TWENTY-NINTH REPORT

STANDING COMMITTEE ON PETROLEUM & CHEMICALS (2002)

(THIRTEENTH LOK SABHA)

PRICING AND AVAILABILITY OF DRUGS/PHARMACEUTICALS

MINISTRY OF CHEMICALS AND FERTILISERS (DEPARTMENT OF CHEMICALS & PETROCHEMICALS)

[Action Taken by the Government on the recommendations contained in the Fifteenth Report (Thirteenth Lok Sabha) of the Standing Committee on Petroleum & Chemicals (2001) on 'Pricing and Availability of Drugs/Pharmaceuticals']

Presented to Speaker on 17.10.2002
Presented to Lok Sabha on 25.11.2002
Laid in Rajya Sabha on 25.11.2002

LOK SABHA SECRETARIAT
NEW DELHI

August 2002/Bhadrapada, 1924 (Saka)

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COMPOSITION OF THE STANDING COMMITTEE ON PETROLEUM AND CHEMICALS
(2002)

SHRI MULAYAM SINGH YADAV- Chairman

Members
Lok Sabha

2 Shri Ashok Argal
3 Dr. Chellamella Suguna Kumari
4 Shri Ram Chander Bainda
5 Shri Ananda Mohan Biswas
6 Shri Padam Sen Choudhry
7 Prof. Kailasho Devi
8 Shri P.D. Elangovan
9 Shri Dilipkumar Mansukhlal Gandhi
10 Smt. Sheela Gautam
11 Shri Paban Singh Ghatowar
12 Shri Bijoy Handique
13 Shri Shriprakash Jaiswal
14 Shri C. Kuppusami
15 Shri Jagannath Mallick
16 Shri Punnulal Mohale
17 Shri P. Mohan
18 Shri Ashok N. Mohol
19 Dr. Debendra Pradhan
20 Shri Ram Sajivan
21 Shri Mohan Rawale
22 Shri Shyama Charan Shukla
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24 Dr. Chhatrapal Singh
25 Shri Prabhunath Singh
26 Shri Ramjiwan Singh
27 Dr. Ram Lakhan Singh
28 Shri Shankersinh Vaghela
29 Shri Ratilal Kalidas Varma
30 Dr. Girija Vyas

Rajya Sabha
31 Shri Balkavi Bairagi
***32 Shri Ram Nath Kovind
33 Shri Anil Kumar
34 Shri Shyam Lal
35 Shri Rajiv Ranjan Singh `Lalan'
36 Shri Mool Chand Meena
37 Shri Deepankar Mukherjee
**38 Shri Pritish Nandy
39 Shri Ahmed Patel
***40 Shri Keshubhai Savdasbhai Patel

41 Shri Yadlapati Venkat Rao
42 Ms. Mabel Rebello
43 Shri Gaya Singh
*44 Shri Thanga Tamilselvan
45 Prof. Ram Gopal Yadav

Secretariat

1. Shri P.D.T. Achary - Additional Secretary
2. Shri K.V. Rao - Joint Secretary
3. Shri P.K. Grover - Director
4. Shri J.N. Oberoi - Under Secretary
5. Shri Ram Raj Rai - Assistant Director

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* Nominated w.e.f. 8th April, 2002.
** Nominated w.e.f. 8th May, 2002.
*** Nominated w.e.f. 14th May, 2002.

COMPOSITION OF SUB-COMMITTEE ON CHEMICALS & PETROCHEMICALS
A SUB-COMMITTEE OF THE STANDING COMMITTEE
ON
PETROLEUM & CHEMICALS
(2002)

Shri Mulayam Singh Yadav - Chairman

2. Dr. Girija Vyas - Convenor

Members

Lok Sabha

3. Sh. P.D. Elangovan
4. Sh. Shriprakash Jaiswal
5. Sh. C. Kuppusami
6. Sh. P. Mohan
7. Sh. Ashok N. Mohol
8. Sh. Mohan Rawale
9. Dr. V. Saroja
10. Sh. Ramjivan Singh
11. Dr. Ram Lakhan Singh

Rajya Sabha

12. Shri Ram Nath Kovind
13. Sh. Mool Chand Meena
14. Shri Pritish Nandy
15. Sh. Yadlapati Venkat Rao
16. Sh. Gaya Singh

Secretariat

1.	Shri P.D.T. Achary	-	Additional Secretary
2.	Shri K.V. Rao	-	Joint Secretary
3.	Shri P.K. Grover	-	Director
4.	Shri J.N. Oberoi	-	Under Secretary
5.	Shri Ram Raj Rai	-	Assistant Director

INTRODUCTION

I, the Chairman, Standing Committee on Petroleum & Chemicals (2002) having been authorised by the Committee to submit the Report on their behalf present this Twenty-Ninth Report on Action Taken by Government on the recommendations contained in Fifteenth Report (Thirteenth Lok Sabha) of the Standing Committee on Petroleum & Chemicals (2001) on 'Pricing and Availability of Drugs/Pharmaceuticals'.

2. The Fifteenth Report of the Committee was presented to Lok Sabha on 29th August, 2001. The Updated Replies of Government to all the recommendations contained in the Fifteenth Report were received on 19th June, 2002. The Sub-Committee on Chemicals & Petrochemicals considered the Action Taken Replies received from the Government and adopted the Report at their sitting held on 1st August, 2002.

3. The Standing Committee on Petroleum & Chemicals (2002) considered and adopted this Report at their sitting held on 12th August, 2002. The Committee place on record their appreciation of the work done by the Sub-Committee on Chemicals & Petrochemicals.

4. An analysis of the Action Taken by Government on the recommendations contained in the Fifteenth Report (Thirteenth Lok Sabha) of the Committee is given in Appendix-III.

5. 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.

6. The Committee place on record their appreciation for the valuable assistance rendered to them by the officials of the Lok Sabha Secretariat attached to the Committee.

NEW DELHI
August 29, 2002
Bhadrapada 7, 1924 (Saka)

MULAYAM SINGH YADAV
Chairman
Standing Committee on
Petroleum & Chemicals.

CHAPTER – I

REPORT

This Report of the Committee deals with the action taken by the Government on the recommendations contained in the Fifteenth Report (Thirteenth Lok Sabha) of the Standing Committee on Petroleum & Chemicals (2001) on ' Pricing and Availability of Drugs/Pharmaceuticals' which was presented to Lok Sabha on 29th August, 2001.

2. Action taken notes have been received from the Government in respect of all the 35 recommendations/conclusions contained in the Report. These have been categorised as follows:-

(i) Recommendations/conclusions that have been accepted by the Government:-
Sl. Nos. 2,3,6,7,8,19,22,25,27,31,32,34 and 35

(ii) Recommendations/conclusions which the Committee do not desire to pursue in view of the Government's replies:
Sl. Nos. 1, 12, 21,24,26 and 29

(iii) Recommendations/conclusions in respect of which replies of the Government have not been accepted by the Committee.
Sl. Nos. 11,12,13,16,17 and 18

(iv) Recommendations/ observations in respect of which final replies of the Government are still awaited:
Sl. Nos. 4,5,9,10,14,15,20,23,28,30 and 33

3. The Committee desire that the final replies in respect of the recommendations for which only interim replies have been furnished by the Government and recommendations which have been commented upon by the Committee in Chapter-I should be furnished expeditiously.

4. The Committee will now deal with the action taken by the Government on some of their recommendations and make suggestions thereupon.

A. New Pharmaceutical Policy

(i) Pharmaceutical Policy - 2002

Recommendations (Part-II, Para Nos. 2 and 3)

5. The Committee had observed that the Government had been regularly modifying the national Drug Policy as per the demand of time and with certain objectives. They had specifically noted that with a view to find the requirements of medicines, Hathi Committee was set up in 1974 and on the basis of the report of that Committee the first Drug Policy was formulated in 1978. After that Policy frame work was revised in 1986 and 1994. In the same context the Committee had found that despite of the significant changes in the economic scenario and life style of the people, the basic structure and thrust of the Drug Policy had not changed to

the desired level. The Department of Chemicals & Petrochemicals had accepted the fact and informed that they were in a process to review the present Drug Policy so as to make that more dynamic and result oriented. The Committee had supported the views of the Ministry and had desired that the Government should announce a rational Drug Policy in the shortest possible time. Simultaneously, the Committee had urged strongly that the Government should ensure incorporating all the desired changes arising due to dismantling of industrial licensing and policies relating to import, trade controls, lowering of tariff protection, unfolding of product patent regime and globalisation of industry. They had also cautioned that the Ministry should be careful that health aspects like therapeutic need, essentiality, efficacy, safety of drugs and availability of drugs to the masses at affordable prices are not ignored at any stage of policy formulation.

6. While analysing the performance of earlier Drug Policy, the Committee had noted that the first Drug Policy of 1978 had yielded the desired results and strengthened the infrastructure for bulk drug manufacture. In regard to pricing aspects, the policy had categorized the drugs according to their relative essentiality and prices were maintained at reasonable levels through Drugs (Prices Control) Order, 1979. It had also laid stress on quality control and rational use of drugs and called for strengthening drug control systems and organizations for effective implementation of Drugs and Cosmetics Act, 1940. In their view, further amendments in the Drug Policy in 1984 and 1994 and DPCO in 1987 and 1995 had given impetus to development of viable processes which in turn not only helped in meeting the demand of medicines in the country but also a boost to exports and as a result the industry had become an important foreign exchange earner. Foreign investment had increased in Pharma Sector and an environment had been created to channalise new investments into the pharmaceutical industry. However, the Committee had felt that the Government was far behind in the direction of achieving the key objective of adequate availability of quality medicines at affordable prices. The Committee had treated that performance as one sided since it had helped the industry to grow but the Government had not got the desired success in providing the modern medicines to a common man at affordable prices. The Committee had desired that the Government must analyse all the factors which were responsible for such type of performance before bringing the new Drug Policy in existence.

7. About the new Drug Policy, the Government have submitted the following detailed reply:-

> "The (Hathi) Committee on Drugs and Pharmaceuticals Industry, had submitted its report in April, 1975. Government laid a Statement on the Table of the Lok Sabha on 29.3.1978 containing its decisions on the said recommendations which later came to be known as Drug Policy, 1978.
>
> The Government reviewed the Drug Policy, 1978 and restructured it in 1986 by announcing 'Measures for Rationalisation, Quality Control and Growth of Drugs & Pharmaceutical Industry in India. The importance of quality control and rational use of drugs was reiterated in the 'Modifications in Drug Policy, 1986', announced in September, 1994.
>
> The Government have regularly modified the Drug Policy as per the changes in the health needs of the country and the general economic and industrial scenario. A reorientation of the objectives of the Drug Policy announced in 1994 had become necessary on account of the following:-

(a) The essentiality of improving incentives for research and development in the Indian pharmaceutical Industry, to enable the industry to achieve sustainable growth particularly in view of anticipated changes in the patent Law; and

(b) The need for reducing further the rigours of price control particularly in view of the on-going process of liberalization.

In March, 1999 the Government had constituted a Drug Price Control Review Committee (DPCRC) to review the current drug price control mechanism and to suggest alternate models, if any, with a view to reducing the rigours of price control where they had become counter productive. Another Committee, namely, the Pharmaceutical Research & Development Committee (PRDC) was also constituted in March, 1999 to recommend measures to strengthen the research and development capability of the pharmaceutical industry in the country and to identify the support required by Indian Pharmaceutical companies to undertake domestic research and development. Both the Committees have submitted their reports to the Government. The recommendations of these Committees have been taken into account in recently announced Pharmaceutical Policy-2002.

The main objectives of this policy are:-

(a) Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.

(b) Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.

(c) Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian Pharmaceutical industry and promoting rational use of pharmaceuticals.

(d) Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conductive to channelising a higher level of investment into R&D in pharmaceuticals in India.

(e) Creating an incentive framework for the pharmaceutical industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs."

8. About the considerations on price control in the new Pharmaceutical Policy the Ministry have clarified the position as under:-

"In March, 1999 the Government had constituted a Drug Price Control Review Committee (DPCRC) to review the current drug price control mechanism and to suggest alternate models, if any, with a view to reducing the rigours of price control where they

had become counter productive, to suggest the criteria of market competition and monopoly and turnover for inclusion of drugs under price control and to suggest measures for improving quality of products within the drug price control mechanism to suggest pricing policies for newer generation of drugs, new drug delivery systems and non prescription drugs. Based on the recommendations of this Committee, a note on the Pharmaceutical Policy was submitted to the Cabinet which has been approved by the Cabinet. Government have since announced 'Pharmaceutical Policy-2002'."

9. The Committee are happy to note that the Government have announced the new Pharmaceutical Policy –2002 based on the recommendations of the Drug Price Control Review Committee (DPCRC) and Pharmaceutical Research and Development Committee (PRDC). The Committee also observe that the Government have decided to pursue the basic objectives of the earlier Drug Policies like ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption. As a reorientation of objectives of earlier policy, some new priorities have also been fixed in the new policy for encouraging R&D in the Pharmaceutical Sector and reducing further the rigours of price control particularly in view of the on-going process of liberalization. The Committee find that the next important initiative in this direction is to make suitable amendments in Drug Pricing Control Order, 1995 to achieve the objectives of the new Pharmaceutical Policy. The Committee, therefore, reiterate that the Government should analyse all the factors responsible for not achieving the desired success in regard to this key objective of adequate availability of quality medicines at affordable prices and further amendments should be done to achieve the dual objective to ensure accelerated growth of the pharmaceutical industry as well as abundant availability of quality medicines of mass consumption at affordable prices particularly after the implementation of TRIPS agreement by the year 2005.

(ii) <u>Establishment of National Drug Authority</u>

Recommendation (Part II, Para No. 4)

10. While going into the details of pending issues of earlier Drug Policies, the Committee had noted that National Drug Authority which was first recommended by Hathi Committee long back even before the first Drug Policy of 1978 and was meant to facilitate and supervise inter-sectoral coordination in issues related to drugs and pharmaceuticals, was not formed till date. In view of the demand expressed by various experts, manufacturer associations/consumer organisations/voluntary health organisations etc., the Committee had strongly recommended that the Department of Chemicals & Petrochemicals should persuade the Ministry of Health and Family Welfare for an immediate setting up of the National Drug Authority. In their view, it was essential since in absence of such Authority the objectives of National Drug Policy as well as National Health Policy could not achieved.

11. The Government have stated the position as under:-

"The Ministry of Health and Family Welfare has informed that formation of a National Drug Authority will require major structural changes considering the present federal nature of the system and Drug Regulatory structure. In the existing regulatory system, licensing of manufacturers etc. as well as enforcement of the Drugs and Cosmetics Act, 1940 and Rules thereunder are ordinarily done by the State authorities. However, the first step towards formation of a National Drug Authority requires

strengthening of the Drug Regulatory set up at the Centre. A proposal has been sent to Ministry of Finance for creation of 82 posts and revival of 46 lapsed posts for CDSCO and the Central Drug Laboratories. 33 posts have since been revived. National Health Policy 2002 recognized the need for efficient enforcement of quality standards and rational use of drugs etc."

12. The Committee regret to note that no stress has been given either in pharmaceutical policy-2002 or Health Policy-2002 to establish a National Drug Authority as visualized by the Hathi Committee and Drug Policy of 1986 for achieving the objectives of better monitoring of quality control, rational use of drugs and related matters. While agreeing with the views of the Government that this will require major structural changes the Committee feel this may not be treated as an excuse for delaying the setting up of the National Drug Authority. In Committee's view, the steps of strengthening the CDSCO and Central Drug Laboratories are not sufficient. The Committee, therefore, desire that the Government should take all necessary initiatives to establish the National Drug Authority in the shortest possible time.

(iii) <u>Preparation of essential Drug List</u>

Recommendation (Part-II, Para No. 5)

13. The Committee had taken a serious note that even though Hathi Committee had listed 116 essential drugs in 1975, the Drug Policy of 1978 and 1986 and later modifications of the Drug Policy in 1994 failed to provide the nation with a clear essential drug list except a list prepared by the Health Ministry in 1996. Similarly in the Drugs (Prices Control) Order, 1995 the criteria was related to production monopoly and turn over ignoring the universal concept of essentiality. The Committee had felt that due to this reason there was a completely distorted pattern of drug production and the proliferation of non-essential and irrational drugs and Indian markets are flooded with several thousand formulations with decreased production of essential drugs. The Committee had strongly recommended that the National Essential Drugs list must be prepared by the Department of Chemicals and Petrochemicals and implemented without any further delay to guide the production, distribution, prescription and consumption of drugs and pharmaceuticals in the country. They had also desired that irrational and hazardous drugs must be withdrawn. The Committee had directed the Government that while preparing such a list, the Department of Chemicals and Petrochemicals should consider all the relevant factors like pattern of prevalent diseases, treatment facilities, training and experience of the available personnel, financial resources, demographic and environmental factors in the country.

14. The Government have responded to this recommendation as under:-

"The Ministry of Health and Family Welfare has informed that the National Essential Drugs List (NEDL) has already been published in 1996.

The issue of production and proliferation of non-essential and irrational drugs is complex. Since there are more than 9000 licensed manufacturers in the country, even if some formulation is made by number of companies under different brand names, the total number of products is bound to be in thousands. Recently announced Pharmaceutical Policy-2002 envisages application of criteria for identification of drugs for price control to the list of essential drugs in National Essential Drug List and the list of drugs considered important from the point of view of their use in various Health Programmes in emergency care etc. prepared by the Ministry of Health and Family Welfare.

As regards irrational drugs, an ongoing review process has been established through an Expert Committee constituted by Drug Technical Advisory Board (DTAB). In the year 2001 (upto October), 9 drug formulations were prohibited under Section 26 (A) of the Drugs and Cosmetics Act and use of two drugs was restricted. Directions have also been issued by the Deptt. of Health to all State Governments under Section 33 (P) of the Drugs and Cosmetics Act to refrain the State Licensing Authorities from permitting manufacture of combination of drug formulations which fall in the category of new drugs so as to check proliferation of irrational combination.

Rules 69 and 71 of the Drugs and Cosmetics Rules have been amended vide Notification GSR 311 (E) dated 1.5.2002 to specifically ensure that State Licensing Authorities do not permit new drug formulations at their own level. It is, however, a fact that the drug regulatory system which allows manufacturing license to be issued by respective State Licensing Authorities has led to certain aberrations including proliferation of drug formulations. The National Health Policy 2002 has recommended for periodic review of essential drug list and to encourage use of essential drug. The policy also recommends for prohibition of production and sale of irrational combinations of drugs through drug standards statue."

15. The Committee are happy to note that the Pharmaceutical Policy-2002 envisages application of criteria for identification of drugs for price control to the list of essential drugs in the National Essential Drug List and the list of drugs considered important from the point of view of their use in various Health Programmes, in emergency care etc. prepared by the Ministry of Health and Family Welfare. Moreover, National Health Policy-2002 has recommended for periodic review of essential drug list and to encourage use of essential drugs. The Committee, however, desire that there is a need for revision of the list published by the Ministry of Health and Family Welfare in 1996 and desire that the National Essential Drug List be updated considering all the relevant factors particularly the production and consumption pattern, prevalent diseases, treatment facilities etc. The Committee also desire that a separate National Essential Drug List should be prepared by the Department of Chemicals and Petrochemicals on the pattern of Essential Drug List of World Health Organization in consultation with the Ministry of Health and Family Welfare. This would not only facilitate taking care of most of the health problems of the country but would also act as a guiding factor for production, distribution, prescription, consumption and price control of drugs and pharmaceuticals in the country.

B. National Health Policy

Recommendations (Part –II, Para Nos. 6 & 7)

16. The Committee had noted that the goal of 'Health for All by the year 2000' had proved to be a total failure and there were gross disparities in health status and availability of healthcare services all over the country. The Committee had expressed serious concern to note that even under these circumstances the Government had not felt any need to amend the National Health Policy since 1983. They had felt an urgent need for framing a comprehensive Health Policy for effective healthcare needs of people. They had desired that this policy should evolve through the indepth/critical analysis of the factors which were responsible for such failure of health schemes. The Committee had also desired that the new Health Policy should synchronize with the National Drug Policy so that they complement each other and become able to take care of health needs of all the citizens of the country. In Committee's view the prevention and control of communicable and non-communicable tropical diseases should be the plank of the policy since these were likely to emerge as new health challenges over the next few decades.

17. In the same context the Committee had specifically noted that the actual expenditure on healthcare as percentage of total plan outlay had gradually declined from an abnormally low of 3.3% in the First Five Year Plan (1951-56) to an even lower percentage of 1.7% in Eighth Five Year Plan. This small expenditure was far below the guidelines of WHO to spend 5% of GDP outlay on healthcare. The Committee had specifically noted the views of the Ministry of Health and Family Welfare that the fund constraints had been the main obstacle in achieving the targets of National Health Programme. The Committee had an opinion that the small amount was not able to address the objective of 'Health for All' in any case. The Committee had treated this budget as inadequate and urged upon the Government to raise the Central health outlay appropriately and also direct the State Governments to enhance their health budget in view of the emerging newer challenges to health and to ensure proper healthcare facilities in all parts of the country.

18. About the new Health Policy the Ministry have submitted the following details:-

> "The Ministry of Health and Family Welfare has informed that the National Health Policy 2002 has while recognising the formidable challenges relating to health care in India, conceptualized various initiatives and policy measures to take care of the emerging challenges and to extend the reach of public health care and to ensure equity."

19. About the Central Health Policy the Government have stated as under:-

> "The Ministry of Health and Family Welfare has informed that outlay on health as percentage of total plan outlay and not GDP, as stated in the report of the Committee, has declined from 3.33% during 1st Plan to 1.75% during 8th Plan. During 9th Plan, the percentage of health outlay to total plan outlay has increased to 2.25% . However, when viewed in totality, it is seen that the outlay on health and family welfare as percentage of total plan outlay has remained more or less stagnant (3.33% in 1st Plan and 3.24% in 8th Plan). This has increased to 4.01% during 9th Plan. In terms of percentage to GDP, Government expenditure on health and family welfare is 0.9% of GDP whereas aggregate expenditure on this sector is 5.2% of the GDP.
>
> According to the NHP-2002, it is planned to increase the share of Central grants to 25% from the existing 15% by 2010. The State sector health spending is proposed to be increased from the existing 5.5 to 7% of the budget by 2005 and further to 8% by

2010. It is also proposed that Government expenditure on Health and Family Welfare should reach 2% of GDP by the year 2010. Utilisation of public health facilities has been envisaged to provide 75% coverage by 2010 as against the current level of < 20%."

20. The Committee are happy to note that the Government after the concern expressed by the Committee have announced the new National Health Policy-2002 after a long gap of a decade. The Committee also find that the policies highlighted in the document are very important and the Government have tried to analyse the factors responsible for failure of earlier Health Policy and understand the current needs of public health care. They hope that the Government will take a realistic approach for proper implementation of the ambitious and holistic goals set in the policy in a time bound manner. The Committee are happy to note that the Government have realised the need for injection of substantial resources into health sector from the Central Government Budget in view of poor resources availability in most of the States. The Committee specifically desire that the Government should stick to the proposed Government expenditure of 2% of GDP by 2010 on Health and Family Welfare and the targets set for coverage of Public Health facilities.

C. Revival of Pharma Sector PSUs

Recommendation (Part II, Para No. 10)

21. The Committee had observed that during the successive drug policies certain drugs were exclusively reserved for production by the public sector. In 1978 Drug Policy this number was 17 which came down to 15 in 1986 drug policy and it was reduced to 5 bulk Drugs only in the Drug Policy announced in 1994. Ultimately, the reservation for public sector has been totally abolished. The Committee had certain information that production of most of the deserved drugs has been stopped either because their cost of production was not economical or their place was taken by new generation medicines. Moreover, all the PSUs in this sector had been declared as sick and were able to produce a negligible quantity of medicines produced by them earlier. Under these circumstances, the Government were spending a huge amount of foreign exchange on import of these medicines. Therefore, the Committee had desired that the Government should compare the amount being spent on the import of these medicines which could be produced by pharma PSUs every year and the amount to be spent for revival of these PSUs. The Committee had desired an immediate revival of these PSUs for the basic healthcare of poor people. They had a strong view that these PSUs would not only be in a position to produce the drugs by using their large manufacturing capabilities rather their capacilities could be utilised for manufacturing generic drugs for weaker sections since private sector had been avoiding the production of such medicines due to less profitability. The Committee had, therefore, recommended that the Government should take all possible initiatives for quick revival of all the sick PSUs in pharma sector particularly IDPL, HAL, BCPL etc. so that once again they might be able to serve the nation's poor population.

22. In their reply, the Government have submitted the following details about each Pharma Sector PSU:-

"The present status of PSUs in pharma sector is as follows:-

IDPL: The company was declared sick by the BIFR in August, 1992. A revival package approved by the BIFR in February, 1994 failed to improve the prospects of the

company in spite of the fact that Government of India extended financial assistance much more than what was envisaged in the scheme approved by the BIFR. The BIFR consequently treated the sanctioned package as failed in January, 1996. The efforts made by the Government of India subsequently to work out a viable rehabilitation proposal did not culminate in any worthwhile result. Accordingly, with a view to facilitate privatization of IDPL the Government has communicated to the BIFR its intention to provide the following concessions/facilities for cleaning up of the balance sheet of IDPL:-

(a) Conversion of Government loan into equity;
(b) Waiver of interest/penal interest and guarantee free by the Government of India;
(c) Payment of outstanding statutory dues and funding of VRS.

HAL: The company was declared sick by the BIFR in March, 1997. Although various rehabilitation proposals have been considered by the Operating Agency appointed by the BIFR for its rehabilitation, none of them could culminate in a concrete proposal. After inter-departmental consultation, the Department of C&PC has framed proposals for rehabilitation of HAL and this is expected to be placed before the Cabinet shortly.

The BIFR has already taken the stand that since no fully tied up viable proposal has been framed in the case of HAL, they would be passing orders for change of management in terms of the provisions of SICA. In the hearing held on 29.08.2001, the BIFR granted two more months for the company/Government of India to submit a fully tied up rehabilitation scheme.

BCPL: BCPL was formally declared sick by BIFR on the 14th January, 1993 and a revival package was approved on the 4th April, 1995. The Government released all the funds as envisaged in the revival scheme. In the meantime, the cost of the revival package based on the revised projections as directed by the BIFR has gone up. BCPL has sought upward revision of the project cost. The revised package is under examination/formulation by the Operating Agency. However, the company is showing signs of turning around.

BIL: BIL was formally declared sick by the BIFR on the 9th March, 1993 and a revival package for the company was approved on the 3rd January, 1995. The performance of the company during the first three years of the revival period had been far below the targets envisaged. The BIFR reviewed the performance of the company on the 5th April, 1999 and declared the sanctioned scheme as failed and further directed the Operating Agency to conduct a techno-economic viability study through a reputed consultant. It also directed the Government of India to submit the revised rehabilitation plan to the OA, BIFR and others concerned based on the report of the consultants. IIM, Kolkata was appointed as consultant to conduct the techno-economic viability study of the company. After examining the report of the IIM, Kolkata, the Government has informed BIFR that the Government is not in a position to formulate a revised rehabilitation plan as directed by the BIFR and also that the Government is not willing to continue as promoter of the company any more and that any decision of the BIFR to wind up the company would be acceptable to the Government. In the hearing held on 9.11.2001 BIFR has, inter-alia, ordered for issuing advertisement for change of management.

SSPL: SSPL was formally declared sick by the BIFR on the 21st December, 1992 and a revival package for the company was approved on the 31st August, 1994. In its review hearings, the BIFR noted that the performance of the company during the first two years of operations was far behind the targets envisaged in the Scheme. After further reviewing the performance of the company on the 17th October, 2000 BIFR declared the sanctioned as failed and inter-alia directed the Operating Agency to issue advertisement inviting offers for the take over/leasing/amalgamation/merger for rehabilitation of the company. The Operating Agency informed the BIFR that they had not received any proposal within the stipulated time period in response to the advertisement. The BIFR formed its opinion that there is not scope for revival of the company and that the company would not be able to make its net worth positive after meeting all its financial obligations and that it would be just, fair, and in public interest that the company should be wound up. Accordingly, BIFR in its hearing held on 3.12.,2001 has confirmed its opinion that SSPL was not likely to make its net worth exceed its accumulated losses within a reasonable time while meeting all its financial obligation and that the company as a result thereof was not likely to become viable in future and it was just, equitable and in public interest that it should be wound up under Section 20 (1) of the SICA. It has also directed to forward its opinion to the concerned High Court. This opinion has since been forwarded to the High Court of West Bengal in Calcutta."

23. The Committee express their anguish over the casual approach being shown by the Government in the matter of revival of sick Pharma Sector PSUs. The Committee are surprised to note that the Government did not care to give a serious thought to the observations of the Committee whereby they had highlighted the need for revival of Pharma Sector PSUs. The Ministry have not even found it necessary to express their views in this regard. The Committee do not hesitate to say that the Government have not been paying due attention towards the revival or rehabilitation proposals of these companies. They, therefore, desire that the Government should take special measures for revival of Pharma Sector PSUs since it is the PSUs only who can play a pivotal role in production of generic drugs for weaker sections of the society particularly during the WTO regime in coming years. The Committee are sure that the Government will be able to recognise the importance of revival of these PSUs, if they consider all the related matters together including import bill on medicines which were being produced or can be produced by these companies and the health care needs of common man. They do not find any justification in keeping all the proposals relating to these companies pending for such long periods. The Committee, therefore, desire that the Government should come out with concrete final proposals for revival/rehabilitation of these companies in the shortest possible time.

D. Availability of Medicines

(i) Availability of single ingredient medicines

Recommendation (Part- II, Para No. 11)

24. The Committee were not convinced with the Government's claim of self-dependency in drugs and pharmaceuticals sector and had observed that Indian consumer was still facing the problem of availability of single ingredient reasonable drugs in each part of the country. The common drugs which were required in day to day ailments by common public, for masses and also by upper class population of the country were being substituted by new molecules not covered under the DPCO. NPPA were also not able to detect/ observe or control such cases since they mainly fix the prices of controlled bulk drugs and formulations.

Reportedly various manufacturers were busy in creating such formulations which did not come under the purview of DPCO, 95. In such condition, even if NPPA had detected such cases and fixed the prices of such products, they were not able to enforce their decision or stop the production of such medicines. The Committee had expected that the Government would find ways and means to stop this unhealthy trend henceforth.

25. The Government have submitted the following reply:-

> "The NPPA fix/revise the prices of formulations based on 74 specified bulk drugs listed under the First Schedule of DPCO 1995. NPPA have noted some instances where manufacturers had changed the composition of the existing formulations by replacing Schedule drugs with non Schedule drugs so as to shift the product from price controlled category to price decontrolled category. Replacement of the product (brand), 'Disprin' containing Aspirin (a Scheduled bulk drug) with Disprin Plus containing Paracetamol, (a non Scheduled bulk drug) is the latest example. As new drugs introduced in the country after 1991 (the latest year for which production/availability data were analysed for placing drugs under price control), had not been examined for inclusion under price control, they have remained in the non-Scheduled category and the prices of such drugs are fixed by the manufacturers themselves. The Pharmaceutical Policy-2002 has been announced by the Government wherein the ORG-MARG data of March, 2001 has been used to identify the drugs to be put under price control. This data will reflect the recent market situation.
>
> NPPA monitor movement of prices of all non-scheduled formulations having considerable sale value and take appropriate action wherever abnormal/unjustified price increases are noticed."

26. The Committee are not satisfied with the initiatives taken by the Government in the matter of creation of new formulations by the manufacturers to avoid coming under the purview of DPCO, 1995. It is a common experience that single ingredient common drugs are not available in the market. The Committee are anguished to note the fact that new drugs introduced in the country after 1991 had not been examined for inclusion under price control, they have remained in non-Scheduled category and prices of such drugs are being fixed by the manufacturers themselves. This means that such business has been running for the last 10 years without any control. The Committee observe that after announcement of new Drug Policy-2002, the Government are in the process of amending Drug (Prices Control) Order 1995. The Committee, therefore, desire that this amendment should make sufficient provisions to stop this unhealthy trend in future. The Committee also desire that NPPA should be given sufficient powers to tackle such situation efficiently.

(ii) Availability of Medicines in Rural Areas

Recommendation (Part-II, Para No 13)

27. While going into the issue of availability of medicines the Committee were dismayed to note that despite the huge production of medicines in the country, the modern medicines were reaching about only one fourth of the population of the country and that too mostly in urban areas. They had further noted that although the industry had developed

comprehensive network of distribution of medicines through agents, stockists, wholesalers and retailers, the difficulties in distribution of medicines in rural areas still persist. The Committee had urged the Government to prepare a time bound marketing plan with the help of concerned State Government for sufficient and smooth distribution of medicines particularly in the rural areas. They had further desired that in this regard the Government must take the help of pharmaceutical companies through their Associations/ Alliances etc. and Doctors, Chemists and NGOs engaged in rural upliftment should be encouraged through tax incentives to set up establishment there.

28. In their reply the Government have stated as under:-

> "The Ministry of Health and Family Welfare has informed that instituting a mechanism in partnership with the health care and pharmaceutical industry to expand the reach in medicine to uncovered and weaker sections of society is a complex issue involving on one hand the extended reach of medical facilities in rural areas and on the other hand availability of low cost quality medicine, and their judicious use.
>
> Pharmaceutical Industry does have representation on the Drug Technical Advisory Board (DTAB) and the Vaccine Production Board, both headed by DGHS. The country is virtually self-sufficient in production of most of the essential drugs. Large number of drugs are exempted from custom duty, excise duty and or sale tax. However, considering the commercial and other logistic issues, pharma industry should spell out the kind of partnership it would like to have with the public sector health care delivery system in the country.
>
> The NHP 2002 specifically recognises the contribution which the private sector can make in all area of health activities. Department of Health is entirely open to the idea of entrusting public health services on an 'as-is-where-is' basis to NGOs/private entities for providing health care at the level of PHCs/CHCs/Sub-centres. So far these responsibilities have been undertaken by NGOs only to a very limited extent. It is self evident that taking on such responsibilities in remote and rural areas requires a very high degree of motivation and public spirit. It is also to be noted that the quantum of fluid/medical supplies made available to these levels in the public health administration are fairly limited. Any NGO/Private entity which undertakes a partnership for extending public health services, will have to live with such constraints."

29. The Committee are happy to note that the National Health Policy-2002 has also recognized the potential contribution of private sector in all areas of health activities. Government have specifically expressed that Department of Health is entirely open to the idea of entrusting public health services on an 'as-is-where-is' basis to NGO/Private entities for providing health care at the level of Primary Health Centres/Sub-centres. The Committee desire that the Ministries concerned with production as well as distribution of medicines should sit together along with State Governments and Pharmaceutical producers/dealers and Associations to finalise a time bound programme for developing a smooth and balanced public health care delivery system for drugs/pharmaceuticals. The Government must make some lucrative proposals to motivate the concerned agencies. They must not wait for suo-moto proposals from NGOs or Pharma companies side since any initiative taken by them may not be able to fulfil the objectives of the Government in real terms.

(ii) <u>Review Screening of Drugs in the Market</u>
Recommendation (Part-II, Part No. 14)

30. While observing the trend of drug distribution and trading practices of retailers and chemists, the Committee had expressed a clear opinion that distorted drug production along with distorted drug distribution, responding to market forces rather than health needs could in no way be expected to meet the health needs of the people. They, therefore, had desired that the Government should immediately review all the drugs in the market and undertake the Central registration with computerisation and enlisting all the drugs in the market followed by screening of the drugs based on the principles of rationality of a National Drug Formulary with inclusion of rational drugs i.e. drugs acceptable within pharmacology and medical text books. The Committee had further desired that after such analysis all the information about irrationality of all the commonly used drugs should be made public and publicised in media and audio-visual means for public awareness.

31. In their reply the Government have stated as under:-

> "The Ministry of Health and Family Welfare has informed that there is no system of prescription audit in the country and most of the health care activity is now in the private sector. Undertaking central registration of drugs is a monumental task and would need major amendments in the Act and Rules as well as in the over all drug regulatory system in the country. This responsibility cannot be undertaken within the present regulatory structure available with the Central Drugs Standards Control Organisation, which is already overburdened with the present task required to be performed by it. The NHP-2002 recognises the need of encouraging use of essential drugs and periodic review of essential drug list. Looking at such scenario it has been proposed in the Pharmaceutical Policy-2002 that the Ministry of Health and Family Welfare would set up a world class CDSCO by modernizing, restructuring and reforming the existing system and establish an effective work of drugs standard enforcement administrations in the states with the CDSCO as a nodal centre, to ensure high standard of quality, safety and efficacy of drugs and pharmaceuticals."

32. The Committee agree with the view of the Government that registration of drugs is a monumental task and it would need major amendment in the Act and Rules. They also understand the problem of shortage of staff in CDSCO. The Committee welcome the steps taken by the Government to stop indiscriminate approval of drug formulation by State Licencing Authorities and for modernization and restructuring of CDSCO. But in Committee's view the Central Registration Review and Screening of all the drugs in the market is essential to stop distorted drug production and distribution in the country. They, therefore, desire that the Government should take all necessary steps for this purpose in a time bound manner.

(iii) <u>Distribution of medicines by Private Doctors/Nursing Homes</u>
Recommendation (Part-II, Para No 15)

33. The Committee had noted that Section 18 of the Drugs and Cosmetics Act, 1940 required every dealer to take a licence for distribution, stock and sale of drugs. But it was a common experience that the Doctors and Nursing Homes were stocking medicines for distribution to the patients without taking licences resulting into the occurrences of spurious medicines. The Committee had desired that this practice should be stopped immediately. The Committee had strongly recommended that a mandatory clause should be introduced in the Act to the effect that the drugs were to be supplied to the consumers only through the licenced Retial Pharmacist and they might be held responsible in case of any wrongful act in the drug supply.

However, the Committee had no objection if such licences were given to the qualified Doctors or Nursing Home owners also so that they may also be held responsible for every wrongful act done by them.

34. About the amendment in Act/Rules to stop distribution of medicines through Nursing Homes and Private Doctors the Ministry have submitted their reply as under:-

"The Ministry of Health and Family Welfare has informed that with the available drug regulatory infrastructure, this recommendation appears to be difficult to implement. There is already a shortage of Drug Inspectors in States and vacancies are not being filed up because of financial constraints. These establishments are presently exempted under Sch. K of the Drugs and Cosmetics Rules for requirement of license. The suggestion of Standing Committee would be placed before the Drugs Consultative Committee in its next meeting. (D/o Health has not indicated the date of next meeting)."

35. The Committee are not convinced with the argument of the Ministry of Health and Family Welfare that with the available drug regulatory infrastructure, the implementation of the recommendation of the Committee appears to be difficult. The Committee had simply desired an amendment in Drugs and Cosmetics Act, 1940 and Rules made thereunder to remove the exemption clause for the establishments like Private Doctors and Nursing Homes. The Committee do not find any justification for not initiating this process with an excuse of poor infrastructure for implementation. The Committee, therefore, reiterate their earlier recommendation and desire that the Government should make appropriate amendment in Schedule K of the Drugs and Cosmetics Rules to stop such unauthorised distribution of medicines by the Private Doctors and Nursing homes.

(iv) <u>Licencing System for sale of drugs</u>
Recommendations (Part-II, Para Nos. 16 & 17)

36. While going into the details of Licencing System the Committee had noted that under the Drugs and Cosmetics Act, 1940, the sales of Allopathic drugs were regularised through licencing system and it was also required to employ pharmacist to supervise the sale of drugs. The Licencee had to satisfy the Licencing Authority about the conditions regarding experience, qualification etc. of the pharmacist and the minimum area of the shop for which the Licence is applied. The Committee had opined that the clause of employing Pharmacist was more relevant at the time when the Act was first written in 1940 and the drugs were dispensed by the chemist (compounding/mixing with more ingradients to get compound or mixture). They had observed that now, most of the medicines were available in ready to use form. Moreover, more than 80% of the drugs produced in the country were supposed to be of International standard. Simultaneously, Drugs Control Department in the states were reviewing such units on the basis of certain manufacturing practices and norms and the prices of drugs fixed by NPPA were also being monitored by them. The Committee had, therefore, desired that these provisions required review to increase the availability of quality medicines to the masses including rural and difficult areas.

37. In the same context the Committee had agreed to the common suggestion made by Drug producers, Voluntary Health Associations and others that supply of essential drugs should be attached with Public Distribution System since this would expand the ambit of access to modern medicine to 90 per cent of population. The Committee had welcomed the

practicability of the proposal given by the Indian Pharmaceutical Alliance that the industry, through consortium of ORG companies, would undertake to supply these drugs to PDS at subsidised rates. The proposed scheme would not entail any expenditure/subsidy by the Government unlike many other items in PDS. The proposals of other organisations/Associations that the drugs under PDS might form a part of a basket of new items such as tea, detergent cake, toothpaste, notebooks etc. being offered under 'Sarvapriya Scheme' was also welcomed, since through the scheme, medicines could be made available at people's doorstep. The Committee had, therefore, desired that the Government should work out a scheme in cooperation with the representatives of various organisations/Associations in the field of drugs and pharmaceuticals. For this purpose they had desired that the Department of Chemicals & Petrochemicals and Ministry of Health & Family Welfare should sit together along with Ministry of Food & Civil Supplies to discuss the modalities of such scheme and bring the scheme in action in a shortest possible time.

38. On the issue of reviewing the provisions employing Pharmacists for distribution on medicines the Ministry submitted the following reply:-

"The Ministry of Health and Family Welfare has informed that a pharmacist is considered as an interface between the patient and the physician in the overall health care delivery system and the sale of drugs is not considered as that of a mere commodity.

It is felt that supervision over distribution/sale of drugs by duly qualified registered pharmacist, is necessary in the interest of the patients and is a norm practiced world over and more so in the developed countries. However, in order to facilitate using a pharmacist by chemists in India, the qualification for registered pharmacist has been kept at Diploma level as against a graduate qualification in most of the countries."

39. The Government have submitted the following reply:-

"D/o Consumer Affairs has informed that - 1) Retail sale of drugs can not be taken up by anybody as certain specified legal and educational requirements have to be fulfilled by the retailer coming from any sector such as State Civil Supplies Corporations, Cooperatives, Private Bodies, Fair Price Shops etc. This is true in respect of all States/Union Territories. In addition to this, the conditions also vary from State to State. Many of these conditions are, however, mandatory in nature and can not be relaxed by any authority. 2) The NCCF also has stated that it may not be possible for ration shops/cooperatives to observe the formalities like appointing Pharmacists, issuance of medicines on the prescription of Doctors etc. Therefore, the drugs of common use require to be identified which could be sold without the prescription of the Doctor and without observing the formalities regarding storage and sale of drugs and medicines. With regard to the implementation of Sarvpriya Scheme, the NCCF has clarified that the response from the States/Uts is not very encouraging."

40. The Committee do not hesitate to say that the Government have not actually understood the intention of the Committee. The Committee had noted the tall claims of the Government in getting self-dependency in medicine production and quality maintenance. In Committee's view the responsibility of the Government is not only to achieve good standards in this field but they are also supposed to do a lot to ensure availability of quality medicines in every nook and corner of the country. This is why, Committee had tried to find the best ways for achieving these

targets. For this purpose they had desired to find whether there could be any possibility to review the licencing conditions or whether these medicines could reach the common man through Public Distribution System or Sarvapriya Scheme. From the analysis of both replies, the Committee have a firm opinion that the essential provision of employing qualified registered pharmacist to supervise the distribution/sale of drugs is the main hurdle in the way of enhancing the access of medicines particularly in the rural areas. The Committee, therefore, reiterate their recommendation and desire that the Government should understand the ground reality, analyse the hurdles in the way of easy accessibility of medicines and come out with concrete proposals. Government should explore the possibilities of relaxing the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder so that the educated persons other than Pharmacists could get better job opportunities to sell the medicines after some short training. However, it should be ensured at the same time that the medicines made available to people through this mechanism are safe and conform to the prescribed standards. In Committee's view this will serve the dual purpose. On one side more educated persons will get jobs and on the other side the medicines will reach maximum number of population. The Committee also desire that the Government should also identify the medicines which could be sold without prescription of the Doctors and without observing the formalities regarding storage and sale of drugs and medicines so that the drugs and pharmaceuticals may reach the common man through Public Distribution System or Sarvapriya Scheme. The quality control measures may also be changed accordingly.

E. <u>Quality Control of Medicines</u>
Recommendations (Part-II, Para Nos. 18 & 20)

41. While going into the matter of quality of drugs, the Committee had noted the poor quality in the large purchases of drugs for Government Institutions on the basis of lowest tender and also, the drugs in the retail market had been known to have quality problems including those from reputed companies. The Committee had desired that minimum standards and quality of drugs and pharmaceuticals should be maintained irrespective of the size of manufacturer, brand generic name and irrespective of the price. Production and purchases of low cost spurious drugs by Government Institutions should be stopped immediately. The Committee had strongly recommended that in case of Central Government purchases, lowest tender purchase system should be stopped and bulk purchase of quality and cheaper drugs should be done somewhat on the lines of State level Essential Drug Policies of the State Governments of Delhi and Tamil Nadu.

42. While analysing the quality control mechanism the Committee had noted that State Drugs Control Organisations were responsible to ensure manufacture of quality drugs through a system of licencing. The main responsibility in this area was with the Drug Inspector. The Committee specifically noted that the number of 1100 of DIs in the States and 32 Inspectors in CDSCO was very inadequate to carry out the work relating to 7000 manufacturing establishments and more than 3 lakh sales outlets. The Ministry of Health & Family Welfare had also accepted the fact that there was paucity of DIs and testing laboratories also. Country's 16 drug testing laboratories in 14 States presented a very dismal picture. Many states had no testing laboratory at all. The Ministry had informed that the Central Government was negotiating for funding a project with the World Bank but the Committee were dismayed to note that only 14 States were participating in the project. The Committee had urged that the Ministry of Health & Family Welfare should call all the State authorities and persuade them to participate in such project so that the objective of updating the facilities and strengthening the Central and State enforcement machinery and augmenting the testing capacity could be achieved by implementing such projects in all States uniformly. They had also desired that the Government should also

persuade the States to appoint more Drug Inspectors in the States and the Central Government should also study the workload and appoint the desired number of Inspectors in CDSCO to make the system more effective. They had further desire the Ministry should also pursue the matter vigorously with Ministry of Finance to get the desired resources.

43. About the system being followed in large purchases in Government system, reply of the Government is as under:-

> "Deptt. of Health in the Ministry of Health and Family Welfare is in agreement with the Committee's recommendation that minimum standards of quality of drugs should be maintained irrespective of size of manufacturer and price. The requirements of Good Manufacturing Practices have therefore been upgraded. The rules are equally applicable to all sectors of industry. The Deptt. has been repeatedly advising the State drug control authorities to augment their drug testing facilities and to undertake GMP audits through well trained enforcement officials.
>
> Bulk procurement of drugs is already being done by the Medical Stores Organisation (MSO) for the National Programmes, Central Government Health Scheme (CGHS) etc. but the established procedure of considering the lowest tender has to be followed.
>
> As far as the quality is concerned, supplies are accepted only after testing has been done."

44. About the inadequacy of drug inspector, the Government have submitted the following reply:-

> "The Ministry of Health and Family Welfare has informed that the recommendations of the Standing Committee to appoint more Drug Inspectors by the State and to establish adequate drug testing labs has to be taken up with the States Governments. As far as CDSCO is concerned that Ministry is vigorously pursuing the matter with Ministry of Finance to sanction adequate staff including revival of lapsed posts which are considered bare minimum to cope with its multifarious and multidisciplinary responsibilities. This recommendation of the Standing Committee will be further taken up with the Ministry of Finance.
>
> In regard to drug testing labs it would be pertinent to note that a drug testing labs as the inflow of samples may not be adequate to support viable testing establishment has to have optimum viability in terms of experienced manpower, sophisticated equipment and funds for various consumables etc. It may not be feasible for small States to have their own independent drug testing equipments. The new Central labs. which are coming up at Guwahati, Chandigarh and Hyderabad may cater to the drug testing needs of all remaining States.
>
> The NHP 2002, while recognizing the need for efficient enforcement of quality standards in the country envisage appropriate policy recommendation on the issue.

The concern towards quality aspects of the pharmaceutical products has been addressed in the Pharmaceutical Policy-2002 too and it has been proposed that the Ministry of Health and Family Welfare would set up a world class CDSCO by modernizing restructuring and reforming the existing system and establish an effective work of drugs standard enforcement administrations in the States with the CDSCO as a nodal centre, to ensure high standard of quality, safety and efficacy of drugs and pharmaceuticals."

45. The Committee are anguished to note that the Government have not undertaken the matter relating to appointment of Drug Inspectors in the States promptly. While appreciating the concern shown towards enforcement of drugs quality standards in the National Health Policy – 2002 and Pharmaceutical Policy-2002, the Committee feel that it does not seem possible to achieve these objectives with a small number of CDSCO staff and without strengthening the State machinery. The Committee are also not satisfied with the justification given by the Ministry that the existing number of testing laboratories is sufficient to cater the drug testing needs of all the States. They, therefore, require that the Government should make concrete efforts on their part and also through persuading the State Governments to appoint more Drug Inspectors along with the modernization, structuring and reforming the CDSCO. The Committee also desire that the Government should develop the drug testing laboratories in a balanced manner so that these are able to cater the needs of all States without any problem.

F. Quality Control of Ayurvedic/Herbal Medicines
Recommendation (Part-II, Para No. 23)

46. The Committee had noted that there was a great demand of Ayurvedic/herbal medicines in the market. Simultaneously, the Committee had observed that the manufacturing of Ayurvedic drugs was controlled by licences but the sale of items were not controlled in any manner. The Committee had recommended that Government should come with some regulatory mechanism for pricing, sale and quality control of Ayurvedic medicines and the medicines of other Indian medicine systems. Necessary licencing for sale of these medicines might also be introduced. They had further desired that separate Drugs Inspectors having knowledge of these systems should also be recruited to control the quality and pricing of these medicines being manufactured in organised sector.

47. The Ministry have submitted the following reply:-

"The Deptt. of ISM&H has informed that keeping in view the high demand for Ayurvedic/herbal medicines in domestic/international market, Government has taken various steps to improve standards of Ayurvedic/Unani/Siddha medicines. At the moment, there is no policy decision for controlling price as well as sale of these products. Though these are very valid and desirable goals, it would be difficult to ensure this in the present scenario. As the market is growing very fast, it will be counter productive to regulate the sale of these drugs. State Governments have been instructed to appoint Drug Inspectors having qualification in ISM and some of the States have designated in-service District Ayurvedic Officers to act as Drug Inspectors for ISM&H. The Government have taken the following measures to promote as well as to ensure the quality of ISM drugs:-

(i) A Central Scheme for functioning of Ayurvedic, Siddha and Unani Pharmacopoeia Committees to develop Pharmacopoeial standards of Ayurvedic, Siddha and Unani drugs.

(ii) 385 single drugs of plant origin of Ayurvedic, Siddha and Unani drugs have been allocated to various laboratories to develop Pharmacopoeial standards under a Central Scheme.

(iii) Research in Ayurvedic, Siddha and Unani drugs is being promoted by setting up Central Council for Research in Ayurveda and Siddha and Central Council for Research in Unani Medicine.

(iv) For quality control of Ayurvedic, Siddha and Unani drugs, a separate Drugs Technical Advisory Board under Drugs and Cosmetics Act has been set up to advise the Govt. on quality control of Ayurvedic, Siddha and Unani drugs.

(v) Good manufacturing Practices (GMP) of Ayurvedic Siddha and Unani drugs have been notified on 23rd June, 2000 to ensure the quality production of Ayurvedic Siddha and Unani drugs.

(vi) Rs. 20.46 crores have been sanctioned during financial year 2000-2001 under Centrally Sponsored Scheme for strengthening of State Govt. Drug Testing Laboratories and Pharmacies of Ayurvedic Siddha and Unani drugs.

(vii) To recognize private Drug Testing Laboratories for Ayurvedic Siddha and Unani drugs, notification has been issued on 27th September, 2001 under the Drugs and Cosmetics Rules for testing of Ayurvedic Siddha and Unani drugs.

(viii) Rule 161 under the Drugs & Cosmetics Rules has been amended for exemption from labelling and packing of Ayurvedic Siddha and Unani drugs for export."

48. The Committee welcome the measures taken by the Government to promote as well as to ensure the quality of Indian systems of medicine drugs. But they do not find these steps to be sufficient. In view of high demand, production and very high prices of these drugs a specific mechanism to control price as well as sale of these drugs has become essential. The Committee understand that this task is tough but not impossible. They, therefore, reiterate their recommendation that the Government should come out with some stringent regulatory mechanism for pricing, sale and quality control of these medicines in consultation with the State Governments and other concerned Departments. Strengthening of State machinery to ensure the quality of ISM Drugs should also be undertaken for proper implementation of already declared measures and the future measures for this sector.

G. **Price Control Mechanism and Role of NPPA**
Recommendation (Part II, Para No. 28)

49. The Committee had found that the objective of creation of NPPA was being defeated in absence of proper monitoring and enforcement of the prices fixed by them. They had

observed that NPPA are dependent on a small number of drug inspectors who were not even under the control of the Department of Chemicals and Petrochemicals/ NPPA. They were least concerned with the implementation of prices fixed by NPPA or detecting the cases of exhorbitant sale price charged by the companies. This had been further proved by the fact that NPPA suo moto had detected several cases even against major pharma companies who were avoiding the prices fixed by NPPA and charging more exhorbitant prices. The Committee had expressed their awareness about NPPA constraints regarding limited number of staff/officers and that too placed at Delhi but in their view that could not be the excuse of non-performance. The Committee had strongly recommended that the Government should strengthen the monitoring system of NPPA for better monitoring of prices fixed by them. The Committee had criticised the Government for delay in submission of Report of the Committee constituted for improving the functioning of NPPA. The Committee had viewed this as non-seriousness on the part of the Government and deprecated it. The Committee had recommended that the Government should take proactive role and make the NPPA more professional in tune with times and needs of the society.

50. In their reply the Government have stated the position as under:-

"As acknowledged by the Committee in the first paragraph, NPPA have been making efforts to perform the responsibilities entrusted to it, to the extent possible. Adequate measures are taken for effective monitoring and enforcement of prices of scheduled and non-scheduled formulations. The Committee are aware of constraints faced by NPPA in terms of man power and powers provided under DPCO for dealing with the industry which comprises of about 20 thousand manufacturers/companies and about 60 thousand formulations. The Committee are also aware that NPPA do not have field officers of its own for enforcing the prices. Even with the existing manpower limitations, the various measures taken by NPPA towards effective monitoring of prices of formulations are given below.

1, Enforcement of prices of Scheduled Formulations

(a) The prices fixed/revised by NPPA for scheduled formulations are promptly communicated to the enforcing agencies, i.e. State Drugs Controllers and Public through mail and postings on NPPA's Website.

(b) Follow up action is taken by writing to all major manufacturers for ensuring implementation of prices fixed/revised by NPPA. Several manufacturers had implemented the prices fixed by NPPA due to such action and submitted copies of supplementary price lists to NPPA indicating implementation of revised/reduced prices.

(c) The State Drugs Controllers are alerted/advised whenever contraventions by manufacturers are noticed from published data like monthly retail pharma audit reports of ORG-MARG, MIMS, Drug Today etc.

(d) A consolidated list of notified bulk drug prices/ceiling prices for all scheduled drugs has been prepared and circulated to the Drugs Control Organizations and Industry Associations for use as a reference copy for implementation. Such fortnightly updated information is also maintained on the Website of NPPA.

(e) Quarterly DPCO implementation returns are called from the State Drugs Controllers to review the performance.

(f) Regional/National level meetings of State Drugs Controllers are organized to review the position.

(g) Interaction with State Drugs Controllers/Industry/Trade is maintained through periodical visits to various States by Senior Officials including Chairman, NPPA.

(h) Cases of organized sector companies circumventing price control mechanism are referred to the MRTP Commission also as cases of unfair trade practices.

2. Monitoring of prices of non-scheduled formulations

A general provision under paragraph 10(b) provides power to Govt./NPPA to fix/revise the retail price of any formulation including a non-scheduled formulation if it considers necessary so to do in public interest. In spite of the absence of guidelines/powers under DPCO, NPPA has formulated some procedures/methodology for monitoring prices of non-scheduled formulations. NPPA has developed a data-base covering all medicines having minimum annual sale value of Rs. 1 crore as reported in ORG. The movement of prices of each such drug is available now in NPPA from 1994 onwards. NPPA is carefully analyzing changes in prices of medicines with a considerable sale value of (Rs. 1 crore and above) and taking action whenever abnormal price increases are noticed. NPPA is also keeping a watch on issues like aberration in retail prices of medicines based on the same bulk drug and abnormal trade margins offered on non-scheduled formulations etc. NPPA has conducted studies on movement of prices of scheduled/non-scheduled formulations during the years 1999 and 2000. Database on consumption pattern of medicines in trade channels has been developed, bulk drug wise. Such exhaustive data is useful in monitoring the trend in usage pattern of various drugs in the domestic market. NPPA has noted that, in general, adequate competition exists in the market and the prices of medicines in the non-scheduled category have not gone up unreasonably. However, individual cases, warranting action are examined and action taken if public interest is adversely affected. The non-cooperation/lukewarm response of the manufacturers in providing information/cost data in respect of non-scheduled formulations is contributing to the constraints faced by NPPA in respect of non-scheduled formulations.

The Pharmaceutical Policy-2002 has laid emphasis over monitoring of prices of drug. It has been proposed that in cases of drugs/formulations listed by the Ministry of Health and Family Welfare in the National Essential Drug List (1996) and 173 items which are considered important by that Ministry from the point of view their use in various Health Programmes, in emergency care etc. and those presently under price control, having significant MAT value as per ORG-MARG but not covered under the proposed criteria in Pharmaceutical Policy-2002, the NPPA would specially monitor intensively their price movement and consumption pattern. If any unusual movement of prices is observed or brought to the notice of the NPPA, the Authority would work out the price in accordance with the relevant provisions of the price control order. It has been further proposed in the Pharmaceutical Policy-2002 that the NPPA would be revamped and reoriented for the purpose of effective monitoring. It is also proposed to strengthen the NPPA by providing appropriate powers under the DPCO which would make it mandatory for the manufacturer to furnish all information as called for by the NPPA.

The Committee of Experts has since submitted its report and NPPA is taking appropriate action over it."

51. The Committee are not satisfied with the performance of NPPA and find that all this is due to non-serious approach on the part of the Government. They have been assigned very important and wide responsibility but they have not been equipped with the appropriate powers and staff. In Committee's view the prices can not be controlled only through notifications. Monitoring of prices fixed by NPPA is the most important aspect which is being ignored. NPPA is facing non-cooperation from the producers also. Under these circumstances, monitoring process becomes an ineffective and futile exercise. The Committee, therefore, strongly recommend that the Government should immediately implement the recommendations of the Committee constituted to give suggestions to improve the functioning of NPPA. The Committee specifically desire that NPPA must be given sufficient powers in the next amendment of DPCO, 95 to make this body more effective in fixation and monitoring of prices of drugs/pharmaceuticals. The Government should also provide the required manpower for proper monitoring of prices fixed by NPPA.

H. <u>Retail Price fixation of Medicines</u>
Recommendation (Part-II, Para No. 30)

52. The Committee had noted that Para 14 and 15 of the DPCO, 95 required the manufacturers to print the minimum retail price of the formulations mandatory with the words 'Retail price not to exceed' preceding it and local taxes extra' succeeding it. They had specifically observed that the multiplicity of taxes (Central, States Entry tax, Octroi etc.), lack of uniformity of tax in various states created confusion in calculating the tax and the dealers face difficulties. In most of the cases consumers paid more price. Increase in number of litigation cases in consumer courts and other forums showed the seriousness of problem. While referring to the demand of chemists and druggists of whole the country to fix retail prices of the medicines as 'MRP inclusive of all taxes' to avoid such confusion, the Committee had strongly recommended that the Government should take all initiatives to fix the uniform retail prices of medicines inclusive of at least all the Central taxes in the shortest possible time for the benefit of the consumers as well as the chemists. They had also directed that after implementation of uniform Sales Tax the objective of 'MRP inclusive of all taxes' should also be achieved.

53. The Government have clarified the position as under:-

> "Under para 14 of DPCO'95, the prices of Scheduled formulations are printed as 'retail price not to exceed…. local taxes extra'. Under para 15 of DPCO'95, prices of non-Scheduled formulations are printed as 'retail price not to exceed local taxes extra'. In both the cases, central taxes are included and local taxes as defined under para 2(kk) of DPCO'95 are to be levied at the regional levels. The issue of printing of prices of medicines inclusive of all taxes has been thoroughly examined in this department from time to time. A Working Group having members from the Industry Consumer Forum & AIOCD was constituted to look into this issue. The Working Group in its report had forwarded the idea of weighted average of taxes to replace local taxes, however, the same has not been found legally sustainable by the Department of Legal Affairs. The High Powered Price Monitoring Board under the Chairmanship of Department of Consumer Affairs is also examining this issue and a status note on this issue has already been made available to the Board."

54. The Committee are not satisfied with the steps being taken by the Government in the matter of printing of retail prices on the scheduled and non-scheduled formulations inclusive of all taxes. For several years the matter has been under consideration without any result. The Committee find it very necessary to minimise the difficulties of consumers and chemists as well as to avoid court cases. They, therefore, strongly recommend that the issue should be resolved properly and promptly before the proposed amendment in DPCO, 95.

I. Separate Drug Policy for Indian Systems of Medicine
Recommendation (Part-II, Para No. 33)

55. The Committee had noted that the Department of Indian Systems of Medicine and Homeopathy was established in 1995. Since then they had undertaken some Research work through four Research Councils under that Department. The Department had also established a medicinal plant cell for development and cultivation of medicinal plants. The Committee had a firm opinion that drugs from plants were very important from Indian point of view as plants were the source that would give an idea about the new molecules which could be proven as new drugs in future. The Committee had desired that the Department of Indian Systems of medicine should prepare a time bound R&D programme for development, quality achievements and standardisation of herbal drugs and drugs from traditional remedies and other natural resources. The Committee had also urged the Government to formulate and announce the national policy on medical plants which was initiated by the Department of Alternative Medicines in the Health Ministry with the help of scientists, Pharmaceutical companies and conservation experts. The Committee had also desired that Government should formulate a separate Drug Policy to regulate the various issues relating to the various Indian Systems of Medicine.

56. In their reply the Government have submitted as under:-

"The Department of ISM&H has informed that the medicinal plants are the single most important source for ISM &H drugs as well as for development of new drug molecules. To give focused attention on this sector, a Medicinal Plants Board has been set up on the 24th November, 2000 to promote the medicinal plant sector. Similar State Medicinal Plants Boards are being set up by the State Governments.

The object of these Boards is to coordinate Programmes, schemes to promote cultivation, conservation, sustainable use and trade of the medicinal plants.

To develop new molecule/drug from plant source, Council for Scientific & Industrial Research has formulated a very ambitious scheme and is working through its network of CSIR Laboratories. The Department of ISM&H is also providing technical advice on the selection of drugs as well as its textual references of medicinal uses.

Department of Science & Technology and Department of Bio-technology are also supporting the new drug development Programmes.

Intra-mural research by the Research Councils and extra-mural research are being made focused and re-oriented. Several areas have been identified for collaborative research in modern institutes. Established protocols for clinical research, efficacy trials and toxicity studies are being followed to enhance credibility and standardization of ISM&H research.

Although a number of measures to ensure the availability and quality of Ayurvedic/ISM drugs have been taken up yet a separate drug policy has not been formulated so far."

57. The Committee take a serious view over the fact that the Department of Indian Systems of Medicine and Homoeopathy has been working for the last seven years without any specific policy. The Committee consider that there is an urgent need for extensive exploration of plant resources of the country having medicinal value for better survival in the Product Patent regime in future. The Committee, therefore, desire that the Government should prepare and announce a separate National Policy on medicinal plants for proper development, quality achievements and standardization of herbal drugs and other natural resources and regulate all the issues relating to the various Indian systems of Medicine.

CHAPTER-II
RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

Recommendation (Part –II, Para No. 2)

The Committee observe that the Government have regularly modified the national Drug Policy as per the demand of time and with certain objectives. With a view to find the requirements of medicines , Hathi Committee was set up in 1974 and on the basis of the report of this Committee the first Drug Policy was formulated in 1978. Since then, revisions have been done in Policy frame work in 1986 and 1994. The stated objective of all the Drug Policy Statements since 1978 has been to ensure adequate availability of quality medicines at reasonable prices.

The Committee find that despite of the significant changes in the economic scenario and life style of the people, the basic structure and thrust of the Drug Policy has not been changed to the desired level. The Department of Chemicals & Petrochemicals have accepted the fact and informed that they are in a process to review the present Drug Policy so as to make it more dynamic and result oriented. The Committee constituted by the Ministry for this purpose has also submitted their report. The Committee support the views of the Ministry and desire that the Government should announce a rational Drug Policy in a shortest possible time. Simultaneously, the Committee urge strongly that the Government should ensure incorporating all the desired changes arising due to dismantling of industrial licensing and policies relating to import, trade controls, lowering of tariff protection, unfolding of product patent regime and globalisation of industry. At the same side, they should be careful that health aspects like therapeutic need, essentiality, efficacy, safety of drugs and availability of drugs to the masses at affordable prices are not ignored at any stage of policy formulation.

REPLY OF THE GOVERNMENT

The (Hathi) Committee on Drugs and Pharmaceuticals Industry, had submitted its report in April,1975. Government laid a Statement on the Table of the Lok Sabha on 29.3.1978 containing its decisions on the said recommendations which later came to be known as Drug Policy,1978.

The Government reviewed the Drug Policy,1978 and restructured it in 1986 by announcing 'Measures for Rationalisation, Quality Control and Growth of Drugs & Pharmaceutical Industry in India. The importance of quality control and rational use of drugs was reiterated in the 'Modifications in Drug Policy,1986' , announced in September,1994.

The Govt. have regularly modified the Drug Policy as per the changes in the health needs of the country and the general economic and industrial scenario. A reorientation of the objectives of the Drug Policy announced in 1994 had become necessary on account of the following :-

a) The essentiality of improving incentives for research and development in the Indian pharmaceutical industry, to enable the industry to achieve sustainable growth particularly in view of anticipated changes in the patent Law; and
b) The need for reducing further the rigours of price control particularly in view of the ongoing process of liberalization.

In March, 1999 the Government had constituted a Drug Price Control Review Committee (DPCRC) to review the current drug price control mechanism and to suggest alternate models, if any, with a view to reducing the rigours of price control where they had become counter productive. Another Committee, namely, the Pharmaceutical Research & Development Committee (PRDC) was also constituted in March, 1999 to recommend measures to strengthen the research & development capability of the pharmaceutical industry in the country and to identify the support required by Indian Pharmaceutical companies to undertake domestic research & development. Both the Committees have submitted their reports to the Government. The recommendations of these Committees have been taken into account in recently announced Pharmaceutical Policy-2002.

The main objectives of this policy are :-

a) Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.
b) Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
c) Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.
d) Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to channelising a higher level of investment into R&D in pharmaceuticals in India.
e) Creating an incentive framework for the pharmaceutical industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.

M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.

Comments of the Committee

(Please see Para No. 9 of Chapter I of the Report)
Recommendation (Part –II, Para No. 3)

The Committee note that the first Drug Policy of 1978 yielded the desired results and strengthened the infrastructure for bulk drug manufacture. In regard to pricing aspects, the policy has categorized the drugs according to their relative essentiality and prices were maintained at reasonable levels through Drugs (Prices Control) Order, 1979. It also laid stress on quality control and rational use of drugs and called for strengthening drug control systems and organisations for effective implementation of Drugs and Cosmetics Act, 1940. No doubt, further amendments in the Drug Policy in 1984 and 1994 and DPCO in 1987 and 1995 gave impetus to development of viable processes which in turn not only helped in meeting the demand of medicines in the country but also gave a boost to exports and as a result the industry has become an important foreign exchange earner. Foreign investment has increased in Pharma Sector and an environment has been created to channalise new investments into the pharmaceutical industry. However, the Committee feel that the Government is far behind in the direction of achieving the key objective of adequate availability of quality medicines at affordable prices. The Committee treat this performance as one sided since it has helped the

industry to grow but the Government have not got the desired success in providing the modern medicines to a common man at affordable prices. The Committee desire that the Government must analyse all the factors which are responsible for such type of performance before bringing the new Drug Policy in existence. The Committee also desire that the new policy should be people friendly and it must be able to serve and nurture and satisfy the common man and the industry both.

REPLY OF THE GOVERNMENT

In March, 1999 the Government had constituted a Drug Price Control Review Committee (DPCRC) to review the current drug price control mechanism and to suggest alternate models, if any, with a view to reducing the rigours of price control where they had become counter productive, to suggest the criteria of market competition and monopoly and turnover for inclusion of drugs under price control and to suggest measures for improving quality of products within the drug price control mechanism to suggest pricing policies for newer generation of drugs, new drug delivery systems and non prescription drugs. Based on the recommendations of this Committee, a note on the Pharmaceutical Policy was submitted to the Cabinet which has been approved by the Cabinet. Government have since announced "Pharmaceutical Policy-2002".

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 9 of Chapter I of the Report)
Recommendation (Part –II, Para No. 6)

The Committee feel that the challenges relating to healthcare in India are formidable. The Government's goal of 'Health for All by the year 2000' has been found to be a total failure. In Committee's view, a total collapse of healthcare machinery during any epidemic crisis, lack of basic health services for the majority of the population, environmental degradation and a population which has already crossed the 1 billion mark tell the story of realities the country is facing after more than fifty years of planned development. Gross disparities in health status and availability of healthcare services exist all over the country. The Committee express serious concern to note the fact that the Government have not felt any need to review or amend the National Health Policy since 1983. It is ironical that India with one of the best developed drug industry in the third world has not been able to ensure availability of essential and life saving drugs to the people at affordable prices. Needless to say that there is an urgent need for framing a comprehensive Health Policy for effective healthcare needs of our people. This policy should evolve through the in depth / critical analysis of the factors which are responsible for failure of existing schemes to meet the health needs. The Committee also desire that the Government should ensure that the new Health Policy synchronizes with the National Drug Policy so that they complement each other and are able to take care of health needs of all the citizens of the country. In Committee's view the prevention and control of communicable and non-communicable tropical diseases should be the plank of the policy since these are emerging as new health challenges over the nest few decades.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that the National Health Policy 2002 has while recognising the formidable challenges relating to health care in India, National Health Policy 2002 has conceptualized various initiatives and policy measures to take care of the emerging challenges and to extend the reach of public health care and to ensure equity.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 20 of Chapter I of the Report)

Recommendation (Part –II, Para No. 7)

The Committee are dismayed to note that the Government expenditure on healthcare as a percentage of GDP has been declining whereas healthcare needs have grown steadily over the years. The actual expenditure on healthcare as percentage of total plan outlay has gradually declined from an abnormally low of 3.3% in the First Five Year Plan (1951-56) to an even lower percentage of 1.7% in Eighth Five Year Plan. This small expenditure is far below than the guidelines of WHO to spend 5% of GDP outlay on healthcare. The representatives of the Ministry of Health & Family Welfare deposed before the Committee that the fund constraints have been the main obstacle in achieving the targets of National Health Programme. The Committee also find this small budget as inadequate and have a firm opinion that this small amount is not able to address the objective of 'Health for All' in any case. The Committee urge upon the Government to raise the Central health outlay appropriately and also direct the State Governments to enhance their health budget in view of the emerging newer challenges to health and to ensure proper healthcare facilities in all parts of the country.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that outlay on health as percentage of total plan outlay and not GDP, as stated in the report of the Committee, has declined from3.33% during 1st Plan to 1.75% during 8 th Plan. During 9th Plan, the percentage of health outlay to total plan outlay has increased to 2.25%. However, when viewed in totality, it is seen that the outlay on health and family welfare as percentage of total plan outlay has remained more or less stagnant (3.33% in 1st plan and 3.24 % in 8th plan). This has increased to 4.01% during 9th Plan. In terms of percentage to GDP, Government expenditure on health and family welfare is 0.9% of GDP whereas aggregate expenditure on this sector is 5.2% of the GDP.

According to the NHP-2002, it is planned to increase the share of Central grants to 25% from the existing 15% by 2010. The State sector health spending is proposed to be increased from the existing 5.5 to 7% of the budget by 2005 and further to 8% by 2010. It is also proposed that Government expenditure on Health and Family Welfare should reach 2% of GDP by the year 2010. Utilisation of public health facilities has been envisaged to provide 75% coverage by 2010 as against the current level of < 20 %.

M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.

Comments of the Committee

(Please see Para No. 20 of Chapter I of the Report)

Recommendation (Part –II, Para No. 8)

The Committee note that Department of Chemicals and petrochemicals is responsible for licensing, overall production and pricing aspects and Ministry of Health & Family Welfare is responsible to maintain quality and distribution of drugs. Therefore, there is a paramount need of very close and efficient coordination between these two Government Departments to achieve the solemn function of the Government to ensure safety, efficacy and quality of drugs supplied to the public. Similarly, they have to play an important role in several important matters like recommending the levy of Customs and Central Excise Duty on drugs and deciding the matter to keep drugs under OGL or Negative List of imports and exports. The Committee find that there is communication gap between the Ministries and there is a need of more close coordination in the matters relating to drugs and pharmaceuticals. Simultaneously, in distribution and quality control the State Governments also have to play a very important role. The Committee, therefore, would like the Health Ministry and Department of Chemicals & petrochemicals to work together with better structured coordination so that the access to medicines with good quality and reasonable prices improved to the desired level. They must work together to overcome the problems in ensuring the abundant availability at reasonable prices particularly of essential and life saving drugs of good quality. They must also ensure the direct / indirect participation of concerned State Government at each stage of decision making in the matters of distribution, availability and pricing of drugs.

The Committee desire that aim of the Government's Policy should be to generate competition within the Pharma industry so as to avoid monopolies and keep prices under check. This should be one of the objectives of Patents Bill which is being thought of in Pharma Sector. It is a well known fact that product patents make pharmaceutical prices prohibitive, Government should exercise its powers through designated agencies to keep prices under reasonable control.

REPLY OF THE GOVERNMENT

Ministry of Health and Family welfare and D/o C&PC have a very close and efficient coordination and have always attempted to evolve common strategy on all important matters. This coordination and close interaction has helped in addressing the important issues effectively in Pharmaceutical Policy-2002 with a view to ensuring the abundant availability at reasonable prices particularly of essential drugs of good quality. The recommendations of the Committee regarding objectives of Patent Bill have been communicated to D/o IP&P.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 19)

The Committee have drawn a firm opinion that solution to improve quality control is not by making consumers pay more but streamlining the Good Manufacturing Practices, quality control systems and increasing accountability of manufacturers, drug testing labs and FDA officials. The Committee desire that the Government should introduce severe penal action for violators of quality control and those producing spurious and sub standards drugs. The Committee have come across various press reports suggesting mass availability of spurious drugs in the whole sale market in metro cities especially in Delhi. Involvement / connivance of the enforcement agencies cannot be ruled out in adding this crime. The Committee desire that the Government should come down heavily on such people who not only manufacture spurious drugs but also on those who sell them. As an initial institutional measure to control this menace, companies should be encouraged to use special packaging materials and a suitable provision therefore should be made in the DPCO.

The Committee also recommend that the Government should strengthen the existing law and if needed enact new legislation to curb spurious manufacturing. Penal action should not be less than the cancellation of licences of individuals and companies and quality control laboratories making it impossible for individuals to float companies in other names to continue business as usual. Not only this, but penal and severe deterrent action should be taken including suspension of FDA officials where found guilty of giving clearance to substandard spurious drugs or giving licences to manufacturers / quality control, labs not meeting minimum requirements for production and quality control. The Committee believe that this type of instilling fear of law among spurious drugs manufacturers and distributors can only minimize the problem and improve the quality control.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that the Committee's recommendation that the solution to improve quality control is through streamlining the GMPs, quality control system, drug testing labs and drug regulatory mechanism which is in tune with Ministry of Health and Family Welfare's approach. In this regard (i) the GMP requirements have been thoroughly revised (ii) all testing labs have been audited (iii) workshops have been held on GLP and GMP (iv) financial assistance is being provided for augmentation of stage drug testing facilities (v) information system with State and Central regulatory agencies are being improved for which a countrywide computer network is being set up (vi) licensing system in respect of validity period and fees has been streamlined. A Capacity Building project has also been posed to the world bank to further assignment and strengthen drug testing facilities in both the Central and Stats Sector.

As far as the penal action for violators of quality control and producers of spurious drugs are concerned, the existing provisions under Section 27 of the Act appear to be adequate. However, it has been observed that court cases linger on for number of years. The clandestine activity of manufacture and distribution of spurious / counterfeit drugs is also difficult to contain without efficient police assistance and focused surveillance by State Drug Control Organisations.

The Department has been repeatedly advising the State Drugs Control Organisations to give top most consideration to fight the menace of spurious drug. HFM has also taken up this issue with all States Health Ministers, in the 7th Conference of CCH and FW held o 12th – 13th July, 2001.

That Ministry has also constituted a committee under DGHS to examine all underlying issues concerning the problem of spurious / counterfeit drugs and come out with recommendations.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 22)

It has been brought to the notice of the Committee that many irrational and unscientific drug combinations are available in the market and the consumer is suffering a lot by using such medicines. The drugs moving in the market are identified as harmful or irrational by practicing doctors, academicians, NGOs and reported by WHO. The Government is in possession of a list of such medicines, which are irrational / harmful identified by Common Cause (an NGO), Voluntary Health Association of India and others under the direction of Supreme Court of India. The Committee desire that the Government should consider the report and all the irrational / harmful drugs should be weeded out / eliminated immediately. The information of weeding out should be announced widely through print media and mass media both for public awareness.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that the issue of irrational/ harmful drugs was raised by Voluntary Health Association of India in a writ before Supreme Court. This has already been decided wherein the Hon'ble Court has observed that the initiatives taken by the Govt. to convene frequent meetings of DTAB and its Expert Committee for screening of drug formulations is an adequate mechanism. This is an ongoing process in which information received through WHO or any other agency about a drug being harmful or irrational is examined and necessary action to prohibit its manufacture under Section 26 (A) of the Act or restrict its use for certain specific indications etc. is being undertaken. As suggested by the Standing Committee, the action so taken would be announced through mass media as well.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 25)

The Committee have noted that task of striking a balance between attending to the needs of the pharmaceutical industry and the needs of the public healthcare makes the drug pricing a highly complex subject. However, this is an area of much importance and of such massive financial implications that most countries adopt some sort of price control. The implementation of DPCO'95 has also revealed some interesting results. For example, the price increase in some of the decontrolled category of drugs has been, by an large, less than the increases granted by the Government to the controlled category of drugs. This shows that the price control does not necessarily ensure lower prices. There are two types of views amongst Drug producers also. Some of them support the system of price control but not in the current form and other have a view that there should not be any price control and the regulation of prices should be left to be decided by market forces. There is a third type of view also which says that prices of all the drugs should be under control. The Committee have clear view that drug price control mechanism has undoubtedly protected the interests of the consumers and this should continue but the present system should be reviewed to make it more transparent and effective. The review will have to address the current framework of price and profitability control, the mode of their

implementation and their carefulness in the context of changed scenario. It should be able to push the national sector and in the interest of the consumer. The Committee desire that the expert Committee report on this subject should be implemented with a view to fulfil above mentioned objectives.

REPLY OF THE GOVERNMENT

In March, 1999 the Government had constituted a Drug Price Control Review Committee (DPCRC) to review the current drug price control mechanism and to suggest alternate models, if any, with a view to reducing the rigours of price control where they had become counter productive. The recommendations of this Committee have been examined and taken into account while formulating the "Pharmaceutical Policy-2002", which has been announced.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 27)

The Committee find that for the same bulk drug there may be several manufacturers also. In such cases, NPPA are not able to take the help of ORG-Marg data since they do not provide data for bulk drugs. On the other side, the Government has accepted that response of manufacturers is very poor in providing data. The Committee reasonably understand that manufacturers must be showing interest in the cases of upward revision mainly. They would not be showing interest in the cases where there is a possibility of lowering of prices. In case of decontrolled medicines can be regulated by the Government if warranted in public interest. This power has been used by NPPA only once in lowering the prices of I.V. fluids. The Committee understand that public interest can not be justified in present situation when a large number of alternatives of same medicines are available in the market. The Committee desire that NPPA should consider comparative percentage of use of various brands particular medicine and not their higher percentage for this purpose. The Committee also desired that that NPPA should be equipped with a power to enable them to obtain the production data from all the controlled bulk drug and formulations manufacturers and in specific cases from the manufacturers of decontrolled bulk drug and formulations also so that the prices fixed by them is justified and reasonable and public welfare oriented and not the business oriented.

REPLY OF THE GOVERNMENT

NPPA agrees with the recommendation that it should be equipped with adequate powers to obtain information in respect of production data.

In the Pharmaceutical Policy – 2002 specific provision has been made regarding monitoring of prices of essential drugs by NPPA. It has been proposed that in cases of drugs/formulations listed by the Ministry of Health and Family Welfare in the alphabetical list of Essential Drugs in the National Essential Drug List (1996) and those considered important by that Ministry from the point of view of their use in various Health Programmes, in emergency care (173 items excluding Sera & Vaccines, Blood products, Combinations etc.) and those presently under price control, having significant Moving Annual Total Value as per ORG-MARG but not covered by the criteria for price control, the NPPA would specially monitor intensively their price movement and consumption pattern. If any unusual movement of prices is

observed or brought to the notice of the NPPA, the Authority would work out the price in accordance with the relevant provisions of the price control order.

NPPA has also been monitoring the prices of non-scheduled formulations in the past.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 31)

The Committee observe that present investment in Drug R&D in the country has been very low. In developed countries R&D investment has been of the order of 12-15% of the total sales turn over as against 1-1.5% in India. CSIR is spending a very small amount on drug research. Some of the major drug companies have established their ultra modern / laboratories. The Committee agree with the opinion of drug industry that the impact of WTO and implementation of TRIPs agreement would open the Indian Drug industry to a totally new paradigm which has not been witnessed for the last 30 years, if the industry has to match up the best in the world the existing policy has to change dramatically and the industry has to invest far more in R&D than it has been able to do in the last 20 years. From the current level of R&D spending of Rs.320 crore annually , the industry needs to increase it to Rs. 1500 crore in the next four years which is a five fold increase. This amount has to be generated from the industry's own resources. The Committee recommend that the Government should frame rules that a company should invest at least a part of its annual turn over say 3% in R&D and employ a minimum number of research scientists in this field alone.

To promote R&D activities further, Government should provide financial incentives to such companies who are doing R&D activities upto a specific level. The financial assistance can be in the form of exemption from income tax, excise etc,. R&D intensive companies, which meet a specific level, may be granted exemption from payment of import duty on chemicals, bio-chemicals, special consumables equipment etc,.

Department of Chemicals & Petrochemicals maintains Drug Prices Equalization Account (DPEA) which is hefty account. The Committee recommend that amounts which accrue to DPEA are protected and need for R&D and promoting higher education in Pharma Sector.

The Committee also recommend that the Government should help to do away with undue delays by taking policy initiatives while clearing new drug applications so that indigenous companies move ahead with their R&D efforts in a time bound manner.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that as regards the speedy clearance of new drugs developed through local R&D efforts, necessary modalities have already been put in place by constituting two separate expert panels, one for new molecules and another for new biotech drugs. Guidelines on good clinical practices have also been published.

In regard to DPEA, it is stated that under DPCO,1995 Government has already made a provision that the accumulation in DPEA shall be, inter-alia, utilized for promoting higher

education and research in pharmaceutical Sciences and Technology and for the purposes incidental thereto as per Para 12(2) (c) of the DPCO,95. Accordingly, this Deptt. has already allocated Rs.12.50 crores to NIPER for such purpose.

The Pharmaceutical Policy-2002 has envisaged measures to encourage R&D such as, in principle approval to the establishment of the Pharmaceutical Research & Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology which will also constitute a Drug Development Promotion Board on the lines of the Technology Development Board to administer the utilization of the PRDSF. It has also been proposed that with a view to encouraging generation of intellectual property and facilitating indigenous endeavors in pharma R&D, appropriate fiscal incentives would be provided.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 32)

The perspective of drug research and development in India requires drastic changes in the post WTO period. There is a need to discover and introduce new drugs. Multinational companies are selective in their research on priorities and are concentrating only in few areas. There is practically no research directed to drugs in tropical diseases such as leprosy, filaria, Malaria, Diarrhea, Helminthiasis, amoebiasis and iron deficiency. The Committee, therefore, urge the Government to prepare a time bound programme for new drug development programme in tropical diseases relevant to the country. Since the drug development require huge investment, the Government should try to arrange the required fund as per the suggestions of Dr. Mashelkar Committee.

REPLY OF THE GOVERNMENT

The Pharmaceutical Policy-2002 provides for in principle approval to the establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology, which will also constitute a Drug Development Promotion Board (DDPB) on the lines of the Technology Development Board to administer the utilization of the PRDSF.

The NHP 2002 envisages increase in Govt. funded health research to a level of zx2 % of total health spending with a focus on new therapeutics and vaccines for tropical disease, sub types of HIV/AIDS. Encouragement to private entrepreneurs in the field of medical research for new molecule through fiscal incentives has been recommended.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 34)

Through the in depth study the Committee find that traditional systems of medicines still have an important role in urban and rural areas and inputs in appropriate use of health system and non-drug therapies as an important component. The Committee urge that local health resources must be used and preventive and promotive health work must get the support of the Government. If these options are wiped out increasing dependency on unregulated use of allopathic medicines and medical services may create more problems in terms of increasing indebtedness, major side effects of drugs and emergence of drug resistance.

REPLY OF THE GOVERNMENT

The Deptt. of ISM&H has informed that 2% of the Pradhan Mantri Gramin Yojana health budget has been decided to be earmarked for purchase of ISM drugs by the States, which ought to improve the availability of such drugs within the hospitals and dispensaries run by the State Governments.

To utilize the local health traditions and practices of our country as well as to utilize non-drug therapies, various steps have been taken. Central Council for Research in Ayurveda & Siddha and Central Council for Research in Unani Medicine have documented various folklore practices prevalent in the country to examine them critically for larger use. Similarly, Yoga and Naturopathy, the drugless therapies are being used for various drugless promotive health objectives. The health traditions and knowledge will also be subjected to validation. The documentation of folk medicines, tribal remedies and other such practices will continue as one of the activities of our research councils. NGOs and other agencies will also get legitimate support for their work in this area. Simple home remedies of Ayurveda/Unani systems of medicine are also propagated through published literature in the country.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 35)

The Committee are aware of India's obligations under WTO. But it is heartening to note that the country is having strong domestic manufacturing expertise capable of supplying cost-effective generic drugs. Brazil's initial success against the US in the AIDS drugs may be a source of inspiration for a host of developing countries on the degree to which they can tailor their national laws to ensure access to medicines even while not infringing 'TRIPs'. The Committee desire that India should develop mechanism with like minded developing countries with an aim to ensure protection of commercial interests of indigenous firms in the regime of free trade.

The Committee have apprehensions that under WTO obligations 'free trade system' may not hit indigenous industry. Therefore, import should be highly excised and proper import procedures be set up so that low quality formulations do not come to India under the guise of 'free trade'.

REPLY OF THE GOVERNMENT

M/o Health and Family Welfare has informed that Imports attract customs duty and not excise duty. Drugs and Pharmaceuticals attract duty @ 35% i.e. peak customs duty, which has been reduced to 30% in the Union Budget proposals for 2002-2003.

The M/o Health and Family Welfare has already taken necessary steps to lay down elaborate requirement for registration of all imported drugs in the country including the registration of overseas manufacturers. The Drugs & Cosmetics Rules have been suitably amended vide Notification No.GSR 604(E) dated 24.8.2001. The new registration system will ensure level playing to Indian Drug Industry under a 'free trade' environment and would also ensure strict check on the quality of formulations likely to be imported.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

CHAPTER III

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

Recommendation (Part –II, Para No. 1)

The Standing Committee on Petroleum and Chemicals (10th Lok Sabha) as back as 1993 had examined the proposed Draft national Drug Policy and in their 2nd Report submitted to Parliament on 6th August, 1993 had made several recommendations on the subject. Important ones are as under :-

(i) Govt. to ensure abundant availability of essential and life saving drugs / medicines of good quality at reasonable prices.
(ii) Govt. asked to raise Health budget (from 1% of GDP to WHO guidelines of 5%).
(iii) Govt. to protect indigenous industry from MNCs.
(iv) Reservations of drugs for PSU's and revival of PSUs.
(v) Govt. asked to simplify pricing mechanism
(vi) Safeguards in patent regime
(vii) Expenditure on R&D to be augmented and Govt. to give incentives to attract funds in R&D.
(viii) Govt. to weed out irrational drugs. Also Govt. to consider use of generic names in drug industry.
(ix) Govt. to encourage Indian Systems of medicine.

The Committee further reiterated some of their recommendations in their 10th Report presented to Parliament in March, 1995.

However, Committee's examinations of the related aspects after a gap of 7-8 years has revealed that Govt. Commitments seems to be on paper only and much has not changed in between the 7 long years. The Committee, therefore desire that Govt. should furnish specific reply as to how much progress has been achieved in implementing the Committee's recommendations stated above. The Committee's recommendations arising out of examining the subject afresh are given in the following paragraphs.

REPLY OF THE GOVERNMENT

1(i) After the submission of the 2nd Report to Parliament in August, 1993 by the Standing Committee on Petroleum and Chemicals, the Drug Policy was reviewed and 'Modifications in Drug Policy,1986' were announced in September, 1994, outlining the main objectives of Drug Policy, inter alia, to ensuring abundant availability at reasonable prices of essential and life saving and prophylactic medicines of good quality. Thereafter in August, 1997, the National Pharmaceutical Pricing Authority (NPPA) was set up as an attached office of this department , which handles, inter alia, pricing of Scheduled bulk drugs and formulations and implementation of various provisions of the Drugs (Prices Control) Order, 1995.

Pharmaceutical Policy-2002 announced in Febraury,2002 also has the objective of, interalia, ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.

(ii) Government is conscious of the need to raise public expenditure on Health and accordingly under the Draft National Health Policy, 2001, it is planned to increase public health investment to 2% of GDP by the year 2010. However, keeping the overall financial constraints in view, it may not be possible to raise the Health budget to the level of WHO guidelines.

(iii) After the submission of the 2nd Report to Parliament in August, 1993 by the Standing Committee on Petroleum and Chemicals, the Drug Policy was reviewed and 'Modifications in Drug Policy,1986' were announced in September, 1994, outlining the main objectives of Drug Policy, which include interalia, the objective of strengthening the indigenous capability for production of drugs. Government have recently announced "Pharmaceutical Policy-2002" with the objective of, interalia, strengthening the indigenous capability for cost effective quality production.

(iv) As the production of drugs reserved for PSUs was negligible or their cost of production was not economical or their place has been taken over by new generation drugs, reservation for the PSUs was abolished. Details of revival of PSUs are given in the reply of the Government to Recommendation No.10.

(v) The Government constituted in August, 1997 National Pharmaceutical Pricing Authority (NPPA), an expert body to streamline and simplify the procedure and to bring about a greater degree of transparency as well as objectivity. This Authority is entrusted with the task of price fixation – revision and other related matters such as updating the list of drugs under price control by inclusion and exclusion on the basis of established criteria / guidelines. The National Pharmaceutical Pricing Authority is empowered to take final decisions, which are subject to review by the Central Government as and when considered necessary. The Authority monitors the prices of decontrolled drugs and formulations and oversee the implementation of the provisions of the Drugs (Prices Control) Order.

(vi) The Patent Act, 1970 contains several provisions intended to safeguard public interest. These provisions are :-

(b) Conditional grant of patent (Section 47)
(c) Revocation of patent in public interest (Section 66)
(d) Grant of compulsory license (Section 84,85,89,90,95 and 96)
(e) Grant of compulsory license on notification by Central Government (Section 97)
(f) Use of invention for the purpose of Government (Section 100 and 101)
(g) Acquisition of invention and patent for public purpose (Section 102)

Some of these provisions are proposed to be aligned with the obligations under the TRIPs Agreement of the WTO Agreement. The Patents (Second Amendment) Bill, 1999 which seeks to fulfil India's obligations under TRIPs Agreement by amendment to the Patents Act, 1970 also contains additional provisions in this regard which are as under :-

(a) Bolar provision which ensures production and marketing of products covered by patent including drugs, just after expiry of patent protection (clause 51 of the Bill)
(b) Provision for parallel import to ensure availability of patented products, including drugs at lowest international price (Clause 51 of the Bill)

A Joint Committee of the Parliament which has examined the provisions of the Bill has restructured some of the provisions in its report in December, 2001 relating to public interest, compulsory licensing, Government use, national security, protection of public health and nutrition. The report of the Joint Committee is under consideration. However, at present the product patent regime is not applicable in India.

Keeping in view the fact that a number of countries have sought and obtained patents on the medicinal uses of various plants on which knowledge is already available and documented in India, the Deptt. of Indian Systems of Medicine & Homoeopathy has taken steps to prevent such claims of innovations. Traditional Knowledge Digital Library (TKDL) is being established to document the available knowledge on the medicinal use of plants used in Ayurveda already in the public domain, in patent compatible format. This is being done with a view to forestall the grant of patents for claims which are neither inventions nor discoveries. It is a novel approach and has been supported by the World Intellectual Property Organisation. Once this information is documented in patent compatible format in the languages the patent examiners generally access, it would be obligatory on the Patent Examiner to scan the information while considering claims for patents and deny if these are prior existing knowledge.

About 35 Ayurveda Experts, 5 I.T. Experts and 5 Patent Examiners will complete documentation of about 35,000 formulations available in 14 identified classical books. The work has already begun and is expected to be completed in 10 months. Similarly, TDKL will be established for Siddha and Unani in due course.

(vii) The Government had constituted a Pharmaceutical Research & Development Committee under the chairmanship of Dr. R.A. Mashelkar, Director General, CSIR, with a view to recommend measures to strengthen the research and development capability of the Pharmaceutical Industry in the country and to identify the support required by the Indian Pharmaceutical companies to undertake domestic R&D. The Committee, in its report submitted to the Government , has recommended the establishment of a Pharmaceutical Research and Development Support Fund (PRDSF) to help the drug industry in research & development. When the EFC note was submitted to Ministry of Finance for the establishment of this fund, the Department of Expenditure in that Ministry advised that this note should be prepared and submitted by the Department of Science & Technology. This matter has since been transferred to that Department and further action is being taken by them.

(viii) Reply on weeding out irrational drugs is submitted under Recommendations No.5.

(a) In order to promote generic name for drugs, it has already been provided under Drugs & Cosmetics Rules (Rule96) that proper name of the drug i.e., generic name shall be printed or written in more conspicuous manner than the trade name if any, which shall be done immediately after or under the proper name.

(b) Through amendment made in 1981, it was also provided that any drug in Schedule W to the Rules and all New drugs as single active ingredient, should be marketed only under a generic name. However, writs were filed in Delhi High Court against this amendment and the case had gone up to the Supreme Court of India which has finally struck down this amendment.

(ix) The Department of Indian Systems of Medicine & Homoeopathy was set up as a separate Department in the Ministry of Health & Family Welfare in 1995 to give focussed attention to the development of Indian Systems of Medicine & Homoeopathy.

The following six thrust areas have been identified for the Government intervention and support.

(i) Improvement and upgradation of standards of education in ISM&H;
(ii) Standardisation of drugs;
(iii) Ensuring sustained availability of raw materials, i.e., medicinal plants, metals, minerals and materials of animal origin etc.;
(iv) Research and Development;
(v) Participation of ISM&H in the National Health Care Delivery System, National Health and Family Welfare Programmes;
(vi) Information, Education and Communication.

Central Council for Research in Ayurveda & Siddha, Central Council for Research in Unani Medicine and Central Council for Research in Homoeopathy are engaged in drug research, clinical research, literary research and survey of medicinal plants, etc. Central Council for Research in Yoga & Naturopathy assists institutions for running diploma course, propagation and treatment centres. In addition, extra mural research is being finalised by the Department.

The Department has formulated and implemented the following schemes -

1. Scheme for improving and strengthening of the existing undergraduate colleges of Indian Systems of Medicine & Homoeopathy.
2. Scheme for upgradation of departments for postgraduate training and research in ISM&H.
3. Scheme for Re-orientation Training Programme for ISM&H personnel.
4. ISM component under Re-productive & Child Health programme of Deptt. of Family Welfare.
5. Scheme for Extra Mural Research Projects on Indian Systems of Medicine & Homoeopathy.
6. Scheme for providing Central assistance for development of agro-techniques and cultivation of medicinal plants used in Ayurveda, Siddha, Unani & Homoeopathy.
7. Scheme for assisting international exchange programme conference and seminar.
8. Implementation of Information, Education & Communication Scheme for ISM&H.
9. Central Scheme for functioning of Ayurveda/Siddha/Unani Pharmacopoeia Committee to develop pharmacopoeial standards for ISM drugs.

The Pharmacopoeia Committees for Ayurveda, Siddha, Unani and Homeopathy are engaged in preparing formularies and evolving standards. The pending pharmacopoeia work is expected to be completed soon.

The Pharmacopoeial Laboratory of Indian medicine (PLIM) and the Homoeopathy Pharmacopoeial Laboratory (HPL) are being strengthened to assist in the completion of Pharmacopoeial work.

Pending the completion of the Pharmacopoeia work, the Government of India has finalised Good Manufacturing Practices for Ayurveda, Siddha and Unani drugs. The same has been notified on 23.6.2000 to be effective from 23.6.2002. This will add to the credibility of the

ISM&H drugs once the industry adopts it. There is resistance from the small and tiny sector industries.

Govt. of India has constituted an independent National level body called "Medicinal Plants Board" (vide Gazette Notification dated 24th November, 2000) to look after policy formulation, coordination with Ministries/Departments/Organizations and State/U.T. Govts. for ensuring sustained availability of Medicinal Plants and to co-ordinate all matters relating to their development and sustainable use.

A new scheme for upgrading State Drug Testing Laboratories and Pharmacies was introduced to improve the capacity of the States and to monitor the quality of ISM products which is their statutory responsibility. Already 11 states and 21 pharmacies have been assisted and the scheme is continuing. This will greatly help augment production of standard drugs and quality control of drugs of Indian Systems of Medicine.

Notification making provision for the recognition of private laboratories as government approved laboratories for batch-by-batch testing of ISM drugs has been issued on 27.9.2001.

In addition to the existing National Institutes like National Institute of Ayurveda, National Institute of Homoeopathy, National Institute of Naturopathy, National Institute of Unani Medicine, Rashtriya Ayurveda Vidyapeeth, Institute of Post-Graduate Training & Research, National Institute of Siddha, National Ayurveda Hospital and a new complex of Morarji Desai National Institute of Yoga are proposed to further strengthen and propagate Indian Systems of Medicine & Homoeopathy.

The Department has also taken steps to obtain inter-sectoral cooperation, globalisation of ISM&H and integration of ISM&H in health care delivery system and in National Programme

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 12)

The Committee find that there is an availability of multiple alternative of most of the important drugs in the market. As per the available information most of the bulk drugs have 20 to 30 branded formulations and the doctors have many treatment choices. The companies that had once specialized in the manufacture of bulk drugs are now making and selling their own formulations. Several companies are preparing such formulations which do not come under DPCO. There is a total confusion in prescription and therapy as well as making the quality control nightmare. With the entry of high priced newer drugs and aggressive and unethical marketing of new formulations, there is non-availability of safer and lesser-priced common man's drugs. NPPA too is not able to handle this position effectively. In this whole situation, the main sufferer is the consumer. The Committee desire that the Government should come out within a perfect mechanism to analyse all drugs and formulations, dosages forms and pack sizes in the market so as to make quality control more viable and manageable.

The Committee feel that much needs to be done on Quality front. There are disturbing reports that even the medicines which are exported some times do not match the benchmark regulatory standards with the result that consignments are returned. In domestic market such complaints are frequent and blame for low quality medicine is shuttled between one

enforcement to another. There should be bench mark regulatory standards matching with those adopted in the developed countries for manufacturing, harmonize standards for clinical testing with global practices and even stream-lining the procedures for speedy evaluation and clearance of new drug applications locally developed.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that the regulation over drug manufacture is a State activity where as the prescription is prerogative of a Physician. Therefore self regulatory role has to be played by the Medical Associations and medical fraternity regarding rational prescriptions.

While newer drugs are higher priced, it has been observed in India that the prices of most of the new drugs manufactured by Indian firms rapidly decline as a number of firms copy the same molecule. There have been no report/complaint about the non-availability of lesser priced common man's drugs.

In order to improve the bench mark for quality standards and corresponding manufacturing requirements, the Deptt. of Health has amended Sch. M of the Drugs and Cosmetics Rules vide GSR No.894(E) dated 11.12.2001. These requirements are in tune with the internationally recommended guidelines like that of WHO.

There are no separate provisions for regulating export of drugs. All drugs including the one which are exported are required to meet the standards of either the importing country or the standards prevailing within the country .Every importing country has its own registration system and regulatory mechanism to ensure that doubtful quality products do not enter in the market. Deptt. of Health has been recommending that importing countries should insist on WHO GMP certification and drug master file etc. regarding companies from whom they import drugs.

As far as the clinical testing is concerned, the Deptt. of Health has amended Rule 122 (a) to (e) of the Drugs and Cosmetics Rules to prescribe evaluation fees for new drug applications and to prescribe corresponding application requirements etc. in order to ensure timely and speedy evaluation. Separate panels have been constituted to evaluate locally developed totally new molecules. The NHP-2002 emphasis the need to discontinue sale of irrational drug formulation and to encourage rational use of drug.

The Pharmaceutical Policy-2002 has also addressed the concern on quality aspects and it has been envisaged that the Ministry of Health and Family Welfare would

i) progressively benchmark the regulatory standards against the international standards for manufacturing,
ii) progressively harmonize standards for clinical testing with international practices,
iii) streamline the procedures and steps for quick evaluation and clearance of new drug application, developed in India through indigenous R.&D, and
iv) set up a world class Central Drug Standard Control organization (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective net work of drugs standards enforcement administrations in the States with the CDSCO as a nodal center, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 21)

The Committee observe that the Ministry of Health & Family Welfare are unable to monitor the Small Scale Industries in Pharma Sector due to the paucity of inspectable staff. Moreover, the products of these industries are not covered by the Drugs Prices Control Order, 1995. The Committee strongly recommend that all the SSIs should also be brought under the orbit of DPCO'95 since they contribute more than 30% of drug production in the country. The Committee are in favour that SSIs must get all the types of incentives but not at the cost of quality of the products. Since Governments have enhanced the investment limit from Rs.60 lakh to Rs.3 crore, some minimum requirement of Good Manufacturing Practices for these units should be fixed to be observed by them.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that the Standing Committee's observation that that Ministry is unable to monitor the Small Scale Industry (SSI) in pharma sector, appears to be misplaced as licensing and quality monitoring is basically a State function. The requirements of GMPs are statutorily applicable to all units without any sector consideration. As already stated these are in the process of being upgraded. The status of implementation however may vary from state to state due to the variation in their label of regulatory competence and enforcements policies.

The D/o C&PC submits that the exemption from price control for small-scale units is not available for all scheduled products. The small-scale manufacturers are required to comply with the ceiling prices fixed for scheduled formulations wherever available. Scheduled formulations, not covered under ceiling prices, i.e. non-ceiling packs only are exempted from price control, provided the small scale manufacturer complies with certain conditions specified in the order S.O.No. 134(E) dated 2nd March, 1995.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 24)

Although the Ministry of Chemicals and Fertilizers is nodal Government agency in the country for drugs and pharmaceuticals sector, there is no Science and Technology Advisory Committee (STAC) attached to the Department of Chemicals & Petrochemicals. The Committee strongly recommend that STAC should be constituted immediately. As per the recommendations of the Working Group on Drugs and Pharmaceuticals this would help in activating R&D to achieve the national objectives. It is supposed that the Committee will give overall direction for the Drug Research and Development, up gradation of Technology etc,. The Committee desire that the Advisory Committee should give thrust on R&D linked with demand of the drugs and pharmaceuticals sector under long term specific plans and Programmes with necessary evaluation and monitoring.

REPLY OF THE GOVERNMENT

In March 1999 a Committee namely Pharmaceutical Research and Development Committee was set up by the Government under the Chairmanship of Dr. R.A. Mashelkar, Secretary DSIR and Director General CSIR, with eminent persons from the fields of Research and Development and industry as members to recommend measures to strengthen the research and development capability of the pharmaceutical industry in the country and to identify the support required by Indian pharmaceutical companies for undertaking domestic R&D.

The said Committee has given wide ranging recommendations and action agenda on the subject, which have since been forwarded to Ministries/Departments concerned, viz., Ministry of Health & Family Welfare including DCG(I) and ICMR, Ministry of Finance, Department of Science and Technology, Deptt. of ISM&H and Department of Biotechnology for necessary action. In so far as matters related to this Department are concerned, those were examined and appropriate decision were taken while formulating the Pharmaceutical Policy – 2002 announced in February,2002 . The Pharmaceutical Policy-2002 envisages in principle approval to the establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology, which will also constitute a Drug Development Promotion Board (DDPB) on the lines of the Technology Development Board to administer the utilization of the PRDSF. In view of this development a STAC may not be necessary at present.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 26)

The Committee find several lacunae in the price control fixation system of NPPA. NPPA fix the price of bulk drugs on the basis of data provided by the manufacturers. Although the prices of some bulk drugs have moved down, this is not reflected in the retail prices of non-scheduled formulations. Besides, concern has been expressed on the high commission / margins offered to the trade, much detriment of the consumers. The Committee desire that the difference between the first sale price of a formulation by manufacturers and the retail price be limited to a specific level say one third of the first sale price of the maximum retail price in the case of decontrolled drugs. Price control system should encourage use of time-tested effective / safe drugs and to discourage the use of costly drugs which may not be medically superior. Involvement of Drug Controllers at the time of clinical tests may prove beneficial.

The Committee tend to agree with the views of Organisation of Pharmaceutical Producers of India (OPPI) that pharmaceutical industry is the only industry which is subjected to three tier control viz., Control on prices of bulk drugs, control on prices of formulations and control on overall profitability. Perhaps this is the reason that out of total industrial investment including foreign direct investment (FDI) during the period August 1991 to March 2000, the pharmaceutical industry accounted for only 5% in terms of Letter of Intent. However, if Industrial Entrepreneur Memoranda are accounted for, the investment amounts to hardly 1% of the total investment.

The Committee recommend that the Government should take note of the views of the organisations like OPPI and address their constraints suitably so that pharmaceutical growth is not hindered.

REPLY OF THE GOVERNMENT

NPPA fixes/ revises the prices of Scheduled bulk drugs/ formulations as per the various provisions/ formula laid down under DPCO, 1995. Whenever the prices of Scheduled bulk drugs are reduced, NPPA revises the prices of the related formulations on suo-motu basis, if the manufacturers do not submit applications on their own within the prescribed period. However, in respect of Non-scheduled drugs, in general, the prices have declined consequent to the decline in the prices of the concerned bulk drugs, excepting in some cases. It may be noted that not only the cost of bulk drug but other factors like cost of sales promotion, R & D cost, company's overall profitability etc. also play a role in the fixation of the retail price of a formulation.

As regards fixation of a ceiling on trade margins in respect of Non-scheduled formulations, in an earlier occasion, the Ministry of Law had opined that fixation of ceiling on trade margins in respect of Non-scheduled formulations is not legally tenable.

However, it appears that the desire of the Committee that the difference between the first sale price of a formulation by manufacturers and the retail price be limited to a specific level does not find support from the views of Organisation of Pharmaceutical Producers of India that pharmaceutical industry is the only industry which is subjected to three tier control and to which the Committee tend to agree. In order to review the current drug price control mechanism, with the objective, inter-alia, of reducing the rigours of price control, where they had became counter-productive, a Committee, called the Drugs Price Control Review Committee (DPCRC) was set up in 1999. The recommendations of DPCRC have been examined and taken into account while formulating the "Pharmaceutical Policy – 2002" announced in February,2002. It has been envisaged in this policy that the present provision of limiting profitability of pharmaceutical companies, as per the Third Schedule of the present Drugs (Price Control) Order, 1995, would be done away with. However, it has also been provided in the policy that if necessary so to do in public interest, price of any formulation including a non-scheduled formulation would be fixed as revised by the Government.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 29)

The Committee agree with the common view of all the drugs manufacturers' that there is very high taxation on drugs and pharmaceuticals. The Committee observe that total indirect tax burden to consumer on medicines by ways of Customs Duty, Excise Duty, Sales Tax, Octroi etc. work out to 37% of the final price. It is worthwhile to mention that medicines are essential commodities under the Essential Commodities Act. The Committee find that this type of heavy taxation on medicines is not justified. The Committee strongly recommend that Department of Chemicals & petrochemicals should undertake the matter with the Ministry of Finance so that there is maximum curtail in Central taxes on medicines particularly the essential medicines for the benefit of poor people of country. The Department should also pursue the Ministry of Finance to implement the scheme of uniform sales tax in all the States so that the cost variations in States can be removed.

REPLY OF THE GOVERNMENT

The D/o Revenue has informed Life Saving Drugs have already been placed in the category of goods with zero percent rate of sales tax under the new policy of uniform floor rates. Member Secretary of the Empowered Committee of State Finance Ministers constituted by the Union Govt. to monitor implementation of uniform floor rate of sales tax has also intimated that as recommended by the Ministry of Health, all the States/UTs have been advised to adopt, for this purpose, the same schedule of life saving drugs which is recommended for exemption from custom duty.

While it is true that the general effective rate of customs duty applicable to drugs and pharmaceuticals is presently at the peak rate of 35%, as many as 254 life saving drugs are fully exempted from all duties of customs. Moreover, bulk drugs required for the manufacture of exempted life saving drugs are also exempted from basic customs duty. The rationale for charging duty at the peak rate on drugs and pharmaceuticals is that there is a strong and large indigenous industry which requires protection from imported drugs. At the same time, life saving drugs that are either not manufactured in the country or are not available in adequate supply have been fully exempted. The list of exempted drugs is reviewed in every budget from the point of view of withdrawing exemption on drugs of which production has commenced in the country as also adding newly developed drugs and substitutes.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

CHAPTER – IV

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

Recommendation (Part –II, Para No. 11)

The Committee are not convinced with the Government's claim of self-dependency in drugs and pharmaceuticals sector since Indian consumer is still facing the problem of availability of single ingredient reasonable drugs in each part of the country. The Committee find some justification in the observation made by the All India Small Scale Pharmaceutical Manufacturers Association that the drugs have not become costlier rather costlier drugs have come into the market. The common drugs which are required in day to day ailments by common public, for masses and also by upper class population of the country are being substituted by new molecules which are not covered under the DPCO. NPPA are also not able to detect / observe or control such cases since they mainly fix the prices of controlled bulk drugs and formulations. Reportedly various drug manufacturers are busy in creating such formulations which do not come under the purview of DPCO,95. In such condition, even if NPPA detect such cases and fix the prices of such products, they are not able to enforce their decision or stop the production of such medicines. The Committee expect that the Government will find ways and means to stop this unhealthy trend henceforth.

REPLY OF THE GOVERNMENT

The NPPA fix / revise the prices of formulations based on 74 specified bulk drugs listed under the First Schedule of DPCO 1995. NPPA have noted some instances where manufacturers had changed the composition of the existing formulations by replacing Schedule drugs with non Schedule drugs so as to shift the product from price controlled category to price decontrolled category. Replacement of the product (brand), 'Disprin' containing Aspirin (a Schedule bulk drug) with Disprin Plus containing Paracetamol, (a non Schedule bulk drug) is the latest example. As new drugs introduced in the country after 1991 (the latest year for which production / availability data were analysed for placing drugs under price control), had not been examined for inclusion under price control, they have remained in the non-Scheduled category and the prices of such drugs are fixed by the manufacturers themselves. The Pharmaceutical policy-2002 has been announced by the Government wherein the ORG-MARG data of March,2001 has been used to identify the drugs to be put under price control. This data will reflect the recent market situation.

NPPA monitor movement of prices of all non-Scheduled formulations having considerable sale value and take appropriate action wherever abnormal/ unjustified price increases are noticed.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 26 of Chapter I of the Report)

Recommendation (Part –II, Para No. 13)

The Committee are dismayed to note that despite of the huge production of medicines in the country, the modern medicines are reaching about only one fourth of the population of the country and that too mostly in urban areas. Although the industry has developed comprehensive network of distribution of medicines through agents, stockiest, wholesalers and retailers, the difficulties in distribution of medicines in rural areas still persist. The Committee urge the Government to prepare a time bound marketing plan with the help of State Governments form sufficient and smooth distribution of medicines particularly in the rural areas. In this regard, they must take the help of pharmaceutical companies through their associations / alliance etc., The Committee desire that the Government should play the role of promoter in this regard. Doctors, Chemists and NGOs engaged in rural upliftment should be encouraged through tax incentives to set up establishment there.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that instituting a mechanism in partnership with the health care and pharmaceutical industry to expand the reach in medicine to uncovered and weaker sections of society is a complex issue involving on one hand the extended reach of medical facilities in rural areas and on the other hand availability of low cost quality medicine, and their judicious use.

Pharmaceutical Industry does have representation on the Drug Technical Advisory Board(DTAB) and the Vaccine Production Board, both headed by DGHS. The country is virtually self sufficient in production of most of the essential drugs. Large number of drugs are exempted from custom duty, excise duty and or sale tax. However, considering the commercial and other logistic issues, pharma industry should spell out the kind of partnership it would like to have with the public sector health care delivery system in the country.

The NHP 2002 specifically recognises the contribution which the private sector can make in all area of health activities. Deptt. of Health is entirely open to the idea of entrusting public health services on an 'as-is-where-is' basis to NGOs/private entities for providing health care at the level of PHCs/CHCs/Sub-centres. So far these responsibilities have been undertaken by NGOs only to a very limited extent. It is self evident that taking on such responsibilities in remote and rural areas requires a very high degree of motivation and public spirit. It is also to be noted that the quantum of fluid/medical supplies made available to these levels in the pubic health administration are fairly limited. Any NGO/ Private entity which undertakes a partnership for extending public health services, will have to live with such constraints.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 29 of Chapter I of the Report)

Recommendation (Part –II, Para No. 16)

The Committee have noted that under the Drugs and Cosmetics Act, 1940, the sales of Allopathic drugs are regularised through licensing system and it is also required to employ pharmacist to supervise the sale of drugs. The Licensee has to satisfy the Licensing Authority the conditions regarding experience, qualification etc. of the pharmacist and the minimum area of the shop for which the License is applied. The Committee understand that the clause of employing Pharmacist was more relevant at the time when the Act was first written in 1940 and the drugs were dispensed by the chemist (compounding / mixing with more ingredients to get compound or mixture). Now most of the medicines are available in ready to use form. Moreover, more than 80% of the drugs produced in the country are supposed to be of International standard. Simultaneously , Drugs Control Department in the states are reviewing such units on the basis of certain manufacturing practices and norms and the prices of drugs fixed by NPPA are also being monitored by them. The Committee, therefore, desire that these provisions required review keeping in view the need for increasing the availability of quality medicines to the masses including rural and difficult areas.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that a pharmacist is considered as an interface between the patient and the physician in the overall health care delivery system and the sale of drugs is not considered as that of a mere commodity.

It is felt that supervision over distribution / sale of drugs by duly qualified registered pharmacist, is necessary in the interest of the patients and is a norm practiced world over and more so in the developed countries. However, in order to facilitate using a pharmacist by chemists in India, the qualification for registered pharmacist has been kept at Diploma level as against a graduate qualification in most of the countries.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

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

Recommendation (Part –II, Para No. 17)

The Committee observe that the drug industry is in a position to produce almost all the essential drugs of common use, but there is a need to enhance the access of these medicines. The Committee agree to the common suggestion made by Drug producers, Voluntary Health Associations and others that supply of essential drugs should be attached with Public Distribution System. This will expand the ambit of access to modern medicine to 90 per cent of population. The Committee consider the proposal given by the Indian Pharmaceutical Alliance that the industry, through consortium of ORG companies, would undertake to supply these drugs to PDS at subsidized rates as very practical one. They have further justified their suggestion by informing that the proposed scheme would not entail any expenditure / subsidy by the

Government unlike many other items in PDS. The cost of distribution can be covered by appropriate mark up. Other organisations/ Associations have also suggested that the drugs under PDS may form a part of a basket of new items such as tea, detergent cake, toothpaste, notebooks etc., being offered under 'Sarvapriya Scheme'. This will go a long way in strengthening the Primary Health Centres, as medicines would now be available at their doorstep. The Committee welcome the suggestions / proposals made by IPA and other organisations and desire that the Government should work out a scheme in cooperation with the representatives of various organisations / Associations in the field of drugs and pharmaceuticals. Simultaneously, the Department of Chemicals & Petrochemicals and Ministry of Health & Family Welfare should sit together along with Ministry of Consumer Affairs, Food and Public Distribution to discuss the modalities of such scheme and bring the scheme in action in a shortest possible time.

REPLY OF THE GOVERNMENT

D/o Consumer Affairs has informed that– 1) Retail sale of drugs can not be taken up by anybody as certain specified legal and educational requirements have to be fulfilled by the retailer coming from any sector such as State Civil Supplies Corporations, Cooperatives, Private Bodies, Fair Price Shops etc. This is true in respect of all States/Union Territories. In addition to this, the conditions also vary from State to State. Many of these conditions are, however, mandatory in nature and can not be relaxed by any authority. 2) The NCCF also has stated that it may not be possible for ration shops/cooperatives to observe the formalities like appointing Pharmacists, issuance of medicines on the prescription of Doctors etc. Therefore, the drugs of common use require to be identified which could be sold without the prescription of the Doctor and without observing the formalities regarding storage and sale of drugs and medicines. With regard to the implementation of **Sarvpriya Scheme**, the NCCF has clarified that the response from the States/Uts is not very encouraging.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

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

Recommendation (Part –II, Para No. 18)

The Committee have noted that while Indian Pharmaceutical Industry has been capable of production of quality drugs, there have been many cases of poor quality of drugs being sold. These cases are frequently seen in the large purchases of drugs for Government Institutions on the basis of lowest tender. Also, the drugs in the retail market have been known to have quality problems including those from reputed companies. The Committee desire that minimum standards and quality of drugs and pharmaceuticals should be maintained irrespective of the size of manufacturer, brand generic name and irrespective of the price. The Committee strongly recommend that in case of Central Government purchases, lowest tender purchase system should be stopped and bulk purchase of quality and cheaper drugs should be done somewhat on the lines of State level Essential Drug Policies of the State Governments of Delhi and Tamil Nadu. Bulk buying not only reduces cost but also at the same time provides correct prescription to patients.

REPLY OF THE GOVERNMENT

Deptt. of Health in the Ministry of Health and Family Welfare is in agreement with the Committee's recommendation that minimum standards of quality of drugs should be maintained irrespective of size of manufacturer and price. The requirements of Good Manufacturing Practices have therefore been upgraded. The rules are equally applicable to all sectors of industry.. That Deptt. has been repeatedly advising the State drug control authorities to augment their drug testing facilities and to undertake GMP audits through well trained enforcement officials.

Bulk procurement of drugs is already being done by the Medical Stores Organisation (MSO) for the National Programmes, Central Govt. Health Scheme (CGHS) etc. but the established procedure of considering the lowest tender has to be followed.

As far as the quality is concerned, supplies are accepted only after testing has been done.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 45 of Chapter I of the Report)

CHAPTER-V

RECOMMENDATIONS IN RESPECT OF WHICH FINAL REPLIES OF GOVERNMENT ARE STILL AWAITED

Recommendation (Part –II, Para No. 4)

The Committee find that formation of National Drug Authority was first recommended by Hathi Committee long back even before the first Drug Policy of 1978 and was meant to facilitate and supervise inter-sectoral coordination in issues related to drugs and pharmaceuticals. In the 1994 Drug Policy the main objective of the Authority were also outlined but the Committee regret to note that the Authority has still to find the light of the day. The Committee agree with the views expressed by various experts, manufacturer, associations/ consumer organisations / voluntary health organisations etc. that there is an urgent need to establish the National Drug Authority on priority basis. The Committee strongly recommend that the Department of Chemicals & Petrochemicals should persuade the Ministry of Health & Family Welfare for an immediate setting up of the National Drug Authority as visualized in the Hathi Committee and 1986 Drug Policy so that the objectives of better monitoring of quality control, rational use of drugs and related matters is achieved without any further delay. The Committee do not hesitate to say that in absence of such Authority the objectives of National Drug Policy as well as National Health Policy cannot be achieved. Not only this, the purpose of formation of National Pharmaceutical Pricing Authority is also being defeated since there is no proper monitoring of the prices fixed by the NPPA.

REPLY OF THE GOVERNMENT

The Ministry of Health & Family Welfare has informed that formation of a National Drug Authority will require major structural changes considering the present federal nature of the system and Drug Regulatory structure. In the existing regulatory system, licensing of manufacturers etc. as well as enforcement of the Drugs and Cosmetics Act, 1940 and Rules thereunder are ordinarily done by the State authorities. However, the first step towards formation of a National Drug Authority requires strengthening of the Drug Regulatory set up at the Centre. A proposal has been sent to Ministry of Finance for creation of 82 posts and revival of 46 lapsed posts for CDSCO and the Central Drug Laboratories. 33 posts have since been revised. National Health Policy 2002 recognised the need for efficient enforcement of quality standards and rational use of drugs etc.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 12 of Chapter I of the Report)

Recommendation (Part –II, Para No. 5)

The Committee take a serious note that even though Hathi Committee had listed 116 essential drugs in 1975, the Drug Policy of 1978 and 1986 and later modifications of the Drug Policy in 1994 failed to provide the nation with a clear essential drug list. Similarly, in the Drug

(Prices Control) Order, 1995 the criteria was related to production monopoly and turn over rather than the essentiality of drugs as it was before. Concept of essentiality is universal and is based on the principles and criteria of therapeutic need, efficacy, safety and value of money. As per the technical Report of WHO essential drugs are those that satisfy the healthcare needs of the majority of the population. They should, therefore, be available at all times in adequate quantity and in appropriate dosage forms. Unfortunately, these criteria were constantly sidelined. The only approach in this direction was the preparation of essential drug list by the Health Ministry in 1996. In the Committee's view this work should have been done by the Department of Chemicals & Petrochemicals being the nodal department for Drug Policy making. The Committee feels that due to this lacunae, today there is a completely distorted pattern of drug production and the proliferation of non-essential and irrational drugs. It is well known that Indian markets are flooded with over 80,000 formulations with decreased production of essential drugs. As per the views expressed by the experts, the Drug Pricing Policy makes the production of essential /life saving drugs for the National Health Programme the least profitable. The Committee strongly recommend that the National Essential Drugs List must be prepared and implemented without any further delay to guide the production, distribution, prescription and consumption of drugs and pharmaceuticals in the country. Irrational and hazardous drugs must be withdrawn. In Committee's view, the WHO's Essential Drugs List of 250 drugs is sufficient to take care of 90% of the health problems in the country and appropriately this list should be a guiding factors for the Government in preparation of the National Essential Drugs List. The Committee also expect that while preparing such a list, the Department of Chemicals & Petrochemicals would consider all the relevant factors like pattern of prevalent diseases, treatment facilities, training and experience of the available personnel, financial resources, demographic and environmental factors in the country.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that the National Essential Drugs List (NEDL) has already been published in 1996.

The issue of production and proliferation of non-essential and irrational drugs is complex.. Since there are more than 9000 licensed manufacturers in the country, even if some formulation *is* made by number of companies under different brand names, the total number of products is bound to be in thousands. Recently announced Pharmaceutical Policy-2002 envisages application of criteria for identification of drugs for price control to the list of essential drugs in National Essential Drug List and the list of drugs considered important from the point of view of their use in various Health Programmes, in emergency care etc. prepared by the Ministry of Health & Family Welfare.

As regards irrational drugs, an ongoing review process has been established through an Expert Committee constituted by Drug Technical Advisory Board(DTAB). In the year 2001 (upto October), 9 drug formulations were prohibited under Section 26 (A) of the Drugs and Cosmetics Act and use of two drugs was restricted. Directions have also been issued by the Deptt. of Health to all State Governments under Section 33 (P) of the Drugs and Cosmetics Act to refrain the State Licensing Authorities from permitting manufacture of combination of drug formulations which fall in the category of new drugs so as to check proliferation of irrational combination.

Rules 69 and 71 of the Drugs and Cosmetics Rules have been amended vide Notification GSR 311(E) dated 1.5.2002 to specifically ensure that State Licensing Authorities do not permit

new drug formulations at their own level. It is, however, a fact that the drug regulatory system which allows manufacturing license to be issued by respective State Licensing Authorities has led to certain aberrations including proliferation of drug formulations. The National Health Policy 2002 has recommended for periodic review of essential drug list and to encourage use of essential drug. The policy also recommends for prohibition of production and sale of irrational combinations of drugs through drug standards statute.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 15 of Chapter I of the Report)

Recommendation (Part –II, Para No. 9)

The Committee recognize the fact that the Drug Industry has made a remarkable progress during the last three decades. Today, it is manufacturing practically the entire range of therapeutic products, a wide range of basic drugs and pharmaceuticals. This industry is now in a position to meet about 70% of the country's requirement of bulk drugs and almost entire demand of formulations. This industry has become global and foreign exchange earner by exporting a huge quantity of medicines outside the country. However, it is a matter of great concern that engulfing waves of liberalisation and globalisation are squelching the much needed efforts at rationalizing the drug production, drug distribution, drug prescription, drug utilization and drug consumption. The Committee particularly express their concern about the distorted drug production. The greed to earn more, flooded the market with fake, spurious and poor quality medicines. The Committee agree to the views of the experts that a majority of the drugs outside price control are those which should not have been in the market for various considerations like due to their doubtful therapeutic value, secondly, doubtful safety and existence of cheaper alternatives. The Indian markets are flooded with over 80,000 formulations. Problem of spurious and counterfeit drugs has increased several fold. In Committee's view the absence of Central registration and indiscriminate sanction of drug manufacturing license is the main reason for this unhealthy growth. The Committee desire that in this age of computers the Government must take all initiatives to centralize the licensing procedure so that indiscriminate licensing procedure is stopped immediately and manufacturers are permitted to produce only better quality and rational / essential drugs.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that it is true that under the existing provisions of Drugs and Cosmetics Act there is no provision of central registration of drug manufacturers. However, the infrastructure available in the CDSCO is itself very weak to look after its own functions. A major change in the law as well as in the regulatory mechanism/machinery is needed to implement Committee's recommendation on Central Registration. It is, however, not clear as to on what basis the figures of over 80,000 formulations has been arrived. It has to be kept in view that besides the essential drugs and drugs required for critical health care, there are large number of OTC products as well as products for symptomatic

relief and toning up of general health etc. This segment constitutes large number of proprietary products, many of which are historically in existence almost in all the countries. As regards large number of drug formulations, one of the major reasons is the large number of manufacturers in the country as explained in reply to recommendation-5 . Rules have however been amended to check indiscriminate approval of drug formulation by State Licensing Authorities.

Looking at the need to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals, it has been decided in the Pharmaceutical Policy-2002 that a world class CDSCO would be set up by modernizing, restructuring and reforming the existing system and establish an effective net work of drugs standards enforcement administrations in the States with the CDSCO as a nodal centre.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Recommendation (Part –II, Para No. 10)

The Committee observe that during the successive drug policies certain drugs were exclusively reserved for production by the public sector. In 1978 Drug Policy, 17 bulk drugs were reserved for public sector. This number came down to 15 in 1986 drug policy. In the modification in the Drug Policy announced in 1994 only 5 drugs were reserved for production by public sector and now the reservation for public sector has been totally abolished. The Committee have a certain information that production of most of the de-reserved drugs has been stopped either due to their cost of production is not economical or their place has been taken by the new generation medicines. Moreover, since all the PSUs in this sector have been declared as sick and are able to produce a negligible quantity of medicines which were being produced by them earlier. Under these circumstances, the Government are spending a huge amount of foreign exchange on import of these medicines. PSUs in drug sector have so far played a very valuable role in producing medicines low costs. The Committee desire that the Government should compare the amount being spent on the import of these medicines which can be produced by pharma PSUs every year and the amount to be spent for revival of these PSUs. The Committee understand that the immediate revival of these PSUs is the need of the country and it is necessary for the basic healthcare of poor people. The Committee have fIrm opinion that after revival, these PSUs will not only be in a position to produce the drugs by using their large manufacturing capabilities rather their capabilities can be utilized for manufacturing generic drugs for weaker sections since private sector has been avoiding the production of such medicines due to less profitability. The Committee, therefore, recommend that the Government should take all possible initiatives for quick revival of all the sick PSU's in pharma sector particularly, IDPL, HAL, BCPL, etc., so that once again they may be able to serve the nation's poor population. The Committee also desire that till these PSUs achieve their optimum level of production of the medicines produced by them, the Government may continue to get the required quantity of medicines produced from the domestic private sector. Necessary guidance can be also given to State Governments to prefer procurements from PSU.

REPLY OF THE GOVERNMENT

The present status of PSUs in pharma sector is as follows:

IDPL: The company was declared sick by the BIFR in August, 1992. A revival package approved by the BIFR in February, 1994 failed to improve the prospects of the company in spite of the fact that Government of India extended financial assistance much more than what was envisaged in the scheme approved by the BIFR. The BIFR consequently treated the sanctioned package as failed in January, 1996. The efforts made by the Government of India subsequently to work out a viable rehabilitation proposal did not culminate in any worthwhile result. Accordingly, with a view to facilitate privatization of IDPL the Government has communicated to the BIFR its intention to provide the following concessions/facilities for cleaning up of the balance sheet of IDPL.

(a): Conversion of Government loan into equity;
(b): Waiver of interest/penal interest and guarantee fee by the Government of India,
(c): Payment of outstanding statutory dues and funding of VRS.

HAL: The company was declared sick by the BIFR in March, 1997. Although various rehabilitation proposals have been considered by the Operating Agency appointed by the BIFR for its rehabilitation, none of them could culminate in a concrete proposal. After inter-departmental consultation, the Department of C&PC has framed proposals for rehabilitation of HAL and this is expected to be placed before the Cabinet shortly.

The BIFR has already taken the stand that since no fully tied up viable proposal has been framed in the case of HAL, they would be passing orders for change of management in terms of the provisions of SICA. In the hearing held on 29.8.2001, the BIFR granted two more months for the company/Government of India to submit a fully tied up rehabilitation scheme.

BCPL: BCPL was formally declared sick by BIFR on the 14th January, 1993 and a revival package was approved on the 4th April, 1995. The Government released all the funds as envisaged in the revival scheme. In the meantime, the cost of the revival package based on the revised projections as directed by the BIFR has gone up. BCPL has sought upward revision of the project cost. The revised package is under examination/formulation by the Operating Agency. However, the company is showing signs of turning around.

BIL: BIL was formally declared sick by the BIFR on the 9th March, 1993 and a revival package for the company was approved on the 3rd January 1995. The performance of the company during the first three years of the revival period had been far below the targets envisaged. The BIFR reviewed the performance of the company on the 5th April, 1999 and declared the sanctioned scheme as failed and further directed the Operating Agency to conduct a techno-economic viability study through a reputed consultant. It also directed the Government of India to submit the revised rehabilitation plan to the OA, BIFR and others concerned based on the report of the consultants. IIM, Kolkata was appointed as consultant to conduct the techno-economic viability study of the company. After examining the report of the IIM, Kolkata, the Government has informed BIFR that the Government is not in a position to formulate a revised rehabilitation plan as directed by the BIFR and also that the Government is not willing to continue as promoter of the company any more and that any decision of the BIFR to wind up the

company would be acceptable to the Government. In the hearing held on 9.11.2001 BIFR has, interalia, ordered for issuing advertisement for change of management.

SSPL : SSPL was formally declared sick by the BIFR on the 21st Dec., 1992 and a revival package for the company was approved on the 31st August, 1994. In its review hearings, the BIFR noted that the performance of the company during the first two years of operations was far behind the targets envisaged in the Scheme. After further reviewing the performance of the company on the 17th October, 2000 BIFR declared the sanctioned scheme as failed and inter-alia directed the Operating Agency to issue advertisement inviting offers for the take over/ leasing / amalgamation/ merger for rehabilitation of the company. The Operating Agency informed the BIFR that they had not received any proposal within the stipulated time period in response to the advertisement. The BIFR formed its opinion that there is no scope for revival of the company and that the Company would not be able to make its net worth positive after meeting all its financial obligations and that it would be just , fair, and in public interest that the company should be wound up. Accordingly, BIFR in its hearing held on 3.12.2001 has confirmed its opinion that SSPL was not likely to make its net worth exceed its accumulated losses within a reasonable time while meeting all its financial obligation and that the company as a result thereof was not likely to become viable in future and it was just, equitable and in public interest that it should be wound up under Section 20(1) of the SICA. It has also directed to forward its opinion to the concerned High Court. This opinion has since been forwarded to the High Court of West Bengal in Calcutta.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 23 of Chapter I of the Report)

Recommendation (Part –II, Para No. 14)

The Committee observe that even though a large number of drugs produced in the country are essential but poor drug distribution of the essential and life saving drugs has continued to be a big problem. The Doctors are lured to prescribe medicines of the specific companies. It is obvious that the retailers and chemists would prefer trading in the more profitable drugs, specially those non-essential and irrational drugs for which they get a maximum commission. The Committee have a clear opinion that distorted drug production along with distorted drug distribution , responding to market forces rather than health needs in no way be expected to meet the health needs of the people. The Committee, therefore, desire that the Government should immediately review all the drugs in the market and undertake the Central registration with computerization and enlisting all the drugs in the market followed by screening of the drugs based on the principles of rationality of a National Drug Formulary with inclusion of rational drugs i.e., drugs acceptable within pharmacology and medical text books. The Committee further desire that after such analysis all the information about irrationality of all the commonly used

drugs should be made public and publicized in media and audio-visual means for public awareness.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that there is no system of prescription audit in the country and most of the health care activity is now in the private sector.

Undertaking central registration of drugs is a monumental task and would need major amendments in the Act & Rules as well as in the over all drug regulatory system in the country. This responsibility cannot be undertaken within the present regulatory structure available with the Central Drugs Standards Control Organisation, which is already overburdened with the present task required to be performed by it. The NHP-2002 recognises the need of encouraging use of essential drugs and periodic review of essential drug list. Looking at such scenario it has been proposed in the Pharmaceutical Policy-2002 that the Ministry of Health and Family Welfare would set up a world class CDSCO by modernizing, restructuring and reforming the existing system and establish an effective work of drugs standard enforcement administrations in the states with the CDSCO as a nodal centre, to ensure high standard of quality, safety and efficacy of drugs and pharmaceuticals.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 32 of Chapter I of the Report)

Recommendation (Part –II, Para No. 15)

The Committee note that Section 18 of the Drugs and Cosmetics Act, 1940 require every dealer to take a license for distribution, stock and sale of drugs. But it is a common experience that the Doctors and Nursing Homes are stocking medicines for distribution to the patients without taking licenses. This practice results in the occurrences of spurious medicines. The Committee desire that this practice should be stopped immediately. The Committee strongly recommend that a mandatory clause should be introduced in the Act to the effect that the drugs are to be supplied to the consumers only through the licensed Retail Pharmacist and they may be held responsible in case of any wrongful act in the drug supply. However, the Committee have no objection if the Government gives such licenses to the qualified Doctors or Nursing Home owners also so that they may be held responsible for every wrongful act done by them.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that with the available drug regulatory infrastructure, this recommendation appears to be difficult to implement . There is already a shortage of Drug Inspectors in states and vacancies are not being filled up because of financial constraints. These establishments are presently exempted under Sch. K of the Drugs and Cosmetics Rules for requirement of license. The suggestion of Standing Committee would

be placed before the Drugs Consultative Committee in its next meeting. (D/o Health has not been indicated the date of next meeting.)

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 35 of Chapter I of the Report)

Recommendation (Part –II, Para No. 20)

The Committee note that State Drugs Control Organisations are responsible to ensure manufacture of quality drugs through a system of licensing. The main responsibility in this area is with the Drug Inspector who inspects the premises for licensing and to check that the conditions of licences are strictly complied with. The DI draws samples of drugs from the sales outlets to get them tested for quality through the State drug testing laboratories and is also responsible for the porsecution of the offenders. But the Committee find that the number of 1100 of DIs in the State and 32 Inspectors in CDSCO is very inadequate to carry out the work relating to 7000 manufacturing establishments and more than 3 lakh sales outlets. The Ministry of Health & Family Welfare were candid in their admission before the Committee that there is paucity of Drug Inspectors and testing laboratories also. Country's 16 drug testing laboratories in 14 States presents a very dismal picture. Most of the States have no testing laboratory at all. They have informed that the Central Government is negotiating for funding a project with the World Bank but the Committee are dismayed to note that only 14 States are participating in the project. The Committee urge that the Ministry of Health & Family Welfare should call all the State authorities and persuade them to participate in such project so that the objective of updating the facilities and strengthening the Central and State enforcement machinery and augmenting the testing capacity is achieved by implementing such projects in all States uniformly. The Government should also persuade the States to appoint more Drug Inspectors in the States and the Central Government should also study the work load and appoint the desired number of Inspectors in CDSCO to make the system more effective. The Ministry should also pursue the matter vigorously with Ministry of Finance to get the desired resources.

REPLY OF THE GOVERNMENT

The Ministry of Health and Family Welfare has informed that the recommendations of the Standing Committee to appoint more Drugs Inspectors by the State and to establish adequate drug testing labs . has to be taken up with the States Governments. As far as CDSCO is concerned that Ministry is vigorously pursuing the matter with Ministry of Finance to sanction adequate staff including revival of lapsed posts which are considered bare minimum to cope with its multifarious and multidisciplinary responsibilities. This recommendation of the Standing Committee will be further taken up with the Ministry of Finance.

In regard to drug testing labs . it would be pertinent to note that a drug testing establishment has to have optimum viability in terms of experienced manpower, sophisticated equipment and funds for various consumables etc. It may not be feasible for small States to have their own independent drug testing labs as the inflow of samples may not be adequate to support viable testing equipments. The new Central labs . which are coming up at Guwahati, Chandigarh and Hyderabad may cater to the drug testing needs of all remaining states.

The NHP 2002, while recognising the need for efficient enforcement of quality standards in the country envisage appropriate policy recommendation on the issue.

The concern towards quality aspects of the pharmaceutical products has been addressed in the Pharmaceutical Policy-2002 too and it has been proposed that the Ministry of Health and Family Welfare would set up a world class CDSCO by modernizing, restructuring and reforming the existing system and establish an effective work of drugs standard enforcement administrations in the states with the CDSCO as a nodal centre, to ensure high standard of quality, safety and efficacy of drugs and pharmaceuticals

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 45 of Chapter I of the Report)

Recommendation (Part –II, Para No. 23)

The Committee note that there is a great demand of Ayurvedic / herbal medicines in the market. Simultaneously, the Committee observe that the manufacturing of Ayurvedic drugs is controlled by licenses but the sale of items are not controlled in any manner. The Committee recommend that Government should come with some regulatory mechanism for pricing, sale and quality control of Ayurvedic medicines and the medicines of other Indian medicine systems. Necessary licensing for sale of these medicines may also be introduced. The Committee find that the main hurdle in controlling this sector is that these systems are in practice mostly in unorganized manner mainly by Vaidyas and Hakims. However, separate Drug Inspectors having knowledge of these systems should also be recruited to control the quality and pricing of these medicines being manufactured in organised sector.

REPLY OF THE GOVERNMENT

The Deptt. of ISM&H has informed that keeping in view the high demand for Ayurvedic/herbal medicines in domestic/international market, Government has taken various steps to improve standards of Ayurvedic/Unani/Siddha medicines. At the moment, there is no policy decision for controlling price as well as sale of these products. Though these are very valid and desirable goals, it would be difficult to ensure this in the present scenario. As the market is growing very fast, it will be counter productive to regulate the sale of these drugs.

State Governments have been instructed to appoint Drug Inspectors having qualification in ISM and some of the States have designated in-service District Ayurvedic Officers to act as Drug Inspectors for ISM&H. The Government have taken the following measures to promote as well as to ensure the quality of ISM drugs:

(i) A Central Scheme for functioning of Ayurvedic, Siddha and Unani Pharmacopoeia Committees to develop Pharmacopoeial standards of Ayurvedic, Siddha and Unani drugs.
(ii) 385 single drugs of plant origin of Ayurvedic, Siddha and Unani drugs have been allocated to various laboratories to develop Pharmacopoeial standards under a Central Scheme.
(iii) Research in Ayurvedic, Siddha and Unani drugs is being promoted by setting up Central Council for Research in Ayurveda and Siddha and Central Council for Research in Unani Medicine.
(iv) For quality control of Ayurvedic, Siddha and Unani drugs, a separate Drugs Technical Advisory Board under Drugs and Cosmetics Act has been set up to advise the Govt. on quality control of Ayurvedic, Siddha and Unani drugs.
(v) Good Manufacturing Practices (GMP) of Ayurvedic Siddha and Unani drugs have been notified on 23rd June, 2000 to ensure the quality production of Ayurvedic Siddha and Unani drugs.
(vi) Rs.20.46 crores have been sanctioned during financial year 2000 - 2001 under Centrally Sponsored Scheme for strengthening of State Govt. Drug Testing Laboratories and Pharmacies of Ayurvedic Siddha and Unani drugs.
(vii) To recognize private Drug Testing Laboratories for Ayurvedic Siddha and Unani drugs, notification has been issued on 27th September, 2001under the Drugs & Cosmetics Rules for testing of Ayurvedic Siddha and Unani drugs.
(viii) Rule 161 under the Drugs & Cosmetics Rules has been amended for exemption from labeling and packing of Ayurvedic Siddha and Unani drugs for export.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 48 of Chapter I of the Report)

Recommendation (Part –II, Para No. 28)

The Committee find the objective of creation of NPPA is being defeated in absence of proper monitoring and enforcement of the prices fixed by them. NPPA has no effective monitoring mechanism. They are dependent on a small number of drug inspectors who are not even under the control of the Department of Chemicals & Petrochemicals / NPPA. In fact, they are more busy in quality control, control of sale of spurious medicines, granting licenses for production and other similar issues relating to this sector. They are least concerned with the implementation of prices fixed by NPPA or detecting the cases of exorbitant sale price charged by the companies. This has been further proved by the fact that NPPA suo moto have detected several cases even against major pharma companies who are avoiding the prices fixed by NPPA and charging more exorbitant prices. Recently, the Committee has come across a Press Report indicating a specific case wherein consumers were made to buy a medicine at more than ten times of the production cost. The case has been brought before the High Court through a Public

Interest Litigation (PIL). The petitioner has submitted a list of drugs manufactured by leading companies showing differences between the production costs, wholesale prices and the consumer prices. The difference between the wholesale prices and the retail prices of some drugs was as much as 200 per cent to 1600 per cent. Although NPPA has challenged the percentage of differences between the wholesale and the retail price yet the thrust of the case needs to be addressed. The Committee are aware of the NPPA constraints regarding limited number of staff/ officers and that too placed at Delhi but that cannot be the excuse of non-performance. The Committee strongly recommend that the Government should strengthen the monitoring system of NPPA for better monitoring of prices fixed by them. Otherwise, the very exercise of price fixation will become futile and NPPA will be burdened with more and more court cases only.

The Committee are not satisfied with performance of NPPA and also the related monitoring on the part of the Government. The Government had constituted a Committee of experts on 8.2.2001 to undertake a study of the methodologies adopted by NPPA in performing its functions and make suggestions for improving the functioning of NPPA. The Committee was required to submit its report within two months from the date of constitution but the Committee could not start working till April, 2001 as the post of Chairman, NPPA was vacant. The Committee view this as non-seriousness on the part of the Government and deprecate it. The Committee recommend that the Government should take proactive role and make the NPPA more professional in tune with times and needs of the society.

REPLY OF THE GOVERNMENT

As acknowledged by the committee in the first paragraph, NPPA have been making efforts to perform the responsibilities entrusted to it, to the extent possible. Adequate measures are taken for effective monitoring and enforcement of prices of scheduled and non-scheduled formulations. The committee are aware of constraints faced by NPPA in terms of man power and powers provided under DPCO for dealing with the industry which comprises of about 20 thousand manufacturers / companies and about 60 thousand formulations. The committee are also aware that NPPA do not have field officers of its own for enforcing the prices. Even with the existing manpower limitations, the various measures taken by NPPA towards effective monitoring of prices of formulations are given below.

1. Enforcement of prices of Scheduled Formulations

(a) The prices fixed/revised by NPPA for scheduled formulations are promptly communicated to the enforcing agencies, i.e. State Drugs Controllers and Public through mail and postings on NPPA's Website.

(b) Follow up action is taken by writing to all major manufacturers for ensuring implementation of prices fixed/revised by NPPA. Several manufacturers had implemented the prices fixed by NPPA due to such action and submitted copies of supplementary price lists to NPPA indicating implementation of revised / reduced prices.

(c) The State Drugs Controllers are alerted / advised whenever contraventions by manufacturers are noticed from published data like monthly retail pharma audit reports of ORG-MARG, MIMS, Drug Today etc.

(d) A consolidated list of notified bulk drug prices / ceiling prices for all scheduled drugs has been prepared and circulated to the Drugs Control Organizations and Industry Associations for use as a reference copy for implementation. Such fortnightly updated information is also maintained on the website of NPPA.

(e) Quarterly DPCO implementation returns are called from the State Drugs Controllers to review the performance.

(f) Regional / National level meetings of State Drugs Controllers are organized to review the position.

(g) Interaction with State Drugs Controllers / Industry / Trade is maintained through periodical visits to various States by Senior Officials including Chairman, NPPA.

(h) Cases of organized sector companies circumventing price control mechanism are referred to the MRTP Commission also as cases of unfair trade practices.

2. ***Monitoring of prices of non-scheduled formulations****.*

A general provision under paragraph 10(b) provides power to Govt./NPPA to fix/revise the retail price of any formulation including a non-scheduled formulation if it considers necessary so to do **in public interest**. In spite of the absence of guidelines / powers under DPCO, NPPA has formulated some procedures/methodology for monitoring prices of non-scheduled formulations. NPPA has developed a data-base covering all medicines having minimum annual sale value of Rs.1 crore as reported in ORG. The movement of prices of each such drug is available now in NPPA from 1994 onwards. NPPA is carefully analyzing changes in prices of medicines with a considerable sale value (Rs.1 crore and above) and taking action whenever abnormal price increases are noticed. NPPA is also keeping a watch on issues like aberration in retail prices of medicines based on the same bulk drug and abnormal trade margins offered on non-scheduled formulations etc. NPPA has conducted studies on movement of prices of scheduled / non-scheduled formulations during the years 1999 and 2000. Database on consumption pattern of medicines in trade channels has been developed, bulk drug wise. Such exhaustive data is useful in monitoring the trend in usage pattern of various drugs in the domestic market. NPPA has noted that, in general, adequate competition exists in the market and the prices of medicines in the non-scheduled category have not gone up unreasonably. However individual cases, warranting action are examined and action taken if public interest is adversely affected. The non-cooperation / lukewarm response of the manufacturers in providing information / cost data in respect of non-scheduled formulations is contributing to the constraints faced by NPPA in respect of non-scheduled formulations.

The Pharmaceutical Policy-2002 has laid emphasis over monitoring of prices of drug. It has been proposed that in cases of drugs/formulations listed by the Ministry of Health and Family Welfare in the National Essential Drug List (1996) and 173 items which are considered important by that Ministry from the point of view of their use in various Health Programmes, in emergency care etc. and those presently under price control, having significant MAT value as per ORG- MARG but not covered under the proposed criteria in Pharmaceutical Policy-2002, the NPPA would specially monitor intensively their price movement and consumption pattern. If any unusual movement of prices is observed or brought to the notice of the NPPA, the Authority would work out the price in accordance with the relevant provisions of the price control order. It has been further proposed in the Pharmaceutical Policy-2002 that the NPPA would be revamped and reoriented for the purpose of effective monitoring. It is also proposed to strengthen the NPPA by providing appropriate powers under the DPCO which would make it mandatory for the manufacturer to furnish all information as called for by the NPPA.

The Committee of Experts has since submitted its report and NPPA is taking appropriate action over it.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 51 of Chapter I of the Report)

Recommendation (Part –II, Para No. 30)

Para 14 and 15 of the DPCO'95 require the manufacturers print the minimum retail price of the formulations mandatory with the words 'Retail price not to exceed' preceding it and 'local taxes extra' succeeding it. The multiplicity of taxes (Central, States Entry tax, Octroi etc.,) , Lack of uniformity of tax in various States creates confusion in calculating the tax and the dealers face difficulties. In most of the cases consumers pay more price. Increase in number of litigation cases in consumer courts and other forums shows the seriousness of problem. There is a continuous demand of chemists and druggists of whole the country to fix retail prices of the medicines as 'MRP inclusive of all taxes' to avoid such confusion. The Committee strongly recommend that the Government should take all initiatives to fix the uniform retail prices of medicines inclusive of at least all the Central taxes in the shortest possible time for the benefit of the consumers as well as the chemists after implementation of uniform Sales tax the objective of 'MRP inclusive of all taxes' should also be achieved.

REPLY OF THE GOVERNMENT

Under para 14 of DPCO'95, the prices of Scheduled formulations are printed as 'retail price not to exceed…..local taxes extra." Under para 15 of DPCO'95, prices of non-Scheduled formulations are printed as 'retail price not to exceed local taxes extra..". In both the cases, central taxes are included and local taxes as defined under para 2(kk) of DPCO'95 are to be levied at the regional levels. The issue of printing of prices of medicines inclusive of all taxes has been thoroughly examined in this department from time to time. A Working Group having members from the Industry Consumer Forum & AIOCD was constituted to look into this issue. The Working Group in its report had forwarded the idea of weighted average of taxes to replace local taxes, however, the same has not been found legally sustainable by the Department of Legal Affairs. The High Powered Price Monitoring Board under the chairmanship of Department of Consumer Affairs is also examining this issue and a status note on this issue has already been made available to the Board.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee
(Please see Para No. 54 of Chapter I of the Report)

Recommendation (Part –II, Para No. 33)

Globally, medicinal plants are single most important source for new drugs and India is said to be a huge repository of as yet unexploited plant resources. The Committee note that the Department of Indian Systems of Medicine and Homeopathy (ISM&H) was established in 1995. Since then they have undertaken some Research work through four Research Councils under this Department. The Department has also established a medicinal plant cell for development and cultivation of medicinal plants. The Committee have a firm opinion that drugs from plants are

very important from Indian point of view as plants are the source that will give an idea about the new molecules which can be proven as new drugs in future. Therefore, the Department of ISM&H have to play a very important role in coming days. The Committee desire that the Department of Indian Systems of Medicines should prepare a time bound R&D programme for development, quality achievements and standardization of herbal drugs from traditional remedies and other natural resources. The Committee also urge the Government to formulate and announce the national policy on medicinal plants which was initiated by the Department of Alternative medicines in the Health Ministry with the help of Scientists, Pharmaceutical companies and conservation experts. The Committee also desire that Government should formulate a separate Drug Policy to regulate the various issues relating to the various Indian Systems of Medicines.

REPLY OF THE GOVERNMENT

The Department of ISM&H has informed that the medicinal plants are the single most important source for ISM&H drugs as well as for development of new drug molecules. To give focused attention on this sector, a Medicinal Plants Board has been set up on the 24th November, 2000 to promote the medicinal plant sector. Similar State Medicinal Plant Boards are being set up by the State Governments.

The object of these Boards is to coordinate Programmes, schemes to promote cultivation, conservation, sustainable use and trade of the medicinal plants.

To develop new molecule/drug from plant source, Council for Scientific & Industrial Research has formulated a very ambitious scheme and is working through its network of CSIR Laboratories. The Department of ISM&H is also providing technical advice on the selection of drugs as well as its textual references of medicinal uses.

Department of Science & Technology and Department of Bio-technology are also supporting the new drug development Programmes.

Intra-mural research by the Research Councils and extra-mural research are being made focused and re-oriented. Several areas have been identified for collaborative research in modern institutes. Established protocols for clinical research, efficacy trials and toxicity studies are being followed to enhance credibility and standardization of ISM&H research.

Although a number of measures to ensure the availability and quality of Ayurvedic/ISM drugs have been taken up yet a separate drug policy has not been formulated so far.

[M/o Chemicals & Fertilizers, Department of Chemicals & Petrochemicals O.M. No.5(16)/98-PI-I .dated 19.6.2002.]

Comments of the Committee

(Please see Para No. 57 of Chapter I of the Report)

NEW DELHI
August 29, 2002
Bhadrapada 7, 1924 (Saka)

MULAYAM SINGH YADAV
Chairman
Standing Committee on Petroleum & Chemicals.

APPENDIX I

MINUTES

SUB-COMMITTEE ON CHEMICALS & PETROCHEMICALS A SUB-COMMITTEE OF THE **STANDING COMMITTEE ON PETROLEUM & CHEMICALS**

(2002)

THIRD SITTING

(01.08.2002)

The Sub-Committee sat from 1500 hrs. to 1530 hrs.

PRESENT

Dr. Girija Vyas - Convenor

Members

Lok Sabha

2. Shri Ashok N. Mohol
3. Dr. V. Saroja
4. Shri Ramjiwan Singh
5. Dr. Ram Lakhan Singh

Secretariat

1. Shri P.K. Grover - *Director*
2. Shri J.N. Oberoi - *Under Secretary*
3. Shri R.R. Rai - *Assistant Director*

At the outset, Hon'ble Convenor of Sub-Committee on Chemicals & Petrochemicals welcomed the Members to the sitting and explained the purpose of the day's meeting. She invited the Members to give their suggestions, if any, on the Draft Report on action taken by the Government on the recommendations contained in the 15th Report (13th Lok Sabha) of the Standing Committee on Petroleum & Chemicals (2001) on 'Pricing and Availability of Drugs and Pharmaceuticals'. One of the Members suggested to incorporate the reference of WTO Agreement in one of the recommendations of the Committee which was accepted by the Sub-Committee.

2. Thereafter, the Sub-Committee adopted the Draft Action Taken Report.

3. The Sub-Committee authorised the Convenor to finalise the Report and submit it to the Hon'ble Chairman for consideration by the Standing Committee on Petroleum & Chemicals.

The Sub-Committee then adjourned.

APPENDIX-II

MINUTES

STANDING COMMITTEE ON PETROLEUM & CHEMICALS
(2002)

ELEVENTH SITTING
(12.08.2002)

The Committee sat from 1500 hrs. to 1600 hrs.

Present

Shri Mulayam Singh Yadav- Chairman

Members

Lok Sabha

2. Shri Ashok Argal
3. Shri Ram Chander Bainda
4. Dr. Chellamella Suguna Kumari
5. Shri Padam Sen Choudhry
6. Shri Dilipkumar Mansukhlal Gandhi
7. Smt. Sheela Gautam
8. Shri Bijoy Handique
9. Shri Shriprakash Jaiswal
10. Shri Punnulal Mohale
11. Shri Ashok N. Mohol
12. Dr. Debendra Pradhan
13. Shri Ram Sajivan
14. Shri Shyama Charan Shukla
15. Dr. V. Saroja
16. Dr. Chhatrapal Singh
17. Dr. Ram Lakhan Singh

Rajya Sabha

18. Shri Balkavi Bairagi
19. Shri Ramnath Kovind
20. Shri Shyam Lal
21. Shri Rajiv Ranjan Singh 'Lalan'
22. Shri Dipankar Mukherjee
23. Shri Ahmed Patel
24. Shri Keshubhai Savdasbhai Patel
25. Ms. Mabel Rebello

Secretariat

1. Shri K.V. Rao - *Joint Secretary*
2. Shri J.N. Oberoi - *Under Secretary*
3. Shri Ram Raj Rai - *Assistant Director*

At the outset, Hon'ble Chairman referred to the sad demise of Shri Krishan Kant, Vice-President of India and recalled his contribution to Nation's building. The Committee condoled his death and passed a Condolence Resolution. The Committee stood in silence for a while. Thereafter, Hon'ble Chairman welcomed Shri Keshubhai Savdasbhai Patel, to the Committee and hoped that the Committee would be benefitted by his experiences.

2. Hon'ble Chairman then explained the purpose of the day's meeting and invited the Members to give their suggestions, if any on the following four draft Reports being considered for adoption:-

(i) Action Taken Report on action taken by Government on the recommendations contained in the Fifteenth Report (13th Lok Sabha) of the Standing Committee on Petroleum & Chemicals (2001) on 'Pricing and Availability of Drugs/Pharmaceuticals;

(ii) ** ** ** ** ** ** ** ** ** ** **
** ** ** ** ** ** ** ** ** ** **

(iii) ** ** ** ** ** ** ** ** ** ** **
** ** ** ** ** ** ** ** ** ** **

(iv) ** ** ** ** ** ** ** ** ** ** **
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3. After some consideration, the Committee adopted all the Reports without any modification and the Committee authorised the Chairman to finalise the Reports after factual verification from the concerned Ministries/Departments and present them to Speaker or to Parliament as deemed necessary.

4. The Committee placed on record their appreciation of the work done by the Sub-Committees on Petroleum, Chemicals & Petrochemicals, Fertilisers and the Sub-Committee Constituted to look into the complaints on non-observance of Guidelines laid down by the Government in allotting Retail Outlets and LPG Distributorships by Dealer Selection Boards.

5. The Committee also placed on record their appreciation for the valuable assistance rendered to them by the officials of the Lok Sabha Secretariat attached to the Committee.

6. ** ** ** ** ** ** ** ** ** ** **
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7. ** ** ** ** ** ** ** ** ** ** **
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The Committee then adjourned.

**** Matters not related to this Report**

APPENDIX –III

(Vide Para 4 of the Introduction)

Analysis of the Action Taken by Government on the recommendations contained in the Fifteenth Report (Thirteenth Lok Sabha) of the Standing Committee on Petroleum & Chemicals (2001) on 'Pricing and Availability of Drugs/Pharmaceuticals)'.

I	Total No. of Recommendations	35
II	Recommendations which have been accepted by the Government **(Vide Recommendation at Sl. Nos. 2,3,6,7,8,19,22,25,27,31,32, 34 & 35)**	13
	Percentage to Total	37.14%
III	Recommendations which the Committee do not desire to pursue in view of Government Reply **(Vide Recommendations at Sl. Nos. 1, 12, 21, 24, 26 & 29)**	6
	Percentage of Total	17.14%
IV	Recommendations in respect of which replies of the Government have not been accepted by the Committee **(Vide Recommendations at Sl. Nos. 11, 13, 16, 17 & 18)**	5
	Percentage of Total	14.29%
V	Recommendations in respect of which final replies of the Government are still awaited **(Vide Recommendations at Sl. Nos. 4,5,9,10,14,15,20,23,28,30 & 33)**	11
	Percentage of Total	31.43%