & Pharmaceuticals Limited (IDPL) and Hindustan Antibiotic Limited ( HAL) which laid the foundation of drug and

pharmaceutical sector in the country are being neglected and there have been inordinate delays in the approval of their revival packages. For instance, the first revival package of IDPL was approved by the Board for Industrial and Financial Reconstruction (BIFR) as early as 1994. The Committee in their earlier Reports, particularly on Demands for Grants, have been recommending for early revival of sick PSUs under the Department. Considering the fact, that PSUs have been producing medicines for public health and their strategic potentialities in the market, the Committee reiterate that the Government should take urgent steps for revival of PSUs under the Department of Chemicals & Petrochemicals.

17. The Committee are dismayed to note that the Government's expenditure on public health is less than 1 per cent of Plan outlay as against the guidelines of WHO to spend 5 per cent of the GDP. The Secretary, Chemicals & Petrochemicals submitted before the Committee that the Government propose to raise it to 2 to 3 per cent of GDP. Considering the regular outbreaks of deadly diseases in various parts of the country from time to time, the Committee would like the Government to address the issue in its entire significance. They, therefore, would like the Department to prepare a time schedule with specific plans for upgradation of the public healthcare system in the country for the benefit of the poor by raising the outlay for public health.

18. The Committee note that some of the States like Tamil Nadu procure medicines through a centralised tender system at a very low price than MRP for distribution for public health. In Rajasthan also, there are lifeline fluid stores which are working well in selling the fluid to the public through Government dispensaries. The Committee find that one of the terms of reference of the Task Force constituted under the Chairmanship of the Principal Adviser, Planning Commission to explore various options other than price control for achieving the objective of making available life saving drugs at reasonable prices, is to examine the issue of monitoring of prices and bulk/pooled procurement of medicines. The Committee are of the view that medicines can be procured under the pooled procurement system particularly for public hospitals, dispensaries, primary health centres etc. The Committee, therefore, recommend that the system of pool procurement of medicines should be evolved throughout the country in coordination with the State Governments.

19. The Committee find that the Department of AYUSH has been taking various initiatives to augment the quality control and monitoring of Ayurveda, Siddha, Unani and Homeopathy system of medicine. The Committee are of the view that traditional systems of medicine are in use in the country from the ancient times and form an important component in the country's health care system. The

Committee, therefore would like the Government to enhance the budget for these systems substantially to improve the health care in the country, particularly of the poor masses. Adequate publicity should be made of the action taken to propagate these medicines for the information of the public.

20. The Committee note that presently the issues relating to drugs and pharmaceuticals are being dealt by more than one Ministry. While the issue relating to pricing of drugs and pharmaceuticals policy comes under the Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals), the Health Policy is framed by the Ministry of Health and Family Welfare. The Ministry of Science and Technology deal with the Research & Development while patent issue is being looked after by the Ministry of Commerce and Industry. Evidently, there is no single authority at present, to deal with all the issues relating to drugs and pharmaceuticals in a coordinated and unified manner. It is pertinent to point out here that the 'Hathi Committee' recommended as far back as in 1975 for setting up of a 'National Drug Authority' for the purpose. This was also envisaged in the Modified Drug Policy announced in 1994. Unfortunately, the proposed authority is yet to be set up. The Department of Chemicals and Petrochemicals has informed that efforts are being made to strengthen the existing capacity of the Central Drugs Standard Control Organisation (CDSCO) which would be necessary before undertaking

**the new responsibilities and conversion of CDSCO into a full fledged Central Drug Authority. The Committee are of the opinion that a co-ordinated approach to deal with all issues relating to the drugs and pharmaceuticals brooks no delay. They therefore, strongly recommend that as envisaged in the modified Drug Policy, a National Drug Authority should be created without any further delay.**

**21. The Committee are concerned to note that after introduction of the product patent in India w.e.f. January, 2005, the availability of low cost medicines might be affected in the long run and for this the Indian Drug Industries will have to concentrate on Research and Development (R&D). In this context, during the course of evidence the Committee were apprised that a fund called Pharmaceutical Research and Development Support Fund (PRDSF) with a corpus of Rs.150 crore was set up under the Department of Science and Technology. Now, this fund has been converted from this year into an annual grant of Rs.150 crore. Further, as per the information made available to the Committee by the Department of Chemicals & Petrochemicals, the expenditure on R&D by the private sector pharma industry has increased from Rs. 219 crore in 1999-2000 to Rs. 1149 crore during 2003-04. However, this expenditure seems to be inadequate in view of the large amount being spent by the Pharma companies of the advanced countries. The Committee, therefore, recommend that budget for R&D on drugs should be increased substantially. For this, the Government should consider issuing directives to the big drug**

manufactures to earmark certain percentage of their turnover. The Government should also consider provision of fiscal incentives on a long-term basis for research and development efforts in drugs.

22. During examination of the subject, several State Governments have submitted to the Committee various suggestions to strengthen the Government's control over production, supply and marketing of drug formulations across the country. These suggestions which have been listed out elsewhere in the Report *inter-alia* include strengthening the State Drug Control Administration, bringing out publications by NPPA, bringing life saving drugs like anti-cancer and Anti-HIV drugs under price control, strengthening R&D in Pharma Sector, curbing spurious drugs, fixing ceiling on drug prices, pooled procurements for public health, etc. The Committee would like that the suggestions of the State Governments should be considered for incorporation in the proposed new Pharma Policy along with recommendations of the Committee contained in the preceding paragraphs as also the Report/ recommendations of the Task Force constituted under the Chairmanship of Principal Advisor, Planning Commission. The Committee would await Government's conclusive action taken in the matter within a period of six months from the presentation of their Report.

New Delhi;  
September 27, 2005  
Asvina 5, 1927 (Saka)

**ANANT GANGARAM GEETE**  
Chairman,  
Standing Committee on  
Chemicals & Fertilizers.

**FIRST SCHEDULE OF DPCO, 1995**

1. Sulphamethoxazole
2. Penicillins
3. Tetracycline
4. Rifampicin
5. Streptomycin
6. Ranitidine
7. Vitamin C
8. Betamethasone
9. Metronidazole
10. Chloroquine
11. Insulin
12. Erythromycin
13. Vitamin A
14. Oxytetracycline
15. Prednisolone
16. Cephazolin
17. Methyldopa
18. Aspirin
19. Trimethoprim
20. Cloxacillin
21. Sulphadimidine
22. Salbutamol
23. Famotidine
24. Ibuprofen
25. Metamizol (Analgin)
26. Doxycycline
27. Ciprofloxacin
28. Cefotaxime
29. Dexamethasone
30. Ephedrine
31. Vitamin B1 (Thiamine)
32. Carbamazepine
33. Vitamin B2 (Riboflavin)
34. Theophylline
35. Levodopa
36. Tolnaftate
37. Vitamin E
38. Nalidixic Acid
39. Griseofulvin
40. Gentamicin
41. Dextropropoxyphene
42. Halogenated Hydroxyquinoline
43. Pentazocine
44. Captopril
45. Naproxen
46. Pyrental



47. Sulphadoxine
48. Norfloxacin
49. Cefadroxyl
50. Panthoates & Panthenols
51. Furazolidone
52. Pyriethoxine
53. Sulphadiazone
54. Framycetin
55. Verapamil
56. Deleted<sup>x</sup>
57. Glipizide
58. Spironolactone
59. Pentoxifylline
60. Amodiaquin
61. Sulphamoxole
62. Frusemide
63. Pheniramine Maleate
64. Chloroxylenols
65. Becampicillin
66. Lincomycin
67. Chlorpropamide
68. Mebhydroline
69. Chlorpromazine
70. Methendienone
71. Phenyl Butazone
72. Lynestrinol
73. Salazosulphapyrine
74. Diosmine
75. Trimipramine
76. Deleted<sup>x</sup>

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x are omitted vide S.O. No. 626 (E) dated 02.09.1997.

**Appendix-I**

**MINUTES**

**STANDING COMMITTEE ON CHEMICALS & FERTILISERS  
(2004-05)**

**FIFTH SITTING**

**(14.09.2004)**

The Committee sat from 1530 hrs. to 1645 hrs.

*Present*

**Shri Anant Gangaram Geete - Chairman**

***Members  
Lok Sabha***

2. Shri Prahlad Joshi
3. Shri A.K. Moorthy
4. Shri P. Rajendran
5. Shri V.K. Thummar
6. Shri Bhanupratap Singh Verma
7. Shri Bhal Chandra Yadav

***Rajya Sabha***

8. Shri Raju Parmar
9. Shri Ajay Maroo
10. Dr. Chhatrapal Singh Lodha
11. Shri Sanjay Rajaram Raut
12. Shri Raj Mohinder Singh

***Secretariat***

1. Shri M. Rajagopalan Nair - *Joint Secretary*
2. Shri C.S. Joon - *Deputy Secretary*
3. Shri S.C. Kaliraman - *Under Secretary*

**Representatives of Department of Chemicals & Petrochemicals**

1.	Shri Ramesh Inder Singh	-	Joint Secretary
2.	Shri Gurdial Singh Sandhu	-	Joint Secretary
3.	Smt. Veenu Gupta	-	Director
4.	Shri Harish Kumar	-	Director
5.	Ms. Harmeet Singh	-	Director
6.	Shri Gurdeep Singh	-	Director

**Representatives of National Pharmaceutical Pricing Authority (NPPA)**

1.	Shri Vinay Bansal	-	Chairman
2.	Shri Pradip Mehra	-	Member Secretary
3.	Shri A.K. Parashar	-	Director
4.	Shri Y.K. Venkatesh	-	Director
5.	Shri O.P. Sharma	-	Director
6.	Shri B.S. Raghunthan	-	Director

2. At the outset, Hon'ble Chairman welcomed the members to the sitting of the Committee. After sometime, officers of the Department of Chemicals & Petrochemicals and representatives of National Pharmaceutical Pricing Authority (NPPA) were called in. The Chairman welcomed them and on his request they introduced themselves to the Committee.

3. Thereafter, the Committee were briefed by the officers of the Department of Chemicals & Petrochemicals and representatives of NPPA on the subject 'Availability and Price Management of Drugs and Pharmaceuticals'. During the course of briefing, the members were enlightened on various issues relating to price control of drugs, price differentials of drugs and pharmaceuticals, overcharging on drugs by pharmaceutical companies, levy of taxes on medicines, Patent Laws, spurious drugs, drug policies, etc. Members also raised some queries which were replied to by the representatives of Department and NPPA.

4. The Committee, thereafter, decided that a study tour may be undertaken to Jaipur and Mumbai in the month of October, 2004.

5. The verbatim record of the proceedings has been kept.

***The Committee then adjourned.***

## **Appendix- II**

### **MINUTES**

### **STANDING COMMITTEE ON CHEMICALS & FERTILISERS (2004-05)**

#### **SIXTH SITTING**

**(23.11.2004)**

The Committee sat from 1500 hrs. to 1615 hrs.

#### ***Present***

**Shri Anant Gangaram Geete - Chairman**

#### ***Members Lok Sabha***

2. Shri Afzal Ansari
3. Shri Sukhdev Singh Libra
4. Shri P. Rajendran
5. Kunwar Akshyay Pratap Singh
6. Shri V.K. Thummar
7. Shri Bhal Chandra Yadav
8. Shri A.K.S. Vijayan
9. Shri T. Madhusudhan Reddy

#### ***Rajya Sabha***

10. Shri Gireesh Kumar Sanghi
11. Dr. Chhatrapal Singh Lodha
12. Shri Sanjay Rajaram Raut
13. Shri T.R. Zeliang

#### ***Secretariat***

1. Shri M. Rajagopalan Nair - *Joint Secretary*
2. Shri C.S. Joon - *Deputy Secretary*
3. Shri S.C. Kaliraman - *Under Secretary*

**Representatives of Department of Chemicals & Petrochemicals**

- (i) Shri Pratyush Sinha - Secretary
- (ii) Shri G.S. Sandhu - Joint Secretary
- (iii) Shri Ramesh Inder Singh - Joint Secretary

**Representatives of National Pharmaceutical Pricing Authority (NPPA)**

- (I) Shri Vinay Bansal - Chairman
- (ii) Shri Pradip Mehra - Member Secretary

**Representatives of Ministry of Health & Family Welfare**

- (i) Shri B.R. Wadhawan - Deputy Drugs Controller

2. At the outset, Hon'ble Chairman welcomed the Members to the sitting of the Committee and also extended congratulation to Shri Madhusudhan Reddy, MP, Lok Sabha on his nomination to the Committee.

3. Thereafter, the representatives of the Ministry of Chemicals & Fertilizers, Department of Chemicals & Petrochemicals were called in. The Committee, then, took oral evidence of the representatives of the Department of Chemicals & Petrochemicals in connection with examination of the subject 'Availability and Price Management of Drugs and Pharmaceuticals'.

4. During the course of discussion, the main issues which were taken up are as under:-

- (i) Price control of drugs;
- (ii) New category of essential medicines which may not come under the list of life saving drugs;
- (iii) Making provisions for control of Drugs Controller General of India (DCGI) over State Drugs Controller;
- (iv) Monitoring of prices of decontrolled drugs and formulations;
- (v) Role of NPPA in fixation/revision of prices of drugs;
- (vi) Amendment required in Drug Price Control Order, 1995 and Essential Commodities Act, 1955;
- (vii) Export and import of drugs and pharmaceuticals;
- (viii) Exempting medicines from sales tax; and
- (ix) Research & Development activity in drugs and pharmaceuticals sectors.

5. A verbatim record of the proceedings has been kept.

***The Committee then adjourned.***

**Appendix-III**

**MINUTES**

**STANDING COMMITTEE ON CHEMICALS & FERTILIZERS  
(2004-05)**

**FOURTEENTH SITTING**

**(10.06.2005)**

The Committee sat from 1530 hrs. to 1740 hrs.

**Present**

**Shri P. Rajendran**

-

**Acting Chairman**

***Members  
Lok Sabha***

2. Shri Prahlad Joshi
3. Shri Sukhdev Singh Libra
4. Shri Tek Lal Mahto
5. Shri A.Venkatarami Reddy
6. Shri T. Madhusudhan Reddy
7. Shri Narsingrao H. Suryawanshi
8. Shri V.K. Thummar
9. Shri Bhanupratap Singh Verma
10. Shri Bhal Chandra Yadav

***Rajya Sabha***

11. Shri Ajay Maroo
12. Shri Raju Parmar
13. Shri Gireesh Kumar Sanghi
14. Shri R. Shunmugasundaram
15. Shri Raj Mohinder Singh
16. Shri T. R. Zeliang

***Secretariat***

1. Shri S.K. Sharma - Additional Secretary
2. Shri P. Sreedharan - Joint Secretary
3. Shri C.S. Joon - Director
4. Shri S.C. Kaliraman - Under Secretary

**Representatives of Low- Cost Standard Therapeutics (LOCOST)**

- |    |                     |   |                  |
|----|---------------------|---|------------------|
| 1. | Shri S. Srinivasan  | - | Managing Trustee |
| 2. | Dr. Anurag Bhargava | - | Consultant       |

**Representatives of All India Organisation of Chemists and Druggists (AIOCD)**

- |    |                   |   |   |
|----|-------------------|---|---|
| 1. | Shri R. B. Puri   | - | President                                       |
| 2. | Shri J. S. Shinde | - | General Secretary                               |
| 3. | Shri Batu Anwrade | - | Administrative Secretary                        |
| 4. | Shri R.K. Khera   | - | President, HSCDA                                |
| 5. | Shri Satish Vij   | - | General Secretary, HSCDA                        |
| 6. | Mahesh Parekh     | - | President, Sangli District Chemists Association |

At the outset, owing to non-presence of Chairman of the Committee, the Committee chose Shri P. Rajendran, a Member of the Committee to act as Chairman in accordance with Rule 258 (3) of Rules of Procedure and Conduct of Business in Lok Sabha. The Acting Chairman then welcomed the representatives of Low- Cost Standard Therapeutics (LOCOST) to the sitting of the Committee.

2. Thereafter, the representatives of LOCOST made a brief audio-visual presentation highlighting the activities of their organisation as well as problems being faced by the people in availability and pricing of drugs and pharmaceuticals. They specifically mentioned about price distortions in the same category of drugs and high margin being earned by traders.

3. Subsequently, the Committee called the representatives of All India Organisation of Chemists and Druggists (AIOCD) and welcomed them to the sitting. After hearing their views on the subject, the Members raised various queries which were answered by the representatives of AIOCD & LOCOST.

4. During the course of sitting, the following issues came up for discussion:-

- (i) Regulatory Mechanism for drugs & pharmaceuticals.
- (ii) Issues relating to spurious drugs.
- (iii) Issues relating to generic drugs and their high prices.
- (iv) Quality control/ check on drugs and need for National Drug Authority.
- (v) Rationalisation of prices of drugs and pharmaceuticals.
- (vi) Pooling of drugs in the country on the lines as being done in Tamil Nadu and Delhi.
- (vii) High Trade Margin on drugs and pharmaceuticals.

5. A verbatim record of the proceedings has been kept.

***The Committee then adjourned.***

**Appendix-IV**

**MINUTES**

**STANDING COMMITTEE ON CHEMICALS & FERTILIZERS  
(2004-05)**

**FIFTEENTH SITTING**

**(01.07.2005)**

The Committee sat from 1600 hrs. to 1800 hrs.

***Present***

**Dr. Chhatrapal Singh Lodha - In the Chair**

***Members  
Lok Sabha***

2. Shri Sukhdev Singh Libra
3. Shri A.K. Moorthy
4. Shri P. Rajendran
5. Shri Narsingrao H. Suryawanshi
6. Shri V.K. Thummar
7. Shri Bhanupratap Singh Verma
8. Shri A.K.S. Vijayan

***Rajya Sabha***

9. Shri Gireesh Kumar Sanghi
10. Shri Raj Mohinder Singh
11. Shri T. R. Zeliang

***Secretariat***

1. Shri C.S. Joon - Director



***Representatives of Indian Drug Manufacturers' Association (IDMA)***

1. Shri N.R. Munjal - Vice-President
2. Shri G. Wakankar - Executive Director
3. Shri S.K. Arya - Joint Director

***Representatives of Consumer Unity & Trust Society (CUTS)***

1. Shri Vinayak R Pandey - Asstt. Policy Analyst

***Representatives of All India Drug Action Network (AIDAN)***

1. Dr Mira Shiva - Managing Director
2. Dr Arun Kumar - Member

At the outset, owing to non-presence of Chairman of the Committee, the Committee chose Dr. Chhatrapal Singh Lodha, a Member of the Committee to act as Chairman in accordance with Rule 258 (3) of Rules of Procedure and Conduct of Business in Lok Sabha. The Acting Chairman then called the representatives of Indian Drug Manufacturers' Association (IDMA), Consumer Unity & Trust Society (CUTS) and All India Drug Action Network (AIDAN) and welcomed them to the sitting of the Committee.

2. Thereafter, the representatives of IDMA, CUTS and AIDAN expressed their views on the subject 'Availability and Price Management of Drugs & Pharmaceutical.

3. During the course of the sitting, the following issues came up for discussion:-

- (i) Pricing framework of drugs and pharmaceuticals and its rationalisation;
- (ii) Issues relating to spurious drugs;
- (iii) Compulsory licensing and regulations of drugs and pharmaceuticals;
- (iv) Product patent and its effect on prices of drugs;
- (v) High trade margin on drugs and pharmaceuticals;
- (vi) Removal of banned and bannable drugs from the market; and
- (vii) R&D activities on drugs.

4. A verbatim record of the proceedings has been kept.

***The Committee then adjourned.***

## **Appendix-V**

### **MINUTES**

## **STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2004-05)**

### **SIXTEENTH SITTING**

**(20.07.2005)**

The Committee sat from 1500 hrs. to 1800 hrs.

#### ***Present***

**Shri Anant Gangaram Geete - Chairman**

#### ***Members Lok Sabha***

2. Shri Sukhdev Singh Libra
3. Shri A.K. Moorthy
4. Shri P. Rajendran
5. Shri Narsingrao H. Suryawanshi
6. Shri V.K. Thummar
7. Shri Mansukhbhai D. Vasava
8. Shri Bhanupratap Singh Verma
9. Shri Bhal Chandra Yadav

#### ***Rajya Sabha***

10. Dr. Chhatrapal Singh Lodha
11. Shri Ajay Maroo
12. Shri Raju Parmar

#### ***Secretariat***

1. Shri P. Sreedharan - Joint Secretary
2. Shri C.S. Joon - Director
3. Shri S.C. Kaliraman - Under Secretary
4. Shri M.K. Madhusudhan - Under Secretary

**Representatives of Ministry of Chemicals & Fertilizers**  
**(Department of Chemicals & Petrochemicals)**

- |    |                    |   |                 |
|----|--------------------|---|-----------------|
| 1. | Ms. Satwant Reddy  | - | Secretary       |
| 2. | Shri R.I. Singh    | - | Joint Secretary |
| 3. | Shri G.S. Sandhu   | - | Joint Secretary |
| 4. | Shri Mukesh Kakkar | - | Joint Secretary |
| 5. | Shri K.M. Kaul     | - | Consultant      |

**Representatives of other Departments**

- |    |                      |   |   |
|----|----------------------|---|---|
| 1. | Shri Anthony De Sa   | - | Joint Secretary, Deptt. Of Commerce     |
| 2. | Shri Sanjay Kumar    | - | Director, Deptt. Of Commerce            |
| 3. | Shri Ashwini Kumar   | - | Drugs Controller General Of India       |
| 4. | Shri N.N. Prasad     | - | Joint Secretary, Dept.. Of Ipp          |
| 5. | Shri Shiv Basant     | - | Joint Secretary, Deptt. Of Ayush        |
| 6. | Dr. D.C. Katoch      | - | Dy. Adviser, Deptt. Of Ayush            |
| 7. | Dr. G. T. Samathanam | - | Adviser, Deptt. Of Sciency & Technology |
| 8. | Dr. R.R. Abhyankar   | - | Adviser, Dsir                           |
| 9. | Shri G.M. Bagai      | - | Scientist, Dsir                         |

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\*\*      \*\*      \*\*      \*\*      \*\*      \*\*      \*\*      \*\*      \*\*      \*\*      \*\*

2. At the outset, Hon'ble Chairman welcomed the Members and the representatives of the various Ministries/Departments concerned to the sitting of the Committee for examination of the subject 'Availability and Price Management of Drugs and Pharmaceuticals'.

3. Thereafter, the representatives of Department of Chemicals & Petrochemicals made a brief audio-visual presentation highlighting the activities of the Department particularly relating to the subject under examination.

4. The Committee then took evidence of the officials of Departments concerned on the various aspects of the subject. During the course of evidence, the following issues came up for discussion:-

- (i) Aspects relating to spurious drugs;
- (ii) Rationalisation of excise duty/taxes relating to drugs;
- (iii) Effects of introduction of VAT on the prices of medicines;
- (iv) Task Force for new Pharmaceutical Policy;
- (v) Research & Development in drugs and pharmaceutical sectors;
- (vi) Strengthening of drug regulatory mechanism and the National Pharmaceutical Pricing Authority (NPPA);
- (vii) Implementation of recommendations of Mashelkar Committee;
- (viii) Reducing trade margin on generic drugs;
- (ix) Need to create an independent body by Government of India to collect and for cross checking the data provided by ORG-MARG survey;
- (x) Ensuring the availability of essential drugs at reasonable rates; and
- (xi) Pharmaceutical Policy, 2002.

5.     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*

6.     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*

7. A verbatim record of the proceedings has been kept.

***The Committee then adjourned.***

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***\*\* Matter not related to this Report***

**Appendix-VI**

**MINUTES**

**STANDING COMMITTEE ON CHEMICALS & FERTILIZERS  
(2005-06)**

**SECOND SITTING**

**(27.09.2005)**

The Committee sat from 1200 hrs. to 1300 hrs.

***Present***

**Shri Anant Gangaram Geete - Chairman**

***Members***

***Lok Sabha***

2. Shri Prahlad Joshi
3. Sardar Sukhdev Singh Libra
4. Shri Tek Lal Mahto
5. Shri P. Rajendran
6. Shri Narsingrao H. Suryawanshi
7. Shri V.K. Thummar
8. Shri Bhanupratap Singh Verma
9. Shri A.K.S. Vijayan

***Rajya Sabha***

10. Shri Gireesh Kumar Sanghi
11. Shri Raju Parmar
12. Shri Ajay Maroo
13. Shri R. Shunmugasundaram
14. Shri Raj Mohinder Singh
15. Shri T.R. Zeliang

***Secretariat***

- |    |                     |   |                 |
|----|---------------------|---|-----------------|
| 1. | Shri P. Sreedharan  | - | Joint Secretary |
| 2. | Shri Brahm Dutt     | - | Director        |
| 3. | Shri S.C. Kaliraman | - | Under Secretary |

2. At the outset, the Hon'ble Chairman welcomed the Members to the sitting. He invited the Members to give their suggestions, if any, pertaining to the draft report which had been circulated to the Members.

3. Thereafter, the Committee considered the draft Report in detail on 'Availability and Price Management on Drugs and Pharmaceuticals' and adopted the same with some minor changes.

4. The Committee, then, authorised the Chairman to finalise the Report after factual verification from the Department of Chemicals & Petrochemicals. Considering the fact that the Government was in the process of formulation of a new Drug/Pharma Policy, the Committee decided that the Report may be presented to the Hon'ble Speaker instead of waiting for the Winter Session. This would facilitate the Government in considering their recommendations while formulating the new Drug/Pharma Policy.

5.     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*  
       \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*     \*\*

6. The Committee also appreciated the work done by the officials of the Lok Sabha Secretariat attached to the Committee in preparation of the Report.

***The Committee then adjourned.***