20

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2006-07)

FOURTEENTH LOK SABHA

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

AVAILABILITY AND PRICE MANAGEMENT OF DRUGS AND PHARMACEUTICALS

[Action Taken by the Government on the recommendations contained in the Seventh Report (Fourteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2005-06) on 'Availability and Price Management of Drugs and Pharmaceuticals']

TWENTIETH REPORT

LOK SABHA SECRETARIAT
NEW DELHI
July, 2007/Asadha, 1929 (Saka)

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[Action Taken by the Government on the recommendations contained in the Seventh Report (Fourteenth Lok Sabha) of the Standing Committee on Chemicals & Fertilizers (2005-06) on 'Availability and Price Management of Drugs and Pharmaceuticals']

Presented to Hon'ble Speaker on ***24.07.2007***

Presented to Lok Sabha on ***17.08.2007***

Laid in Rajya Sabha on ***17.08.2007***

LOK SABHA SECRETARIAT
NEW DELHI
July, 2007/Asadha, 1929 (Saka)

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2006-07)

Shri Anant Gangaram Geete - Chairman

Members
Lok Sabha

2. Shri Ajit Singh
3. Shri Suresh Angadi
4. Shri Afzal Ansari
5. Shri Jaiprakash (Mohanlal Ganj)
6. Shri Sunil Khan
*7. Shri Shrichand Kripalani
8. Shri Subhash Maharia
9. Shri Punnu Lal Mohale
$10. Shri A. Narendra
11. Shri Prasanta Pradhan
#12. Shri Ramswaroop Prasad
13. Shri P. Chalapathi Rao
14. Shri Ashok Kumar Rawat
15. Shri Anantha Venkata Rami Reddy
16. Shri Narsingrao H. Suryawanshi
17. Shri Mansukhbhai Dhanjibhai Vasava
18. Shri D. Venugopal
19. Shri Bhanu Pratap Singh Verma
+20. Vacant
21. Vacant

Rajya Sabha

22. Shri Devdas Apte
%23. Shri Debabrata Biswas
24. Shri B.S. Gnanadesikan
25. Shri Gireesh Kumar Sanghi
26. Shri V. Hanumantha Rao
@27. Shri Mahendra Sahni
28. Shri Dilip Singh Judev
29. Shri R. Shunmugasundaram
30. Shri Raj Mohinder Singh Majitha
31. Shri T.R. Zeliang

Secretariat

1.	Shri M. Rajagopalan Nair	-	*Additional Secretary*
2.	Shri A.K. Singh	-	*Joint Secretary*
3.	Shri A.S. Chera	-	*Director*
4.	Shri A.K. Srivastava	-	*Deputy Secretary-II*
5.	Smt. Balwant Kaur Saimbhi	-	*Under Secretary*
6.	Shri Prem Ranjan	-	*Senior Executive Assistant*

** Nominated w.e.f. 31.08.2006.*
$ Nominated w.e.f. 25.09.2006
@ Nominated w.e.f. 04.10.2006
 # Nominated w.e.f. 08.12.2006
+ Consequent upon nomination to the Committee on Transport, Tourism and Culture, Shri Prahlad Joshi, MP (LS) ceased to be Member of the Committee w.e.f. 20.03.2007
% Nominated w.e.f. 03.05.2007

INTRODUCTION

I, the Chairman, Standing Committee on Chemicals & Fertilizers (2006-07) having been authorised by the Committee to submit the Report on their behalf, present this Twentieth Report on Action Taken by the Government on the recommendations contained in the Seventh Report (Fourteenth Lok Sabha) of the Standing Committee on Chemicals & Fertilizers (2005-06) on 'Availability and Price Management of Drugs and Pharmaceuticals'.

2. The Seventh Report of the Committee was presented to Hon'ble Speaker on 28th September, 2005 and to Lok Sabha on 25th November, 2005. After its presentation, the Department was asked to furnish Action Taken Replies by 27th December, 2005, but the Department had furnished Action Taken Replies on 25th January, 2006. After examining the Action Taken Replies, it was found that except some replies, the most of the replies were inconclusive. The Department of Chemicals and Petrochemicals was, therefore, asked to furnish conclusive replies. The Department had finally furnished the updated replies on 25th June, 2007. The Standing Committee on Chemicals and Fertilizers (2006-07) considered the Action Taken Replies received from the Government and adopted the Draft Action Taken Report at their sitting held on 20th July, 2007.

3. An analysis of the Action Taken by the Government on the recommendations contained in the Seventh Report (Fourteenth Lok Sabha) of the Committee is given in **Appendix-II**.

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

NEW DELHI
July 20, 2007
Asadha 29, 1929 (Saka)

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

REPORT

CHAPTER – I

This Report of the Committee deals with the action taken by the Government on the recommendations/observations contained in the Seventh Report (Fourteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2005-06) on 'Availability and Price Management of Drugs and Pharmaceuticals' pertaining to the Ministry of Chemicals and Fertilizers (Department of Chemicals and Petrochemicals), which was presented to Hon'ble Speaker on 28th September, 2005 and presented to Lok Sabha on 25th November, 2005.

2. The Ministry of Chemicals and Fertilizers (Department of Chemicals and Petrochemicals) were requested to furnish replies to the recommendations/observations contained in the Seventh Report of the Committee within three months from the presentation of the Report i.e. by 27th December, 2005. The latest Action Taken Replies of the Government in respect of all the 22 recommendations/observations contained in the Report were received on 25th June, 2007. These have been categorised as follows:-

(i) Recommendations/observations which have been accepted by the Government:
Sl. Nos. 14, 15, 16, 19, 20 and 21. Total - 6

(ii) Recommendations/observations which the Committee do not desire to pursue in view of the Government's replies:
Nil

(iii) Recommendations/observations in respect of which replies of the Government have not been accepted by the Committee:
Sl. Nos. 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 17, 18 and 22.
Total - 16

(iv) Recommendations/observations in respect of which final replies of the Government are still awaited:
Nil

3. The Committee hope that utmost importance would be given to the implementation of the recommendations/observations accepted by the Government. In cases, where it is not possible for the Ministry to implement the recommendations/observations in their letter and spirit for any reason, the matter should be reported to the Committee with reasons for non-implementation. The Committee further desire that the Action Taken Notes on the recommendations/observations contained in Chapter-I of this Report should be furnished expeditiously.

4. The Committee will now deal with the action taken by the Government on some of their recommendations in the ensuing paragraphs:

A. National Pharmaceutical Policy, 2006

(Recommendation Sl.No. 1)

5. The Committee had recommended as under:-

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 Public interest Litigation, this new policy has not been enforced.

6. The Ministry, in their Action Taken Reply, have stated as follows:-

"The Government announced the 'Pharmaceutical Policy 2002' in February, 2002. This Policy envisaged substantial reduction in the span of price control. However, a public interest litigation filed in the High Court of Karnataka at Bangalore resulted in an order dated 12.11.2002, which stopped the Government from implementing the price control regime of the Pharmaceutical Policy-2002. This Department filed a Special Leave Petition (SLP) in the Supreme Court against the order of the Karnataka High Court, which has been admitted as SLP (C) No.3668/2003. The Supreme Court vide its order dated 10.3.2003 directed the Government, *interalia*, as follows:- "we suspend the operation of the order to the extent it directs that the Policy dated 15.2.2002 shall not be implemented. However, we direct that the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of the price control and further directed to review drugs, which are essential and life saving in nature till 2nd May, 2003".

Ministry of Health and Family Welfare has brought out the National List of Essential Medicines, 2003 after the review of the National Essential Drugs List, 1996.

Subsequently, a Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the directions of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objectives of National Common Minimum Programme to ensure availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government. The Committee has recommended, *inter-alia*, intensive monitoring of prices of all those drugs out of the selected basket (National List of Essential Medicines, 2003) which are not under price control, ceilings on trade margins of drugs, a system of price negotiations for the new patented drugs, special schemes for people below poverty line, introduction of Rajasthan Model of Life Line Fluid Stores (hospital pharmacy stores run by Medicare Societies) for bulk purchase of drugs directly from manufacturers and selling them at reduced prices, compounding of offences under the Essential Commodities Act, establishment of DPCO cells in all States on the model of Karnataka etc., efforts to increase public awareness, wide publicity to policies and decisions of the Government and NPPA etc. Follow up action has been initiated on the recommendations made by the Committee in its interim report.

Thereafter, a Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force has submitted its report to the Government on the 20th September,

2005. Some of the salient recommendations of the Task Force are, that Price Controls should be imposed on the 'essentiality' of the drug and not on the basis of turnover and it should be applied only to formulations and not to bulk drugs. Some of the other major recommendations of Task Force are to promote generic drugs, to encourage public health facilities, to revive the Public Sector Enterprises in the manufacture of drugs, to provide fiscal incentives in R&D activities in drugs, to provide financial support for implementation of Schedule M of Drugs and Cosmetics Rules, to enact Drugs and Therapeutics (Regulation) Act, to establish a National Authority on Drugs and Therapeutics (NADT), to establish price negotiation process for new patented drugs, to streamline the bulk procurement regime, to exempt the excise duty, customs duty and other levies on cancer and anti HIV/AIDS drugs, to establish the State Illness Funds in the States/Union Territories for BPL families, to reduce the excise duty on drugs from 16 to 8%,to enhance the exemption limit of SSI units from Rs.1 crores to Rs.5 crores, to establish a Settlement Commission which is authorized to settle the disputed overcharged amount from the pharma companies.

Recently, a Core Group under the Chairmanship of Joint Secretary (PI) has been constituted by this Department to examine the recommendations of the Task Force and to draft a new Pharmaceutical Policy.

On the basis of the recommendations of the Committee under the Chairmanship of JS(PI), recommendations of the Task Force and discussions with various stakeholders; draft National Pharmaceutical Policy was prepared by this Department and was considered by the Cabinet in its meeting held on 11.1.2007. The Cabinet has referred the proposed Policy to a Group of Ministers (GOM). The First meeting of the GOM was held on 10.4.2007. No time frame has been set up for finalizing the National Pharmaceutical Policy."

(Recommendation Sl.No. 2)

7. The Committee had recommended as under:-

Recently, the Government had 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 had submitted its draft recommendations to the Government and a new Pharma Policy would be formulated by the Government after considering the recommendations of the Task Force along with other inputs on the subject.

8. The Ministry, in their Action Taken Reply, have stated as follows:-

"The Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices, has submitted its report to the Government on the 20th September, 2005. Some of the salient recommendations of Task Force are, that Price Controls should be imposed on the 'essentiality' of the drug and not on the basis of turnover and it should be applied only to formulations and not to bulk drugs. Some of the other major recommendations of Task Force are to promote generic drugs, to encourage public health facilities, to revive the Public Sector Enterprises in the manufacture of drugs, to provide fiscal incentives in R&D activities in drugs, to provide financial support for implementation of Schedule M of Drugs and Cosmetics Rules, to enact Drugs and Therapeutics (Regulation) Act, to establish a National Authority on Drugs and Therapeutics (NADT), to establish price negotiation process for new patented drugs, to streamline the bulk procurement regime, to exempt the excise duty, customs duty and other levies on cancer and anti HIV/AIDS drugs, to establish the State Illness Funds in the States/Union Territories for BPL families, to reduce the excise duty on drugs from 16 to 8%,to enhance the exemption limit of SSI units from Rs.1 crores to Rs.5 crores, to establish a Settlement Commission which is authorized to settle the disputed overcharged amount from the pharma companies.

The Task Force has recommended the National List of Essential Medicines (NLEM) should form the basis of drugs to be considered for intensive price monitoring, ceiling prices and imposing price control, if any. To initiate this process, the Government should announce the ceiling price of the drugs contained in NLEM (other than the drugs procured by hospitals directly and which an individual does not have to purchase from the market) on the basis of weighted average of the top three brands based on value.

At present, the National List of Essential Medicines, 2002 consists of 354 essential items. Out of which approximately 40 items are being procured by the hospitals directly and, therefore, as per the Task Force recommendations the ceiling price proposal is not applicable on them. This results into the Government fixing the ceiling price of 314 essential ingredients out of the list of 354 prepared by the Health Ministry as per NLEM 2003.

The recommendations of the Task Force have been taken into consideration while framing draft National Pharmaceutical Policy,2006, which is being examined by a Group of Ministers (GOM)."

(Recommendation Sl.No. 3)

9. The Committee had recommended as under:-

The Committee (the erstwhile Standing Committee on Petroleum & Chemicals) had examined the 'Draft National Drug Policy' and had submitted their Second report to Parliament on 6th 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 (13th Lok Sabha) had again examined 'Pricing and Availability of Drugs/Pharmaceuticals' and had presented their 15th Report to Parliament on 29th August, 2001. The Committee's examination of 'Availability and Price Management of Drugs and Pharmaceuticals' has been 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 Report was related 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 had desired that their recommendations were to be considered in the formulation of the new Drug/Pharma Policy, which was being prepared on the basis of the recommendations of the Task Force constituted by the Government.

10. The Ministry, in their Action Taken Reply, have stated as follows:-

"M/o Health and Family Welfare has stated that the Government is committed to increasing the allocation for health sector and as per the Common Minimum Programme, the Government will raise public spending on health to at least 2-3% of GDP over the next five years with focus on primary health care. As a consequence of this commitment of the Government an ambitious National Rural Health Mission has also been launched recently. In respect of the issue of

'strengthening drug control offices throughout the country to have proper control over the production and availability of essential drugs and pharmaceuticals', it is pointed out that under the World Bank assisted Capacity Building Programme drug regulatory officials as well as personnel of drug and pharmaceutical SSI units are being given training in quality control and safety as well as regulation aspects of drugs and pharmaceuticals.

D/o Scientific & Industrial Research has stated that Government has instituted several fiscal incentives from time to time for enhancing R&D expenditure in industry. Many companies in drugs and pharmaceutical sector have increased their R&D expenditure. These companies have created state of the art R&D facilities and are carrying out cutting edge research in their research centers. Many companies have accessed regulated international market by filing patents based on non-infringing processes.

Recommendations of the Standing Committee have been taken into consideration by the Government while framing draft National Pharmaceutical Policy, 2006, which is being examined by a Group of Ministers (GOM)."

B. Inclusion of drugs in the schedule for price control

(Recommendation Sl. No. 4)

11. The Committee had recommended as under:-

The Committee had noted that 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, had strongly recommended 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. The Committee had also recommended that 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 were increasingly affecting the urban and rural poor masses.

12. The Ministry, in their Action Taken Reply, have stated as follows:-

"M/o Health and Family Welfare has stated that these issues are being addressed under the National Cancer Control Programme, National TB Control Programme and the National HIV/AIDSs Control Programme (NACP-II).

Essential Drugs meant for diseases like Cancer, TB, HIV/AIDs are part of National List of Essential Medicines,2003, which has been included as part of draft Pharmaceutical Policy,2006. The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM)."

C. Strengthening of the National Pharmaceutical Pricing Authority (NPPA)

(Recommendation Sl.No. 5)

13. The Committee had recommended as under:-

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 were distressed to note that NPPA depended entirely on a private organisation's Survey reports for price related data in the country. The Committee had recommended the Government to strengthen the wings of NPPA to make it self-sufficient to carry out its activities independently and effectively.

14. The Ministry, in their Action Taken Reply, have stated as follows:-

"National Common Minimum Programme (NCMP) stipulates, inter-alia, that " The UPA Government will take all steps to ensure availability of life saving drugs at reasonable prices". For this purpose, NCMP provides the amount for the following Schemes:-

1. Computerization (Hardware) needed for monitoring Rs.28 lakhs

NPPA has undertaken the exercise of computerization of day to day work of NPPA with the help of M/s C-DAC and M/s C-DAC put most of the data on computer for speedy implementation of decisions of the NPPA and day to day monitoring.

2. Monitoring System (software, data collection etc.) of drug prices Rs.73.70 lakhs

A good monitoring system would put an effective check on the indiscriminate increase in price, which may take place from time to time. This will give a major relief to the common man and fulfill the stated objective of NCMP.

<u>Advertisement in Newspapers :</u>

NPPA have already started advertisement- showing cases of reduction in prices of formulations in various Newspapers with the help of Directorate of Advertisement and Visual Publicity (DAVP).

Strengthening of NPPA has been included as part of draft Pharmaceutical Policy,2006. The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM)."

D. Amendment to Drugs (Prices Control) Order, 1995

(Recommendation Sl. No. 6)

15. The Committee had recommended as under:-

The Committee had noted 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, had desired that DPCO, '95 should be amended suitably to incorporate provisions for compounding offences by stringent fines or penalties therein.

16. The Ministry, in their Action Taken Reply, have stated as follows:-

"A Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the observations of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objective of National Common Minimum Programme to ensure the availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government.

Subsequently, a Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force deliberated upon all the recommendations of the Committee under Chairmanship of JS(PI) made in its interim report and has submitted its report to the Government on the 20th September, 2005.

The Government is examining the recommendations of the Task Force with various stakeholders and based on that Draft Pharmaceutical Policy-2006 (Part-A) (excluding pricing mechanism) has been prepared and circulated amongst various

Ministries/Departments of the Government/States/UTs and various stakeholders inviting their comments on 25.1.2006.

Recommendations received from various State Governments and other stakeholders have been included in the draft National Pharmaceutical Policy,2006. In the draft Policy it has also been recommended to enact a new law i.e. Drug (Price Regulation and Control) Act (DPRCA), to enable a more effective price control/monitoring of the prices of drugs as also to provide for compounding of certain offences and to regulate production, distribution and supply during health emergencies. The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM)."

E. Creation of DPCO Cells in all States

(Recommendation Sl.No.7)

17. The Committee had recommended as under:-

The Committee had found that the prices of drugs were not being monitored effectively at the State level. In this regard, they had been apprised by the Department of Chemicals and Petrochemicals that except in Karnataka where a DPCO Cell had been constituted for monitoring the prices of drugs, which was working well, there was no effective mechanism in other States. There was a proposal by the Department to establish DPCO Cells in all the States on the model of Karnataka, which would report to NPPA. The Committee, therefore, had desired 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.

18. The Ministry, in their Action Taken Reply, have stated as follows:-

"The idea of creation of a DPCO cell in each state has also been supported by the Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser in its report submitted to the Government on 20.9.2005. A DPCO Cell will primarily be responsible for following functions:

- to ensure implementation of prices fixed/revised by NPPA from time to time;

- to detect cases of overcharging and forward the same to NPPA for further action;
- to follow up the overcharging cases for recovery of overcharged amount
- to ensure availability of data from manufacturing units, where units fail to provide •data/information for NPPA;
- to ensure availability of drugs in their states &
- any other work assigned from time to time for enforcement of Drug Policy/DPCO.

The issue of creation of DPCO cell in all States have been included as part of the draft National Pharmaceutical Policy,2006. Such Cells will be constituted after finalization of the Policy."

F. Strengthening of the NPPA and the Drug Regulatory Mechanism in the States

(Recommendation Sl. No. 8)

19. The Committee had recommended as under:-

The Committee's examination had clearly revealed that there was 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 depended on the State Drug Administration for feedback in fixing/regulating the prices of drugs and pharmaceuticals. However, the Committee found that there was 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 had been started and a scheme for its computerization had been approved. The Committee felt 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, had recommended 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.

20. The Ministry, in their Action Taken Reply, have stated as follows:-

"A Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force has submitted its report to the Government on the 20th September, 2005. Some of the salient recommendations of Task Force are, to establish price negotiation process for new patented drugs i.e. all patented drugs and their formulations should compulsory be brought under price negotiation prior to the grant of marketing approval. Failure of such negotiations should then invite either price control or compulsory licensing, to provide financial support for implementation of Schedule M of Drugs and Cosmetics Rules, to enact Drugs and Therapeutics (Regulation) Act, to establish a National Authority on Drugs and Therapeutics (NADT). The Government is examining the recommendations of the Task Force with various stakeholders and based on that Draft Pharmaceutical Policy-2006 (Part-A) (excluding pricing mechanism) has been prepared and circulated amongst various Ministries/Departments of the Government/States/UTs and various stakeholders inviting their comments on 25.1.2006.

NPPA has also initiated an exercise to computerize its day-to-day work and various records with the help of M/s C-DAC. For intensive monitoring of essential medicines, monitoring of non-Scheduled medicines and also day to day work relating to fixation of bulk drug prices, fixation of formulation prices, legal and overcharging cases and other administrative work, it has been decided to make use of computers.

Proposals for Strengthening of NPPA and Drug Regulatory System in the country have been included as part of the draft National Pharmaceutical Policy,2006. The M/o Health and Family Welfare is in the process of constituting the Central Drug Authority by amending the Drugs & Cosmetics Act,1940. Amendment Bill in this regard is likely to be introduced in the Parliament soon."

G. Price Negotiation Mechanism for the new patented drugs

(Recommendation Sl. No. 9)

21. The Committee had recommended as under:-

The Committee had noted that not all patented drugs are under price control in the country. They felt 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 had been expressed about its possible impact on prices, in particular. In this regard, the Department of Chemicals and Petrochemicals had informed that some kind of monitoring strategies, price negotiations etc. were 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, fixed a maximum chargeable price for patented medicines by the pharmaceutical manufacturers and any attempt to impose higher prices than the fixed ones attracted 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 were contemplating that there should be a price negotiation mechanism for the new patented drugs prior to the grant of marketing approval. The Committee had desired that the proposal should be concretized and enforced in the country expeditiously.

22. The Ministry, in their Action Taken Reply, have stated as follows:-

"A Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force has submitted its report to the Government on the 20th September, 2005. One of the salient recommendations of Task Force to establish price negotiation process for new patented drugs i.e. all patented drugs and their formulations should compulsory be brought under price negotiation prior to the grant of marketing approval. Failure of such negotiations should then invite either price control or compulsory licensing.

In the draft National Pharmaceutical Policy,2006, it is proposed that the patented drugs (formulations under product patent) that would be launched in India, would be subjected to price negotiations before granting them marketing approval. A Committee of this Department is examining this issue."

H. Determination of ceiling price for the category of drugs for the same therapeutic use

(Recommendation Sl. No. 10)

23. The Committee had recommended as under:-

The Committee had noted that as per the policy, drugs in which there was sufficient market competition were kept outside price control. The criteria for deciding sufficient market competition was that there were at least 5 bulk producers and 10 formulators and none of them had more than 40 per cent market share in the retail trade. It had been stated by the representatives of non-official organizations during their evidence before the Committee that in actual practice, a fair competitive situation did not exist in the market. According to them, the brand leader was the price leader in most of the cases and hence, the market forces did 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 was a provision that a strict watch would be kept on the movement of the prices and the Government might determine the ceiling levels beyond which increase in prices would not be permissible, this provision had seldom been applied. In this context, some of the State Governments had 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 were unhappy over this unsatisfactory state of affairs and had desired that the situation should be remedied forthwith. They, therefore, had recommended that for the category of drugs for the same therapeutic use, the Government should determine a reasonable ceiling beyond which increase in prices might not be allowed.

24. The Ministry, in their Action Taken Reply, have stated as follows:-

"As per the present Price control policy, the 74 bulk drugs specified in the First Schedule of the Drugs (Prices Control) Order, 1995 (DPCO, 95) and the formulations based thereon are under price control. Their prices are fixed / revised by the National Pharmaceutical Pricing Authority (NPPA) in accordance with the provisions of the DPCO, 95. There has been no instance in the notice of this Department, where the entry of the new drugs is being blocked by present price control policy.

Prices of non-Scheduled 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 where the public interest is found to be adversely affected.

A Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the observations of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objective of National Common Minimum Programme to ensure the availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government. As regards, trade margins, the Committee felt that the present norms for Scheduled Drugs should continue i.e. 8% for wholesalers and 16% for retailers. In case of non-Scheduled Drugs the recommended trade margins are 10% for wholesalers and 20% for retailers for the branded category of drugs and higher margins of 15% and 35% for wholesalers and retailers respectively for the generic drugs. These margin would be inclusive of various trade discounts offered by industry to dealers. However, modalities of implementation need to be worked out in consultation with NPPA and industry.

The Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force has submitted its report to the Government on the 20th September, 2005.

The Government is examining the recommendations of the Task Force with various stakeholders and based on that Draft Pharmaceutical Policy-2006 (Part-A) (excluding pricing mechanism) has been prepared and circulated amongst various Ministries/Departments of the Government/States/UTs and various stakeholders inviting their comments on 25.1.2006.

NPPA regularly monitors the prices of non-Scheduled formulations on the basis of ORG-IMS data. Recently the annual price increase ceiling for all non-Scheduled drugs has been reduced to 10% from the earlier 20% ceiling."

I. Promotion of Generic drugs

(Recommendation Sl. No. 11)

25. The Committee had recommended as under:-

It had come out during examination that Indian Drug Companies exported generic drugs worth thousands of crores of rupees to various developed and developing countries. However, these very companies promoted aggressively the same drugs as highly priced branded drugs/formulations in the domestic market. Reportedly medical representatives influenced the professionals to prescribe branded drugs. This phenomenon had prevented the masses from access to the low cost generic medicines manufactured by the Indian Drug Industry. The Committee were of the considered view that in order to overcome this situation, there was an urgent need for promotion of generic drugs in a big way. They, therefore, had desired 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 were able to get quality drugs at reasonable prices.

26. The Ministry, in their Action Taken Reply, have stated as follows:-

"M/o Health and Family Welfare and DCG (I) have informed that promotion of generic drugs is a policy matter. It has been provided Under the Drugs and Cosmetics Rules that the proper name of generic drug is printed in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name.

The Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force has submitted its report to the Government on the 20th September, 2005. The Task Force has recommended inter-alia to promote generic drugs.

In the draft National Pharmaceutical Policy,2006 several measures have been proposed to promote the use of generic drugs viz. Public procurement and

distribution of drugs through the public health system would preferably be for generic drugs, Quality certification would be provided free of cost to generic drug manufacturers through an appropriate scheme by Health Department, No price control on prices of generic drugs provided prices of these have been fixed by the manufacturer keeping in view the prescribed trade margins.

The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM)."

J. Reduction of the trade margins particularly on essential and life saving drugs

(Recommendation Sl. No. 12)

27. The Committee had recommended as under:-

The Committee found that for non-Scheduled drugs, the Maximum Retail Price (MRP) printed by the manufacturers was very high. While the drug was available to retailers at a substantially low price, the benefit did not percolate to the consumer. When the Committee had drawn 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 had 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 had further observed 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 that 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 were not convinced of the reasons advanced by the Department. They, therefore, had strongly recommended that the Department of Chemicals and Petrochemicals should take concrete steps to reduce the trade margins, particularly on essential and life saving drugs.

28. The Ministry, in their Action Taken Reply, have stated as follows:-

"A Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the observations of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objective of National Common Minimum Programme to ensure the availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government. As regards, trade margins, the Committee felt that the present norms for Scheduled Drugs should continue i.e. 8% for wholesalers and 16% for retailers. In case of non-Scheduled Drugs the recommended trade margins are 10% for wholesalers and 20% for retailers for the branded category of drugs and higher margins of 15% and 35% for wholesalers and retailers respectively for the generic drugs. These margins would be inclusive of various trade discounts offered by industry to dealers. However, modalities of implementation need to be worked out in consultation with NPPA and industry.

A Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force deliberated upon all the recommendations of the Committee under Chairmanship of JS(PI) made in its interim report and has submitted its report to the Government on the 20th September, 2005.

The Government is examining the recommendations of the Task Force with various stakeholders and based on that Draft Pharmaceutical Policy-2006 (Part-A) (excluding pricing mechanism) has been prepared and circulated amongst various Ministries/Departments of the Government/States/UTs and various stakeholders inviting their comments on 25.1.2006.

The issue of trade margin has been included in the draft National Pharmaceutical Policy,2006, which is being examined by a Group of Ministers (GOM)."

K. Dropping of hazardous and obsolete drugs from the list of scheduled drugs

(Recommendation Sl. No.13)

29. The Committee had recommended as under:-

The Committee had noted that there existed 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 had 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 felt that such unscientific and irrational drugs were manufactured and promoted only with the profit motive. They, therefore, had desired 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 had also recommended that the Government should discourage promotion of unscientific and irrational drugs.

30. The Ministry, in their Action Taken Reply, have stated as follows:-

"DCG (I) has stated that no drug is totally safe and there is no such system of drugs getting banned or withdrawn internationally. Drugs used in some countries may not be used in others. As far as drugs like Vitamin E and Analgin are concerned, the current scientific evidence does not indicate them to be unscientific or hazardous. Analgin, Vitamin E etc. continue to be used in large number of countries. However, on the basis of continued examination of drug formulations marketed in the country by the Sub-Committee of DTAB about 76 drug categories have been prohibited for manufacture and sale. This is a continuous exercise. A separate review of the drugs which got listed in the First Schedule to the DPCO could, however, be taken up by the Sub-Committee of DTAB.

In order to discourage proliferation of irrational drug formulations, the M/o Health has amended the relevant provisions in the Drugs and Cosmetic Rules in order to ensure that the State Licensing Authorities on their own do not approve new drug formulations. Besides this, the Secretary Health, has personally taken up the matter with the Chief Secretaries of few States where the State Licensing Authorities were observed to be issuing unauthorized approvals on the basis of turnover criteria. It is, however, pertinent to note that the existing First Schedule under DPCO is likely to undergo total change in the light of the recommendation of Task Force and the subsequent formulation of new Drug Policy by D/o C&PC.

The issue of control on Pharmaceutical brands has been included in the draft National Pharmaceutical Policy, 2006. Further action to check the misbranding of drugs is to be taken by the M/o Health and Family Welfare after finalization of draft National Pharmaceutical Policy, 2006."

L. Raising the outlay for public health

(Recommendation Sl. No. 17)

31. The Committee had recommended as under:-

The Committee had noted that the Government's expenditure on public health was 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 had submitted before the Committee that the Government proposed 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 had asked the Government to address the issue in its entire significance. They, therefore, had asked 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.

32. The Ministry, in their Action Taken Reply, have stated as follows:-

"The Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission constituted to explore options other than price control to make available life saving drugs at reasonable prices has submitted its report to the Government on the 20th September, 2005.

One of salient recommendations of Task Force is that Insurance companies should be encouraged to extend health insurance to cover medicines. Public-private partnership for providing health care services, including insurance and group health plans, should be actively encouraged.

The Government is examining the recommendations of the Task Force in consultation with various stakeholders and based on that a new Pharmaceutical Policy will be announced shortly. New Policy initiatives will include : Health Cess @2% for funding certain schemes relating to healthcare of the poor; introduction of a new scheme by the name of 'Rashtriya Swasthya Bima Yojna' in the country for the BPL families.

Latest requisite information is being called from M/o Health and Family Welfare and will be provided thereafter."

M. System of pool procurement of medicines

(Recommendation Sl. No. 18)

33. The Committee had recommended as under:-

The Committee had noted that some of the States like Tamil Nadu procured medicines through a centralized tender system at a very low price than MRP for distribution for public health. In Rajasthan also, there were lifeline fluid stores which were working well in selling the fluid to the public through Government dispensaries. The Committee had found 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, was to examine the issue of monitoring of prices and bulk/pooled procurement of medicines. The Committee were of the view that medicines could be procured under the pooled procurement system particularly for public hospitals, dispensaries, primary health centers etc. The Committee, therefore, had recommended that the system of pool procurement of medicines should be evolved throughout the country in coordination with the State Governments.

34. The Ministry, in their Action Taken Reply, have stated as follows:-

"A Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the observations of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objective of National Common Minimum Programme to ensure the availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government. The Committee has studied the Rajasthan Model of Medicare Societies through which Life-line Fluid Stores have been opened in all the Government Hospitals at State, Divisional and District levels. Through these stores some of the essential drugs, antibiotics, injections, IV Fluids etc. are procured through open tenders directly from the manufacturing companies. Some of these drugs are made available to patients at less than 50% of the prevailing market prices.

Subsequently, the Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other

than price control to make available life saving drugs at reasonable prices. The Task Force deliberated upon all the recommendations of the Committee under the Chairmanship of JS(PI) and has submitted its report to the Government on the 20th September, 2005. Some of the salient recommendations of Task Force are, to revive the Public Sector Enterprises in the manufacture of drugs, to establish the State Illness Funds in the States/Union Territories and for setting up revolving funds in all Government Hospitals for making available medicines free of cost to the BPL families. Also, there is need to give wide publicity to these schemes so that maximum poor people can take advantage of these schemes.

In the draft National Pharmaceutical Policy, 2006 various measures have been recommended for streamlining system of bulk procurement of drugs by Central Government as well as State Government. The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM)."

N. Suggestions of State Governments

(Recommendation Sl. No. 22)

35. The Committee had recommended as under:-

During examination of the subject, several State Governments had 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 *inter-alia* included 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 had recommended that the suggestions of the State Governments should be considered for incorporation in the proposed new Pharma Policy along with recommendations of the Committee and 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.

36. The Ministry, in their Action Taken Reply, have stated as follows:-

"A Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the observations of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objective of National Common Minimum Programme to ensure the availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government.

Subsequently, a Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force deliberated upon all the recommendations of the Task Force and has submitted its report to the Government on the 20th September, 2005.

During the course of discussions under the Chairmanship of JS(PI) and the Task Force, there was active inter-action with the State Government/UTs on the issue of drafting new Pharmaceutical Policy. Their comments/views have been taken into consideration while drafting new Pharmaceutical Policy.

The Government is examining the recommendations of the Task Force with various stakeholders and based on that Draft Pharmaceutical Policy-2006 (Part-A) (excluding pricing mechanism) has been prepared and circulated amongst various Ministries/Departments of the Government/States/UTs and various stakeholders inviting their comments on 25.1.2006.

Recommendations received from various State Governments and other stakeholders have been included in the draft National Pharmaceutical Policy,2006. In the draft Policy it has also been recommended to enact a new law i.e. Drug (Price Regulation and Control) Act (DPRCA), to enable a more effective price control/monitoring of the prices of drugs as also to provide for compounding of certain offences and to regulate production, distribution and supply during health emergencies. The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM)."

37. The Committee note that their Seventh Report on 'Availability and Price Management of Drugs and Pharmaceuticals' was presented to Hon'ble Speaker on 28th September, 2005 and to Lok Sabha on 25th November, 2005. Most of the important recommendations relate to finalization of New Pharma Policy, inclusion of essential and life saving drugs in the schedule for price control, strengthening of the National Pharmaceutical Pricing Authority, amendment to Drugs (Prices Control) Order, 1995, creation of DPCO Cells in all States, strengthening of the Drug Regulatory Mechanism in the States, Price Negotiation Mechanism for the new patented drugs, determination of ceiling price for the drugs, promotion of generic drugs, reduction of the trade margins particularly on essential and life saving drugs, dropping of hazardous and obsolete drugs from the list of scheduled drugs, raising the outlay for public health and system of pool procurement of medicines. The replies of the Ministry to all the aforesaid issues are inconclusive as these all are subject to the finalization of National Pharmaceutical Policy, 2006. The Committee regret to note that even after the expiry of more than one and half year of presentation of the Report, the Ministry in their replies to almost all the recommendations have stated that recommendations of the Committee have been taken into consideration by the Government while framing draft National Pharmaceutical Policy, 2006 which was considered by the Cabinet in its meeting held on 11.01.2007. The Cabinet has referred the proposed policy to a Group of Ministers (GOM). The first meeting of the GOM was held on 10.04.2007. No time frame has been fixed for finalizing the

National Pharmaceutical Policy. The Committee, therefore, strongly express their anguish about the insensitivity of the Government on such an important policy which is the basis of implementation of various vital issues as enumerated above. The Committee feel that dilly-dallying tactics of the Government on this count is the main reason for non-finalization of the National Pharmaceutical Policy, 2006 so far. Considering these facts, the Committee now hope that all out efforts shall be made by the Government to implement the recommendations of the Committee so as to finalize National Pharmaceutical Policy, 2006.

O. Quality control and check on the sale and distribution of spurious drugs in the market

(Recommendation Sl. No. 14)

38. The Committee had recommended as under:-

The Committee had noted that a number of spurious/fake/counterfeit/sub-standard drugs were available in the market which were becoming a health hazard for the common people. The representative of the Ministry of Health and Family Welfare had admitted candidly during oral evidence before the Committee that unfortunately, the monitoring and regulatory system had been rather fragmented in the country and that spurious drug manufacturing had been done mostly by the criminal elements in a very clandestine manner. In the Committee's view such a situation existed due to unregulated pharmaceutical manufacturing units being run by some unscrupulous drug manufacturers. The Committee, therefore, had recommended 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.

39. The Ministry, in their Action Taken Reply, have stated as follows:-

"DCG(I) has stated that strengthening of drug regulatory authorities including creation of a National Drug Authority is under active consideration of the that Ministry under a Capacity Building Project supported by World Bank. The M/o Health is providing substantial assistance to all States Drug Testing Laboratories in terms of costly equipments, buildings, manpower, training and consumables etc. in order to augment their testing capacities and to reduce the time taken for issuing test reports.

Detailed guidelines in regard to strategies which need to be followed by all States Drug Control Organizations for effective monitoring of possible movement of spurious drugs and to nab the criminal elements involved in such activities has been advised to all States. Draft Bill proposing amendments to the D&C Act in order to enhance the penalties and to empower police to file prosecution etc. has already been introduced in the Parliament.

The M/o Health and Family Welfare has reported that there is a proposal to set up Central Drugs Authority of India to provide technical vision and policy direction for the pharmaceutical and cosmetics sectors and their regulation in the country. For this purpose, Drugs and Cosmetics Act, 1940 is being amended.

So far as the issue of spurious drugs is concerned, it is stated that Drugs & Cosmetics Act,1940 is handled by M/o Health and Family Welfare. They have proposed several amendments in the Act based on the recommendations of the Report (on counterfeit drugs) of the Mashelkar Committee in 2003. Both the amendment bills are likely to be introduced in the Parliament soon."

40. The Committee note that the subject matter pertaining to the check and sale of the spurious drugs falls under the jurisdiction of Ministry of Health and Family Welfare and State Governments. Nonetheless the Committee cannot keep themselves aloof from this burning issue. As such the Committee find it appropriate to comment on the subject which is closely linked with the adherence to quality control of drugs. The Committee also note that strengthening of drug regulatory authorities including creation of a National Drug Authority is under active consideration of the Government. The Committee further note that draft Bill proposing amendments to the Drugs and Cosmetic Act, 1940 in order to enhance the penalties and to empower police to file prosecution has been introduced in the Parliament. Drugs and Cosmetics Act, 1940 is being amended to set up Central Drugs Authority of India to provide technical vision and policy direction for the pharmaceutical and cosmetics sectors and their regulation in the country. The Committee further note that the Ministry of Health and Family Welfare have proposed several amendments in the Drugs and Cosmetics Act, 1940 on the recommendations of Mashelkar Committee in 2003. While taking cognizance of the above-mentioned initiates taken by the Ministry for containing the problem of spurious drugs, the Committee are failed to understand as to why such a long time since 2003 has been taken just to introduce the Bill to amend the Act. The Committee, therefore, express its displeasure over the lackadaisical attitude of the Ministry of Health and Family Welfare and other concerned Ministries on such a vital issue which affects the public at large. The Committee, therefore, recommend that in the ensuing Monsoon Session of Parliament the Government will introduce both the Bills i.e., (i) setting up of Central Drugs Authority of India and (ii) Amendments to Drugs and Cosmetics Act, 1940.

P. Revival of the sick public sector units

(Recommendation Sl. No. 16)

41. The Committee had recommended as under:-

The Committee were 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, had regretted 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 were being neglected and there had 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 had reiterated that the Government should take urgent steps for revival of PSUs under the Department of Chemicals & Petrochemicals.

42. The Ministry, in their Action Taken Reply, have stated as follows:-

"The status of the Rehabilitation/Revival of Pharma PSUs is as under:

INDIAN DRUGS & PHARMACEUTICALS LIMITED (IDPL):-

Board for Industrial and Financial Reconstruction (BIFR) issued winding up orders for IDPL on 4th December, 2003. Department of Chemicals and Petrochemicals filed an Appeal against the opinion of Board for Industrial Financial Reconstruction (BIFR) before Appellate Authority for Industrial & Financial Reconstruction (AAIFR) on 6th January, 2004. Hon'ble AAIFR at its hearing on 13.9.05, set aside the impugned order of BIFR dated 4.12.2003 and remanded the matter back to BIFR for taking further action for rehabilitation of IDPL. The revival proposal of IDPL was considered by BRPSE on 9.3.2007 and the same was recommended. In pursuance of the recommendation of BRPSE, Deptt. sought approval of CCEA vide Note for CCEA dated 11.5.2007. The CCEA at its meeting

held on 17.5.2007 decided that the matter in the first instance, be considered by a Group of Ministers (GOM). GOM has since been constituted.

HINDUSTAN ANTIBIOTICS LIMITED:-

In pursuance of the announcement made by the Finance Minister on July 8, 2004 during the Budget Speech-2004 to provide financial support for the restructuring of HAL, HAL submitted a draft Revised Rehabilitation Scheme to this Department. Having examined the Rehabilitation Scheme, it was placed before the Board for Reconstruction of Public Sector Enterprises (BRPSE) for consideration. BRPSE at its meeting held on 22.7.2005 recommended the Rehabilitation Scheme for approval of the Government. The CCEA approved the Rehabilitation Scheme on 9.3.2006. Government has released Rs.137.59 crores to HAL and waived of past Loans and Interest thereon to the extent of Rs.259.43 crores. HAL has taken further action to implement the revival scheme. BIFR has since sanctioned the scheme in June, 2007.

BENGAL CHEMICALS AND PHARMACEUTICALS LIMITED (BCPL):-

A revised Rehabilitation Scheme was submitted to BRPSE. BRPSE recommended the scheme on 25.7.2006. Thereafter, the Rehabilitation Scheme was considered and approved by CCEA on 21.12.2006. The scheme inter-alia, consists (i) provisions of funds of Rs.207.19 crore and (ii) waiver of past loans and interest thereon to the extent of Rs.233.41 crores. Out of Rs.207.19 crore Government has released Rs.117.19 crores in March,2007. Balance funds of Rs.90.00 crores would be released in the 11th Plan. BCPL is taking further action in implementing the Rehabilitation Scheme."

43. While appreciating the fact that the Cabinet Committee on Economic Affairs (CCEA) has approved the Rehabilitation Scheme of Hindustan Antibiotics Limited (HAL) and Bengal Chemicals and Pharmaceuticals Limited (BCPL) and the Government has released the funds and waived past loans and interest thereon, the Committee hope that these PSUs would be revived soon to fulfil the desired objectives. The Committee desire that revival proposal in respect of Indian Drugs and Pharmaceuticals Limited (IDPL) should be expeditiously considered by the Group of Ministers (GOM) and then decided by the Cabinet without further delay.

CHAPTER- II

RECOMMENDATIONS/OBSERVATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

(Recommendation Sl. No. 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 tht 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.

Reply of the Government

DCG(I) has stated that strengthening of drug regulatory authorities including creation of a National Drug Authority is under active consideration of the that Ministry under a Capacity Building Project supported by World Bank. The M/o Health is providing substantial assistance to all States Drug Testing Laboratories in terms of costly equipments, buildings, manpower, training and consumables etc. in order to augment their testing capacities and to reduce the time taken for issuing test reports.

Detailed guidelines in regard to strategies which need to be followed by all States Drug Control Organizations for effective monitoring of possible movement

of spurious drugs and to nab the criminal elements involved in such activities has been advised to all States. Draft Bill proposing amendments to the D&C Act in order to enhance the penalties and to empower police to file prosecution etc. has already been introduced in the Parliament.

The M/o Health and Family Welfare has reported that there is a proposal to set up Central Drugs Authority of India to provide technical vision and policy direction for the pharmaceutical and cosmetics sectors and their regulation in the country. For this purpose, Drugs and Cosmetics Act, 1940 is being amended.

So far as the issue of spurious drugs is concerned, it is stated that Drugs & Cosmetics Act,1940 is handled by M/o Health and Family Welfare. They have proposed several amendments in the Act based on the recommendations of the Report (on counterfeit drugs) of the Mashelkar Committee in 2003. Both the amendment bills are likely to be introduced in the Parliament soon.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 40 of Chapter-I of the Report)

(Recommendation Sl.No.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.

Reply of the Government

DCG(I) has stated that the recommendations of Mashelkar Committee to check the prevalence of spurious and fake drugs in the country are already been pursued as mentioned in the foregoing paras. The requirements of Good Manufacturing Practices (GMPs), which are critical to maintain batch-by-batch consistency in respect of quality and efficacy of drugs, have already been upwardly revised. Detailed norms have already been prescribed in the Rules for assessment of safety, efficacy and quality of drugs before they are imported or manufactured locally.

Based on the recommendations of the Mashelkar Committee, the M/o Health and Family Welfare has decided to amend the Drugs & Cosmetics Act,1940 to check the prevalence of spurious drugs in the country. Amendment Bill is likely to be introduced in the Parliament soon.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

(Recommendation Sl. No. 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.

Reply of the Government

The status of the Rehabilitation/Revival of Pharma PSUs is as under:

INDIAN DRUGS & PHARMACEUTICALS LIMITED (IDPL):-

Board for Industrial Financial Reconstruction (BIFR) issued winding up orders for IDPL on 4th December, 2003. Department of Chemicals and Petrochemicals filed an Appeal against the opinion of Board for Industrial Financial Reconstruction (BIFR) before Appellate Authority for Industrial & Financial Reconstruction (AAIFR) on 6th January, 2004. Hon'ble AAIFR at its hearing on 13.9.05, set aside the impugned order of BIFR dated 4.12.2003 and remanded the matter back to BIFR for taking further action for rehabilitation of IDPL. The revival proposal of IDPL was considered by BRPSE on 9.3.2007 and the same was recommended. In pursuance of the recommendation of BRPSE, Deptt. sought approval of CCEA vide Note for CCEA dated 11.5.2007. The Cabinet at its meeting held on 17.5.2007 decided that the matter in the first instance, be considered by a Group of Ministers (GOM). GOM has since been constituted.

HINDUSTAN ANTIBIOTICS LIMITED:-

In pursuance of the announcement made by the Finance Minister on July 8, 2004 during the Budget Speech-2004 to provide financial support for the restructuring of HAL, HAL submitted a draft Revised Rehabilitation Scheme to this Department. Having examined the Rehabilitation Scheme, it was placed before the Board for Reconstruction of Public Sector Enterprises (BRPSE) for consideration. BRPSE at its meeting held on 22.7.2005 recommended the Rehabilitation Scheme for approval of the Government. The CCEA approved the

Rehabilitation Scheme on 9.3.2006. Government has released Rs.137.59 crores to HAL and waived of past Loans and Interest thereon to the extent of Rs.259.43 crores. HAL is taking further action to implement the revival scheme. BIFR has since modified the scheme in June, 2007.

BENGAL CHEMICALS AND PHARMACEUTICALS LIMITED (BCPL):-

A revised Rehabilitation Scheme was submitted to BRPSE. BRPSE recommended the scheme on 25.7.2006. Thereafter, the Rehabilitation Scheme was considered and approved by CCEA on 21.12.2006. The scheme inter-alia, consists (i) provisions of funds of Rs.207.19 crore and (ii) waiver of past loans and interest thereon to the extent of Rs.233.41 crores. Out of Rs.207.19 crore Government has released Rs.117.19 crores in March,2007. Balance funds of of Rs.90.00 crores would be release in the 11th Plan. BCPL is taking further action in implementing the Rehabilitation Scheme.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 43 of Chapter-I of the Report)

(Recommendation Sl.No. 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.

Reply of the Government

The Department of AYUSH covers Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH). These systems are popular in large number of states in the country. These systems are very popular in abroad also. The plan and Non-Plan budget of Department of AYUSH during the year 2003-2004 stood at Rs.145crores and Rs.51.47 crores respectively. The overall allocation for the Tenth Five Year Plan stand at Rs.775.00 crores. There are three subordinate offices and 14 autonomous bodies and more than 4000 personnel's are working in these institutions/organizations/subordinate offices. Seven Ayurvedic and 5 Unani drugs have been supplied to 9 states and 4 cities as part of the on going country's national RCH Programme. That Department has identified these drugs keeping in veiw their utility for treatment of common ailments of pregnant women and children. Government have also established specilized clinics of Ayurvedic, Unani and Homoeopathy in the OPD to CGHS Hospital i.e. Safdarganj Hospital and Ram Manohar Lohia Hospital in New Delhi. Department of AYUSH have supported financial assistance under Centrally Sponsored Scheme (Hospitals and Dispensaries) to establish AYUSH poly clinic with regimental therapy on Unani system, Panchkar Setting of up AYUSH wing in Government Distt. Allopathic Hospitals. Government have supplied essential drugs in rural and backward areas dispensaries of AYUSH and identified villages.(RS.25,000/- per Dispensary). Pilot Scheme for supply of home remedy kit to rural areas in identify villages (Rs.11,13,600/-per Distt.)

Department of AYUSH has a IEC Scheme with the objective creating awareness among the general masses about the efficacy of AYUSH system. Their cost effectiveness and the availability of the raw material used for prevention and treatment of common ailments. Under this scheme grant is being given to NGO's to organize activities to promote strengths of AYUSH System. Various media channels are i.e implementation of IEC Scheme through NGO's, Participation in Health Mela's and fairs, dissemination information through print and audiovisual medium. "Arogya Mela" is being organized at Pragati Maidan, New Delhi every year and also in different states. In order to popularize AYUSH

system's particularly of the poor masses to improve the healthcare in the country. Various information of AYUSH system has been published in a small brochure form and being distributed in health mela's and Arogya mela's by the Department.

Latest requisite information is being called from D/o AYUSH and will be provided as and when received.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

(Recommendation Sl.No. 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 co-ordinated approach to deal with all issues relating to the drugs and pharmaceuticals brooks no delay. They therefore, strongly recommended that as envisaged in the modified Drug Policy, a National Drug Authority should be created without any further delay.

Reply of the Government

The M/o Health and Family Welfare has reported that there is a proposal to set up Central Drugs Authority of India to provide technical vision and policy direction for the pharmaceutical and cosmetics sectors and their regulation in the country. For this purpose, Drugs and Cosmetics Act, 1940 is being amended.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

(Recommendation Sl. No. 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.

Reply of the Government

The Department of Science and Technology has a dedicated programme for promoting R&D in the drugs and pharmaceutical sector. A corpus fund of Rs.150 crores has been set up for this purpose. As per the announcement made by the Finance minister in his budget Speech on 28.2.2005 for the year 2005-06, this fund is to be suitably augmented in the coming year. It was proposed that an allocation of Rs.150 crores for R&D activity in pharma sector be disbursed through the existing schemes of Department of Science and Technology.

Government has taken several policy initiatives for strengthening Research & Development in pharma sector. Due to measures such as fiscal incentives to R&D units in pharma sector and steps to streamline procedures concerning development of new drug molecules, clinical research and new drug delivery systems, this activity is seeing progress and new R&D set ups with excellent infrastructure are coming up in the field of original drug discovery and leading drug companies have licensed their NCEs to MNCs. It is gathered that a few products are expected to go for clinical trials in the next few years in the areas of Antiinfective, Anticancer and lifestyle segments. Compared to the reported average R&D spending of 2% of turnover in the sector, a few leading Indian pharma companies have increased their R&D spending to over 5% of their turnover.

a) Finance Minister in his budget speech on 28.2.2007 has announced extending the period of benefit under Section 35(2AB) of the Income Tax Act for another five years i.e. upto 31.3.20012.
b) Department of Biotechnology is in the process of instituting a 'Small Business Innovation Research Initiative' scheme for supporting small and medium size enterprises for innovative research projects in the form of a grant / soft loan. The funding under this scheme would be available for highly innovative, early stage, pre-proof –of concept researches.
c) Small and medium sector pharmaceuticals companies undertaking innovative projects would be encouraged to avail of equity support from the SME Growth Fund of Small Industries Development Bank of India (SIDBI).

d) R&D expenditure in case of bigger Pharma companies has been increasing over the years. It is reportedly in the range of 5% to 7% (average) of the turnover of these companies.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

CHAPTER – III

RECOMMENDATIONS/OBSERVATIONS WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT'S REPLIES

---------- NIL ----------

CHAPTER – IV

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE

(Recommendation Sl.No. 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 Public interest Litigation, this new policy has not been enforced.

Reply of the Government

The Government announced the 'Pharmaceutical Policy 2002' in February, 2002. This Policy envisaged substantial reduction in the span of price control. However, a public interest litigation filed in the High Court of Karnataka at Bangalore resulted in an order dated 12.11.2002, which stopped the Government from implementing the price control regime of the Pharmaceutical Policy-2002. This Department filed a Special Leave Petition (SLP) in the Supreme Court against the order of the Karnataka High Court, which has been admitted as SLP

(C) No.3668/2003. The Supreme Court vide its order dated 10.3.2003 directed the Government, interalia, as follows:- “we suspend the operation of the order to the extent it directs that the Policy dated 15.2.2002 shall not be implemented. However, we direct that the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of the price control and further directed to review drugs, which are essential and life saving in nature till 2nd May, 2003”.

Ministry of Health and Family Welfare has brought out the National List of Essential Medicines, 2003 after the review of the National Essential Drugs List, 1996.

Subsequently, a Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the directions of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objectives of National Common Minimum Programme to ensure availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government. The Committee has recommended, inter-alia, intensive monitoring of prices of all those drugs out of the selected basket (National List of Essential Medicines, 2003) which are not under price control, ceilings on trade margins of drugs, a system of price negotiations for the new patented drugs, special schemes for people below poverty line, introduction of Rajasthan Model of Life Line Fluid Stores (hospital pharmacy stores run by Medicare Societies) for bulk purchase of drugs directly from manufacturers and selling them at reduced prices, compounding of offences under the Essential Commodities Act, establishment of DPCO cells in all States on the model of Karnataka etc., efforts to increase public awareness, wide publicity to policies and decisions of the Government and NPPA etc. Follow up action has been initiated on the recommendations made by the Committee in its interim report.

Thereafter, a Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force has submitted its report to the Government on the 20th September, 2005. Some of the salient recommendations of the Task Force are, that Price Controls should be imposed on the 'essentiality' of the drug and not on the basis of turnover and it should be applied only to formulations and not to bulk drugs. Some of the other major recommendations of Task Force are to promote generic drugs, to encourage public health facilities, to revive the Public Sector Enterprises in the manufacture of drugs, to provide fiscal incentives in R&D activities in drugs, to provide financial support for implementation of Schedule M of Drugs and Cosmetics Rules, to enact Drugs and Therapeutics (Regulation) Act, to establish a National Authority on Drugs and Therapeutics (NADT), to establish price negotiation process for new patented drugs, to streamline the bulk procurement regime, to exempt the excise duty, customs duty and other levies on cancer and anti HIV/AIDS drugs, to establish the State Illness Funds in the States/Union Territories for BPL families, to reduce the excise duty on drugs from 16 to 8%,to enhance the exemption limit of SSI units from Rs.1 crores to Rs.5 crores, to establish a Settlement Commission which is authorized to settle the disputed overcharged amount from the pharma companies.

Recently, a Core Group under the Chairmanship of Joint Secretary (PI) has been constituted by this Department to examine the recommendations of the Task Force and to draft a new Pharmaceutical Policy.

On the basis of the recommendations of the Committee under the Chairmanship of JS(PI), recommendations of the Task Force and discussions with various stakeholders; draft National Pharmaceutical Policy was prepared by this Department and was considered by the Cabinet in its meeting held on 11.1.2007. The Cabinet has referred the proposed Policy to a Group of Ministers (GOM). The First meeting of the GOM was held on 10.4.2007. No time frame has been set up for finalizing the National Pharmaceutical Policy.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl.No. 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.

Reply of the Government

The Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices, has submitted its report to the Government on the 20th September, 2005. Some of the salient recommendations of Task Force are, that Price Controls should be imposed on the 'essentiality' of the drug and not on the basis of turnover and it should be applied only to formulations and not to bulk drugs. Some of the other major recommendations of Task Force are to promote generic drugs, to encourage public health facilities, to revive the Public Sector Enterprises in the manufacture of drugs, to provide fiscal incentives in R&D activities in drugs, to provide financial support for implementation of Schedule M of Drugs and Cosmetics Rules, to enact Drugs and Therapeutics (Regulation) Act, to establish a National Authority on Drugs and Therapeutics (NADT), to establish price negotiation process for new patented drugs, to streamline the bulk procurement regime, to exempt the excise duty, customs duty and other levies on cancer and anti HIV/AIDS drugs, to establish the State Illness Funds in the States/Union Territories for BPL families, to reduce the excise duty on drugs from 16 to 8%,to enhance the exemption limit of SSI units from Rs.1 crores to Rs.5 crores, to establish a Settlement Commission

which is authorized to settle the disputed overcharged amount from the pharma companies.

The Task Force has recommended the National List of Essential Medicines (NLEM) should form the basis of drugs to be considered for intensive price monitoring, ceiling prices and imposing price control, if any. To initiate this process, the Government should announce the ceiling price of the drugs contained in NLEM (other than the drugs procured by hospitals directly and which an individual does not have to purchase from the market) on the basis of weighted average of the top three brands based on value.

At present, the National List of Essential Medicines, 2002 consists of 354 essential items. Out of which approximately 40 items are being procured by the hospitals directly and, therefore, as per the Task Force recommendations the ceiling price proposal is not applicable on them. This results into the Government fixing the ceiling price of 314 essential ingredients out of the list of 354 prepared by the Health Ministry as per NLEM 2003.

The recommendations of the Task Force have been taken into consideration while framing draft National Pharmaceutical Policy,2006, which is being examined by a Group of Ministers (GOM).

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl.No. 3)

The Committee (the erstwhile Standing Committee on Petroleum & Chemicals) examined the 'Draft National Drug Policy' and submitted their Second report to Parliament on 6th 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 (13th Lok Sabha) again examined 'Pricing and Availability of Drugs/Pharmaceuticals' and presented their 15th Report to Parliament on 29th 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.

Reply of the Government

M/o Health and Family Welfare has stated that the Government is committed to increasing the allocation for health sector and as per the Common Minimum Programme, the Government will raise public spending on health to at least 2-3% of GDP over the next five years with focus on primary health care. As a consequence of this commitment of the Government an ambitious National Rural Health Mission has also been launched recently. In respect of the issue of 'strengthening drug control offices throughout the country to have proper control over the production and availability of essential drugs and pharmaceuticals', it is pointed out that under the World Bank assisted Capacity Building Programme drug regulatory officials as well as personnel of drug and pharmaceutical SSI units are

being given training in quality control and safety as well as regulation aspects of drugs and pharmaceuticals.

D/o Scientific & Industrial Research has stated that Government has instituted several fiscal incentives from time to time for enhancing R&D expenditure in industry. Many countries in drugs and pharmaceutical sector have increased their R&D expenditure. These companies have created state of the art R&D facilities and are carrying out cutting edge research in their research centers. Many companies have accessed regulated international market by filing patents based on non-infringing processes.

Recommendations of the Standing Committee have been taken into consideration by the Government while framing draft National Pharmaceutical Policy,2006, which is being examined by a Group of Ministers (GOM).

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl. No. 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.

Reply of the Government

M/o Health and Family Welfare has stated that these issues are being addressed under the National Cancer Control Programme, National TB Control Programme and the National HIV/AIDSs Control Programme (NACP-II).

Essential Drugs meant for diseases like Cancer, TB, HIV/AIDs are part of National List of Essential Medicines,2003, which has been included as part of draft Pharmaceutical Policy,2006. The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM).

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl.No. 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.

Reply of the Government

National Common Minimum Programme (NCMP) stipulates, inter-alia, that " The UPA Government will take all steps to ensure availability of life saving drugs at reasonable prices". For this purpose, NCMP provides the amount for the following Schemes:-

1. Computerization (Hardware) needed for monitoring Rs.28 lakhs

NPPA has undertaken the exercise of computerization of day to day work of NPPA with the help of M/s C-DAC and M/s C-DAC put most of the data on computer for speedy implementation of decisions of the NPPA and day to day monitoring.

2. Monitoring System (software, data collection etc.) of drug prices Rs.73.70 lakhs

A good monitoring system would put an effective check on the indiscriminate increase in price, which may take place from time to time. This will give a major relief to the common man and fulfill the stated objective of NCMP.

Advertisement in Newspapers :

NPPA have already started advertisement- showing cases of reduction in prices of formulations in various Newspapers with the help of Directorate of Advertisement and Visual Publicity (DAVP).

Strengthening of NPPA has been included as part of draft Pharmaceutical Policy,2006. The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM).

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl. No.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 the 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.

Reply of the Government

A Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the observations of the Supreme

Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objective of National Common Minimum Programme to ensure the availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government.

Subsequently, a Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force deliberated upon all the recommendations of the Committee under Chairmanship of JS(PI) made in its interim report and has submitted its report to the Government on the 20th September, 2005.

The Government is examining the recommendations of the Task Force with various stakeholders and based on that Draft Pharmaceutical Policy-2006 (Part-A) (excluding pricing mechanism) has been prepared and circulated amongst various Ministries/Departments of the Government/States/UTs and various stakeholders inviting their comments on 25.1.2006.

Recommendations received from various State Governments and other stakeholders have been included in the draft National Pharmaceutical Policy,2006. In the draft Policy it has also been recommended to enact a new law i.e. Drug (Price Regulation and Control) Act (DPRCA), to enable a more effective price control/monitoring of the prices of drugs as also to provide for compounding of certain offences and to regulate production, distribution and supply during health emergencies. The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM).

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl.No.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.

Reply of the Government

The idea of creation of a DPCO cell in each state has also been supported by the Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser in its report submitted to the Government on 20.9.2005. A DPCO Cell will primarily be responsible for following functions:

- to ensure implementation of prices fixed/revised by NPPA from time to time;
- to detect cases of overcharging and forward the same to NPPA for further action;
- to follow up the overcharging cases for recovery of overcharged amount
- to ensure availability of data from manufacturing units, where units fail to provide data/information for NPPA;
- to ensure availability of drugs in their states &
- any other work assigned from time to time for enforcement of Drug Policy/DPCO.

The issue of creation of DPCO cell in all States have been included as part of the draft National Pharmaceutical Policy,2006. Such Cells will be constituted after finalization of the Policy.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl. No. 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.

Reply of the Government

A Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force has submitted its report to the Government on the 20th September, 2005. Some of the salient recommendations of Task Force are, to establish price negotiation process for new patented drugs i.e. all patented drugs and their formulations should compulsory be brought under price negotiation prior to the grant of marketing approval. Failure of such negotiations should then invite either price control or compulsory licensing, to provide financial support for implementation of Schedule M of Drugs and Cosmetics Rules, to enact Drugs and Therapeutics (Regulation)

Act, to establish a National Authority on Drugs and Therapeutics (NADT). The Government is examining the recommendations of the Task Force with various stakeholders and based on that Draft Pharmaceutical Policy-2006 (Part-A) (excluding pricing mechanism) has been prepared and circulated amongst various Ministries/Departments of the Government/States/UTs and various stakeholders inviting their comments on 25.1.2006.

NPPA has also initiated an exercise to computerize its day-to-day work and various records with the help of M/s C-DAC. For intensive monitoring of essential medicines, monitoring of non-Scheduled medicines and also day to day work relating to fixation of bulk drug prices, fixation of formulation prices, legal and overcharging cases and other administrative work, it has been decided to make use of computers.

Proposals for Strengthening of NPPA and Drug Regulatory System in the country have been included as part of the draft National Pharmaceutical Policy,2006. The M/o Health and Family Welfare is in the process of constituting the Central Drug Authority by amending the Drugs & Cosmetics Act,1940. Amendment Bill in this regard is likely to be introduced in the Parliament soon.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl. No. 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 manufacturers 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.

Reply of the Government

A Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force has submitted its report to the Government on the 20th September, 2005. One of the salient recommendations of Task Force to establish price negotiation process for new patented drugs i.e. all patented drugs and their formulations should compulsory be brought under price negotiation prior to the grant of marketing approval. Failure of such negotiations should then invite either price control or compulsory licensing.

In the draft National Pharmaceutical Policy,2006, it is proposed that the patented drugs (formulations under product patent) that would be launched in India, would be subjected to price negotiations before granting them marketing approval. A Committee of this Department is examining this issue.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl. No. 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 organizations 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.

Reply of the Government

As per the present Price control policy, the 74 bulk drugs specified in the First Schedule of the Drugs (Prices Control) Order, 1995 (DPCO, 95) and the formulations based thereon are under price control. Their prices are fixed / revised by the National Pharmaceutical Pricing Authority (NPPA) in accordance with the provisions of the DPCO, 95. There has been no instance in the notice of this

Department, where the entry of the new drugs is being blocked by present price control policy.

Prices of non-Scheduled 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 where the public interest is found to be adversely affected.

A Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the observations of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objective of National Common Minimum Programme to ensure the availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government. As regards, trade margins, the Committee felt that the present norms for Scheduled Drugs should continue i.e. 8% for wholesalers and 16% for retailers. In case of non-Scheduled Drugs the recommended trade margins are 10% for wholesalers and 20% for retailers for the branded category of drugs and higher margins of 15% and 35% for wholesalers and retailers respectively for the generic drugs. These margin would be inclusive of various trade discounts offered by industry to dealers. However, modalities of implementation need to be worked out in consultation with NPPA and industry.

The Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force has submitted its report to the Government on the 20th September, 2005.

The Government is examining the recommendations of the Task Force with various stakeholders and based on that Draft Pharmaceutical Policy-2006 (Part-A) (excluding pricing mechanism) has been prepared and circulated amongst various

Ministries/Departments of the Government/States/UTs and various stakeholders inviting their comments on 25.1.2006.

NPPA regularly monitors the prices of non-Scheduled formulations on the basis of ORG-MIS data. Recently the annual price increase ceiling for all non-Scheduled drugs has been reduced to 10% from the earlier 20% ceiling.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl. No. 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.

Reply of the Government

M/o Health and Family Welfare and DCG (I) have informed that promotion of generic drugs is a policy matter. It has been provided Under the Drugs and Cosmetics Rules that the proper name of generic drug is printed in a more

conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name.

The Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force has submitted its report to the Government on the 20th September, 2005. The Task Force has recommended *inter-alia* to promote generic drugs.

In the draft National Pharmaceutical Policy,2006 several measures have been proposed to promote the use of generic drugs viz. Public procurement and distribution of drugs through the public health system would preferably be for generic drugs, Quality certification would be provided free of cost to generic drug manufacturers through an appropriate scheme by Health Department, No price control on prices of generic drugs provided prices of these have been fixed by the manufacturer keeping in view the prescribed trade margins.

The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM).

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl. No. 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 that 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.

Reply of the Government

A Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the observations of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objective of National Common Minimum Programme to ensure the availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government. As regards, trade margins, the Committee felt that the present norms for Scheduled Drugs should continue i.e. 8% for wholesalers and 16% for retailers. In case of non-Scheduled Drugs the recommended trade margins are 10% for wholesalers and 20% for retailers for the branded category of drugs and higher margins of 15% and 35% for wholesalers and retailers respectively for the generic drugs. These margins would be inclusive of various trade discounts offered by industry to dealers. However, modalities of implementation need to be worked out in consultation with NPPA and industry.

A Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force deliberated upon all the recommendations of the Committee under Chairmanship of JS(PI) made in its interim report and has submitted its report to the Government on the 20th September, 2005.

The Government is examining the recommendations of the Task Force with various stakeholders and based on that Draft Pharmaceutical Policy-2006 (Part-A) (excluding pricing mechanism) has been prepared and circulated amongst various Ministries/Departments of the Government/States/UTs and various stakeholders inviting their comments on 25.1.2006.

The issue of trade margin has been included in the draft National Pharmaceutical Policy,2006, which is being examined by a Group of Ministers (GOM).

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)
(Recommendation Sl. No.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.

Reply of the Government

DCG(I) has stated that no drug is totally safe and there is no such system of drugs getting banned or withdrawn internationally. Drugs used in some countries may not be used in others. As far as drugs like Vitamin E and Analgin are concerned, the current scientific evidence does not indicate them to be unscientific or hazardous. Analgin, Vitamin E etc. continue to be used in large number of countries. However, on the basis of continued examination of drug formulations marketed in the country by the Sub-Committee of DTAB about 76 drug categories have been prohibited for manufacture and sale. This is a continuous exercise. A separate review of the drugs which got listed in the First Schedule to the DPCO could, however, be taken up by the Sub-Committee of DTAB.

In order to discourage proliferation of irrational drug formulations, the M/o Health has amended the relevant provisions in the Drugs and Cosmetic Rules in order to ensure that the State Licensing Authorities on their own do not approve new drug formulations. Besides this, the Secretary Health, has personally taken up the matter with the Chief Secretaries of few States where the State Licensing Authorities were observed to be issuing unauthorized approvals on the basis of turnover criteria. It is, however, pertinent to note that the existing First Schedule under DPCO is likely to undergo total change in the light of the recommendation of Task Force and the subsequent formulation of new Drug Policy by D/o C&PC.

The issue of control on Pharmaceutical brands has been included in the draft National Pharmaceutical Policy, 2006. Further action to check the misbranding of drugs is to be taken by the M/o Health and Family Welfare after finalization of draft National Pharmaceutical Policy, 2006.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl. No. 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 proposes 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.

Reply of the Government

The Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission constituted to explore options other than price control to make available life saving drugs at reasonable prices has submitted its report to the Government on the 20th September, 2005.

One of salient recommendations of Task Force is that Insurance companies should be encouraged to extend health insurance to cover medicines. Public-

private partnership for providing health care services, including insurance and group health plans, should be actively encouraged.

The Government is examining the recommendations of the Task Force in consultation with various stakeholders and based on that a new Pharmaceutical Policy will be announced shortly. New Policy initiatives will include : Health Cess @2% for funding certain schemes relating to healthcare of the poor; introduction of a new scheme by the name of 'Rashtriya Swasthya Bima Yojna' in the country for the BPL families.

Latest requisite information is being called from M/o Health and Family Welfare and will be provided thereafter.

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl. No. 18)

The Committee note that some of the States like Tamil Nadu procure medicines through a centralized 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 centers 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.

Reply of the Government

A Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the observations of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objective of National Common Minimum Programme to ensure the availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government. The Committee has studied the Rajasthan Model of Medicare Societies through which Life-line Fluid Stores have been opened in all the Government Hospitals at State, Divisional and District levels. Through these stores some of the essential drugs, antibiotics, injections, IV Fluids etc. are procured through open tenders directly from the manufacturing companies. Some of these drugs are made available to patients at less than 50% of the prevailing market prices.

Subsequently, the Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force deliberated upon all the recommendations of the Committee under the Chairmanship of JS(PI) and has submitted its report to the Government on the 20th September, 2005. Some of the salient recommendations of Task Force are, to revive the Public Sector Enterprises in the manufacture of drugs, to establish the State Illness Funds in the States/Union Territories and for setting up revolving funds in all Government Hospitals for making vailable medicines free of cost to the BPL families. Also, there is need to give wide publicity to these schemes so that maximum poor people can take advantage of these schemes.

In the draft National Pharmaceutical Policy, 2006 various measures have been recommended for streamlining system of bulk procurement of drugs by Central Government as well as State Government. The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM).

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

(Recommendation Sl. No. 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.

Reply of the Government

A Committee under the Chairmanship of Joint Secretary (PI) was constituted to examine the span of price control (including trade margin) in the light of National Common Minimum Programme and the observations of the Supreme Court in SLP N0. 3668/2003 and to suggest measures for fulfilling the objective of

National Common Minimum Programme to ensure the availability of life saving drugs at reasonable prices. This Committee has submitted its interim report to the Government.

Subsequently, a Task Force under the Chairmanship of Dr. Pronab Sen, Principal Adviser, Planning Commission was constituted to explore options other than price control to make available life saving drugs at reasonable prices. The Task Force deliberated upon all the recommendations of the Task Force and has submitted its report to the Government on the 20th September, 2005.

During the course of discussions under the Chairmanship of JS(PI) and the Task Force, there was active inter-action with the State Government/UTs on the issue of drafting new Pharmaceutical Policy. Their comments/views have been taken into consideration while drafting new Pharmaceutical Policy.

The Government is examining the recommendations of the Task Force with various stakeholders and based on that Draft Pharmaceutical Policy-2006 (Part-A) (excluding pricing mechanism) has been prepared and circulated amongst various Ministries/Departments of the Government/States/UTs and various stakeholders inviting their comments on 25.1.2006.

Recommendations received from various State Governments and other stakeholders have been included in the draft National Pharmaceutical Policy,2006. In the draft Policy it has also been recommended to enact a new law i.e. Drug (Price Regulation and Control) Act (DPRCA), to enable a more effective price control/monitoring of the prices of drugs as also to provide for compounding of certain offences and to regulate production, distribution and supply during health emergencies. The draft National Pharmaceutical Policy,2006 is being examined by a Group of Ministers (GOM).

[M/o Chemicals & Fertilizers (Department of Chemicals & Petrochemicals)
O.M. No. 5/18/2005-PI.I dated 20.06.2007]

Comments of the Committee

(Please *see* Para No. 37 of Chapter-I of the Report)

CHAPTER - V

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH FINAL REPLIES OF THE GOVERNMENT ARE STILL AWAITED

---------- NIL ----------

NEW DELHI
July 20, 2007
Asadha 29, 1929 (Saka)

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

Appendix-I

MINUTES

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2006-07)

TWLEFTH SITTING

(20.07.2007)

The Committee sat from 1600 hrs. to 1630 hours.

Present

Shri Prasanta Pradhan - In the Chair

Members
Lok Sabha

2. Shri Jaiprakash (Mohanlal Ganj)
3. Shri Shrichand Kripalani
4. Shri A. Narendra
5. Shri Ramswaroop Prasad
6. Shri Narsingrao H. Suryawanshi
7. Shri D. Venugopal
8 Shri Bhanupratap Singh Verma

Rajya Sabha

9. Shri Devdas Apte
10. Shri Gireesh Kumar Sanghi
11. Shri V. Hanumantha Rao
12. Shri Mahendra Sahni

Secretariat

1.	Shri A.K. Singh	-	*Joint Secretary*
2.	Shri A.S. Chera	-	*Director*
3.	Shri A.K. Srivastava	-	*Deputy Secretary-II*
4.	Smt. Balwant Kaur Saimbhi	-	*Under Secretary*

2. At the outset, owing to the non-presence of Chairman of the Committee, the Committee chose Shri Prasanta Pradhan 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. ** ** ** ** ** ** ** ** **

3. Thereafter, the Committee considered the Draft Report on Action Taken by the Government on the recommendations contained in the Seventh Report of the Standing Committee on Chemicals and Fertilizers (2005-06) on 'Availability and Price Management of Drugs and Pharmaceuticals'. The draft Report was adopted by the Committee without any amendment.

4. The Committee authorised the Chairman to make consequential changes, if any, arising out of the factual verification of the Report by the Ministry of Chemicals and Fertilizers (Department of Chemicals and Petrochemicals) and present the same to both the Houses of Parliament in the ensuing Monsoon Session, if the Session of Parliament commences before 5th August, 2007. The Committee have also decided to present the Report to Hon'ble Speaker under Direction 71A in case the Session does not commence before 5th August, 2007.

The Committee, then, adjourned.

** ***Matters note related to this Report***

Appendix – II

(Vide Para 3 of the Introduction)

Analysis of Action Taken by the Government on the recommendations contained in the Seventh Report (Fourteenth Lok Sabha) of the Standing Committee on Chemicals & Fertilizers (2005-06) on 'Availability and Price Management of Drugs and Pharmaceuticals'.

I	Total No. of Recommendations	22
II	Recommendations/observations which have been accepted by the Government *(Vide Recommendations at Sl. Nos. 14, 15, 16, 19, 20 and 21)*	6
	Percentage to Total	27.27%
III	Recommendations/observations which the Committee do not desire to pursue in view of Government's Replies	Nil
	Percentage of Total	Nil
IV	Recommendations/observations in respect of which replies of the Government have not been accepted by the Committee (*Vide Recommendations at Sl. Nos. 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 17, 18 and 22*)	16
	Percentage of Total	72.73%
V	Recommendations/observations in respect of which final replies of the Government are still awaited	Nil
	Percentage of Total	NIl