FIFTEEENTH REPORT

STANDING COMMITTEE ON PETROLEUM AND CHEMICALS
(2001)

(THIRTEENTH LOK SABHA)

PRICING AND AVAILABILITY OF DRUGS/PHARMACEUTICALS

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

Presented to Lok Sabha on 29.08.2001

Laid in Rajya Sabha on 29.08.2001

LOK SABHA SECRETARIAT
NEW DELHI

August, 2001/Sravana, 1923 (Saka)

CONTENTS

CHAPTER-VIII Strengthening of Indian Systems of Medicine

PART-II
Recommendations/Conclusions of the Committee

COMPOSITION OF THE STANDING COMMITTEE ON PETROLEUM & CHEMICALS (2001)

Shri Mulayam Singh Yadav - Chairman

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* ***Vacancy caused consequent upon retirement of Dr. (Smt.) Joyashree Goswami Mahanta, MP (RS) from the membership of Rajya Sabha w.e.f. 14.06.200a***

COMPOSITION OF SUB-COMMITTEE ON
CHEMICALS & PETRO-CHEMICALS

A SUB-COMMITTEE OF THE STANDING COMMITTEE
ON
PETROLEUM & CHEMICALS
(2001)

	Shri Mulayam Singh Yadav	**-**	**Chairman**
2.	**Shri Ram Nath Kovind**	**-**	**Convenor**
3.	Shri T.T.V. Dhinakaran		
4.	Shri Shriprakash Jaiswal		
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6.	Smt. Nivedita Mane		
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8.	Vacant *		
9.	Shri Mool Chand Meena		
10.	Shri Ashok Pradhan		
11.	Shri Mukesh R. Patel		
12.	Smt. Basanti Sarma		
13.	Shri Gaya Singh		
14.	Dr. (Smt.) C. Suguna Kumari		
15.	Dr. Ramesh Chand Tomar		
16.	Shri B. Venkateshwarlu		

**** Vacancy caused consequent upon retirement of Dr. (Smt.) Joyashree Goswami Mahanta, M.P. (RS) from the membership Rajya Sabha w.e.f. 14.06.2001.***

INTRODUCTION

I, the Chairman, Standing Committee on Petroleum & Chemicals (2001) having been authorised by the Committee to submit the Report on their behalf, present this Fifteenth Report on 'Pricing and Availability of Drugs/Pharmaceuticals'.

2. This subject was selected for examination by the Standing Committee on Petroleum & Chemicals (1998-1999) (Twelfth Lok Sabha). The Committee considered the replies furnished by the Ministry of Chemicals & Fertilisers (Department of Chemicals & Petrochemicals) and Ministry of Health & Family Welfare to the questionnaire issued on the subject from time-to-time and other materials on the subject. The Committee took evidence of the representatives of the Ministry of Chemicals & Fertilisers (Department of Chemicals & Petrochemicals) on 11th January, 1999 and that of the Department of Chemicals & Petrochemicals, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homoeopathy and Ministry of Commerce on 25th November, 1999.

3. After constitution of Thirteenth Lok Sabha, the Standing Committee on Petroleum & Chemicals (1999-2000) decided to continue with this subject. The Sub-Committee on Chemicals & Petrochemicals, a Sub-Committee of the main Committee took evidence of the representatives of Council of Scientific and Industrial Research (CSIR) and National Institute of Pharmaceutical Education and Research (NIPER) on 7th September, 2000. The Committee also heard the views of the representatives of various drugs Producers and Manufacturers and Voluntary Health Organisations on 3rd October, 2000. The Committee also sought updated information from the respective Departments.

4. The Committee wish to express their thanks to officers of the Ministry of Chemicals & Fertilisers (Department of Chemicals and Petrochemicals), Ministry of Heath and Family Welfare, Department of Indian Systems of Medicine and Homoeopathy, Ministry of Commerce and the representatives of Drugs Producers/Manufacturers Associations and Chemists and Druggists Associations for placing their views before them and for furnishing the information desired in connection with examination of the subject.

5. The Sub-Committee on Chemicals & Petrochemicals considered and adopted this Report at their sitting held on 13th August, 2001.

6. The Standing Committee on Petroleum & Chemicals (2001) considered and adopted this Report at their sitting held on 20th August, 2001. The Committee place on record their appreciation of the work done by the Sub-Committee on Chemicals & Petrochemicals.

7. The Committee place on record the deep appreciation for the work done by the Standing Committee on Petroleum & Chemicals (1998-99) on the subject.

8. The Committee also place on record their sense of deep appreciation for the invaluable assistance rendered to them by the officials of the Lok Sabha Secretariat attached to the Committee.

MULAYAM SINGH YADAV
Chairman

NEW DELHI
August 20, 2001
Sarvana 29, 1923 (Saka)

Standing Committee on Petroleum & Chemicals

PART – I

BACKGROUND ANALYSIS

CHAPTER – I

AIMS AND OBJECTIVES OF NATIONAL DRUG POLICY

1.1 Medicines contribute the most cost effective segment of healthcare. They protect patients from prolonged sickness and premature death, reduce the need of hospitalisation and improve the productivity and quality of life. Initially, production of Pharmaceuticals in India covered conventional drugs such as tincture and other spirituous preparations, sera and vaccines etc. by a limited number of Indian companies. Synthetic drugs, antibiotics and steroids were introduced after Second World War. Shortly after independence in 1947, most of the leading multinationals established themselves as trading concerns by improving finished formulations and marketing them. Subsequently, they started first repackaging of finished formulations and later on started formulation activity based on imported drugs. The advent of the public sector between 1954 and 1961 marked an important milestone in the development of pharmaceutical industry in India.

1.2 With a view to find requirements of medicines, the Government had set up a Committee in 1974 popularly known as `Hathi Committee'. On the basis of report prepared by this Committee, submitted in 1975, the first Comprehensive Drug Policy was formulated in 1978. The policy covered manufacture of drugs, stressed on production from indigenous raw material to the extent feasible and linked production of formulations with bulk drug production. This policy yielded the desired results and helped in strengthening the infrastructure for bulk drug manufacture and widening the range of indigenous productions. In regard to pricing aspects, the policy had categorised 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. Subsequently, in 1986 measures were announced to incorporate the changes due to changing economic environment and growth of industry and on that basis Drugs (Prices Control) Order, 1987 was issued replacing the earlier one.

The main objectives of the Drug Policy, 1986 were as under:-

(a) Ensuring abundant availability at reasonable prices of essential and life saving and prophylactic medicines of good quality;

(b) Strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;

(c) Creating an environment conducive to channelising new investment into the pharmaceutical industry to encourage cost effective production with economic sizes and to introduce new technologies and new drugs; and

(d) Strengthening the indigenous capabilities for production of drugs.

The above policies and the provisions of Indian Patent Act, 1970 gave an impetus to development of viable processes which in turn not only helped in meeting the demand in the country but also gave a boost to exports.

1.3 With the opening of the economy and liberalisation effected in licensing policy, import policy and tariff matters, necessary amendments were effected in Drug Policy, 1986 through modifications announced in September, 1994 followed by Drugs (Prices Control) Order, 1995. Various incentives have been provided to give impetus to Research and Development which has assumed greater importance in view of changed world trade scenario. Main challenges being faced by the drug industry include sustaining indigenous industry through vigorous R&D efforts and making it internationally cost effective in bulk drug production.

1.4 During the course of examination the Committee went into the main proposals of the 1994 Drug Policy and observed that there was a proposal to establish a `National Drug Authority' (NDA) under the Ministry of Health & Family Welfare. The Committee enquired about the functions and objectives and functions of the NDA and the steps being taken by the Ministry of Health & Family Welfare to establish the proposed National Drug Authority. The Ministry of Health and Family Welfare submitted the following details in a written reply:-

"The functions and objectives of NDA are in paragraph 22.8 of the Modifications of the Drug Policy 1986 announced in September 1994. Its objectives are to look after the quality control aspects, rational use of drugs and related matters as outlined in paras 16-19 of the said policy.

The functions of NDA as described in paras 16-19 are as follows:

(1) To prepare standards for manufacture, import, supply, promotion and use of drugs;

(2) To register pharmaceuticals for use in the country;

(3) To enforce uniform standards of quality and good manufacturing practices throughout the country;

(4) To monitor and control practices in drug promotion;

(5) To achieve rational prescribing by physicians through guidance;

(6) To provide appropriate information on drugs to the consumers; and

(7) To prepare and publish national formularies.

The policy envisaged additional responsibilities for the NDA in terms of:

(a) Licensing of bulk drug manufacturers;

(b) Preparation of master formulae for formulations;

(c) Developing tests for cosmetics, diagnostics, and devices;

(d) Control of promotional materials;

(e) Stricter control of clinical trials with special emphasis on human rights;

(f) Updating new drug approval processes with formation of expert committees for examination of new drugs;

(g) Centralising all manufacturing licences for inter-state commerce; and

(h) Prescribing procedures for public hearing under the drugs and cosmetics act."

1.5 About the supportive role of proposed NDA the Ministry categorically stated as under:-

"These additional responsibilities were meant to support the existing activities of the Central Drug Standards Control Organisation (CDSCO). Centralising the manufacturing licences for inter-state commerce was expected to bring about more effective enforcement of Good Manufacturing Practices (GMP) and quality control standards in the manufacturing of drugs uniformly throughout the country. It was also expected to bring the regulatory system at par with most of the developed countries, who have federal enforcement systems. Registration of drugs and pharmaceuticals by CDSCO was also expected to eliminate the sale of harmful/irrational formulations from the country. Similarly, updating of new drug approval process was felt to be a necessary step to ensure that only drugs of proven safety and efficacy are available to the public within the shortest possible time of their introduction in the international market. For all intends and purposes CDSCO was anticipated to assume the shape of NDA."

1.6 About the reasons for delay in formation of proposed NDA, the Ministry of Health & Family welfare informed:-

"The NDA was expected to assume a number of additional responsibilities which requires structural changes to be implemented in the current enforcement system and availability of additional manpower to assume the increased workload

at the Central level. Since many issues are involved in this regard and the existing manpower is not adequate to cope with even existing workload, it is not possible to fix any timeframe within which this proposal will materialise."

1.7 Pharmaceutical industry view the utility of National Drug Policy in different manner. They have expressed a desire for a modification/ review in it in view of various changes in national and international economic scenario. The main points submitted by them to justify their views and their suggestions are as under:-

(i) The main factors which influence the drug industry include the dismantling of industrial licencing and import trade controls, lowering of tariff protection, unfolding of product – patent regime and globalisation of industry.
(ii) In view of above factors old system of price control has become ineffective in isolation allowing production of drugs under price control to suffer.
(iii) Efficient and cost effectiveness of production will hold the key and this can only happen through major investments in improved technology, processes and systems.
(iv) The current pricing policy lead very little rather come in the way and impede the process.
(v) The pricing policy framework requires to be amended as become supportive to generate resources for further investment in research.
(vi) The current framework of price controls are outdated and cumbersome and the implementation of policy has been discriminatory and not transparent.
(vii) The information compiled and relied upon for implementation of pricing policy is incomplete, its sources unknown and date questionable.
(viii) Price control requires company by company, product by product and pack by pack examination of cost effective data.
(ix) The review in the policy will have to address the current frame of price and profitability control, the mode of their implementation and their usefulness in the context of changed scenario.
(x) The thrust of the policy must remain on adequate availability of quality medicines at affordable prices.
(xi) Management of new policy must be transparent and have an action plan which has a long term bearing on the health of the industry and actually the consumer should derive the benefits.

1.8 During the course of the examination, the Committee drew the attention of the Government towards Press Report about inviting the views of drug manufacturers with a view to revise the existing Drug Policy and wanted to know the details of the views received in this regard and the action being taken by the Government. The Department of Chemicals and Petrochemicals informed that the Government had constituted a Drug Price Control Review Committee under the Chairmanship of Secretary

C&PC to review the current drug price control mechanism and to suggest alternative models, if any, with a view to reduce the rigours of price control where they had become counter productive. The Committee has already submitted its report to the Government and the modified/ new drug policy is under preparation.

CHAPTER-II

NATIONAL HEALTHCARE SYSTEM

(a) National healthcare programme and new health challenges

2.1 Health is an integral part of social welfare. India has 18% of worldwide mortality and 20% of worldwide morbidity with 16% world population. The healthcare scenario in India like other developing countries, is characterised by malnutrition, poor sanitary conditions, inadequate water supply etc. However, over the years, the health facilities such as drinking water, nutrition, sanitation etc. have improved but still a lot is required to be done.

2.2 Over three decades ago, the Health Survey and Planning Committee also known as `Mudalier Committee', in its report had recommended that around 10% of the plan outlays should be earmarked for health. But actual expenditure on health care 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. The following chart shows the actual declining trend of expenditure on health outlay:-

Plans		**Health Outlay (Rs. in crores)**	**Outlay as Percentage of total**
First Plan	(1951-56)	65.2	3.3
Second Plan	(1956-61)	140.8	3.0
Third Plan	(1961-66)	225.9	2.6
Annual Plans	(1966-69)	140.2	2.1
Fourth Plan	(1969-74)	335.5	2.1
Fifth Plan	(1974-79)	760.8	1.9
Annual Plans	(1979-80)	223.1	1.8
Sixth Plan	(1980-85)	1,821.1	1.9
Seventh Plan	(1985-90)	3,392.9	1.9
Annual Plans	(1990-92)	1,965.6	1.6
Eighth Plan	(1992-97)	7,575.9	1.7

2.3 While enquiring about the performance of Health sector, the Committee referred to '*Health For All By 2000'* - A programme of the Government and wanted to know its performance . The Ministry of Health and Family Welfare stated in a written note:-

> "The concept of Health for All by 2000 contained in the Alma Atta Declaration of 1978, to which India was also a party, envisaged a situation where every individual would be able to lead good quality life. Since quality of life is *inter alia* dependent on the absence of diseases and the accessibility of health care facilities, the control and prevention of diseases and availability of affordable and good quality health care became important objectives to be achieved, in order to attain Health for All.
>
> In India, significant strides were made in the area of immunisation, reduction of infant and maternal mortality, in the control of Leprosy, Guineaworm infection, polio, IDD etc. over the last two decades. Efforts are also underway to tackle problems like Cataract blindness, TB, Malaria, AIDS etc. through provision of proper health care facilities, creation of greater awareness and by trying to achieve greater community participation. For each of these programmes external assistance has been mobilised. The Health infrastructure in the States are also sought to be enhanced through improving the facilities in Primary Healthcare Centres and Community Healthcare Centres thereby creating a proper referral system to make health care more accessible to the common man. Several States have obtained external assistance for this purpose.
>
> However, it is seen that newer challenges to health are emerging world over. This includes the emergence of new life-style related diseases and diseases related to the environment in which we live. Further we also have situations where there is a resurgence of older diseases like TB, e.g. in developed countries. Hence the challenge in the health sector is to address these problems effectively and ensure the availability of proper health care facilities that can help the common man to cope with these challenges and enjoy good quality of life. This is sought to be achieved through various national programmes and through efforts to strengthen the existing health infrastructure. In India we have a well-developed pharma industry that can meet our requirement of most drugs. Our import policy also allows any drug not manufactured in India to be imported. In case of very critical drugs even customs duty is either waived or reduced. Hence there have been no reports of shortage of drugs."

2.4 Pharmaceutical producers have an assumption that the challenges relating to healthcare in India are formidable. This is because we have a mixed pattern of diseases.

The ageing population, greater health consciousness, re-emergence of old diseases like Tuberculosis and Malaria due to drug resistance, limited needs of medicines for dreaded diseases like AIDS, Cancer and the search for more effective and short term therapies for life style diseases like Diabetes, Backaches, Migraines etc. will pose challenges in future.

2.5 Experts have an opinion that in the area of communicable diseases, Malaria, Leprosy, Tuberculosis require prime attention. Similarly, in the area of non-communicable diseases like Blindness control, Goitre and Cancer require major emphasis. In the expanded programme of immunisation efforts have to be focussed on reducing the incidence of Polio. Diptheria, Tetanus, Measles, Whooping Cough and Child Tuberculosis.

2.6 The Voluntary Health Association have submitted that the National Health Policy of 1983 was never implemented in true sense and it has not been reviewed thereafter. They have expressed an urgent need to review the 1983 Health Policy in view of dramatic socio-economic, ecological and epidemiological changes.

(b) Coordination between the Ministries/ State Governments

2.7 It is the solemn function of the Government to ensure safety, efficacy and quality of drugs supplied to the public. Indian Pharma Industry has the responsibility of discovering, developing and making available quality drugs, vaccines and other medical devices for preventing and curing diseases of the people of India at affordable prices. The Department of Chemicals & Petrochemicals is responsible for licensing, overall production and pricing aspects of drugs and pharmaceuticals sector. For making drugs available at reasonable prices the Government have promulgated Drugs (Prices Control) Order, 1995 under the Essential Commodities Act. National Pharmaceutical Pricing Authority has the responsibility to fix the prices of 74 drugs listed in DPCO, 1995. For other drugs and pharmaceuticals the prices are governed by the market forces.

2.8 The Ministry of Health and Family Welfare is responsible to maintain quality and distribution of drugs. Import, manufacture, sale and distribution of drugs is regulated under Drugs and Cosmetics Act, 1940 and Rules, 1945 made thereunder respectively. The Act gives power to the Central Government to regulate imports of drugs and to the States to regulate manufacture, distribute and sale of drugs and cosmetics. It provides rules giving power to the Central Government to enforce the various provisions of the Act, under which a system of licensing has been prescribed. Under the rules, licences are required to manufacture, store, distribute and sell any drug which are to be obtained from the State Licensing Authorities. The Act defines the scope of powers to Drug Inspectors and powers and functions of Government Analysts. Standards of identity, purity, freedom from toxicity and strength in respect of every medicine and related products used for diagnosis profile access and treatment of diseases in human beings or animals have to be specified. Under this Act distinct statutory function and responsibility have been assigned to Central and State Governments. The Central Drug Standards Control Organisation (CDSCO) under the Ministry of Health and Family Welfare, which is entrusted with the enforcement of regulatory responsibility at the

Government of India level. Import of drugs is controlled by the Ministry of Commerce. The Ministry of Finance is responsible to decide the different types of taxes on drugs/pharmaceuticals.

2.9 When the Committee specifically wanted to know about the nature of coordination between two main Ministries i.e. Ministry of Chemicals & Fertilisers (Department of Chemicals & Petrochemicals) and Ministry of Health and Family Welfare in regard to pricing and availability of drugs/pharmaceuticals, the Department of Chemicals and Petrochemicals submitted as under:-

> "There is a close coordination between the Department of Chemicals & Petrochemicals and Ministry of Health. In identifying drugs that are to be brought under price control or kept out of the price control the views and advice of the Ministry of Health is sought. For fixation of prices of drugs that are totally imported, this department fixes the price on the basis of the data given by the Ministry of Health. Similarly, to ensure supply of quality drugs in Ministry of Health who primarily look after such activity, liaise with each other to ensure the same. In matters of recommending levy of Customs and Central Excise Duty on Drugs, the advice of the Ministry of Health by and large is sought by this department before sending our proposal to the Department of Revenue.
>
> In addition, in matters of keeping drugs under the OGL or negative list of imports and exports, under the successive Exim Policies the opinion of the Health Ministry is also considered by this Department before taking a final view in the matter."

CHAPTER - III

DEMAND & PRODUCTION OF DRUGS/ PHARMACEUTICALS

(a) Production Performance of Pharma Sector

3.1 Indian Drugs and Pharmaceuticals Industry is one of the largest and most advanced industries among the developing countries. This industry has made remarkable progress over the years. Today it is manufacturing practically the entire range of the therapeutic products, a wide range of basic drugs and pharmaceuticals. It is capable of producing raw materials for the manufacture of a wide range of bulk drugs from the basic stage and a range of pharma machines and equipment. The primary role of this industry is to discover and develop newer, better and safer medicines, manufacture and distribute them for preventing and curing the diseases of the people at affordable prices. The domestic drug industry comprises about 250 large units and about 8000 small scale units in operation which form the core of the industry and more than 30% production of drugs come from small scale sector.

3.2 The setting up of the penicillin factory at Pimpri, Pune in the early 1950s and the construction of Indian Drugs and Pharmaceuticals Limited (IDPL) Plants at Rishikesh and Hyderabad in 1968 are important milestones in the history of the Pharmaceutical industry in the country. The public sector investment in the Pharmaceutical industry in the initial stages played the role of a catalyst in the development of industry in the last three decades. Indigenous production meets about 70% of the country's requirements of bulk drugs (chemicals having therapeutic value) and almost the entire demand for formulations (medicines ready for consumption by patients). Presently the market capitalisation of pharmaceutical industry is in excess of $ 30 billion and 25 of the companies are also listed in NASDAQ. Pharmaceutical companies have doubled the market capitalisation since 1999 and now account about 20% India's market capital. Foreign investment in this sector has virtually doubled in five years. Indian companies are rapidly acquiring marketing companies in the West to drive up exports which have been rising five-fold.

(b) Demand Projection for 9th Plan & Production of Medicines

3.3 The Working Group on Drugs and Pharmaceuticals for the Ninth Five Year Plan period (1997-98 to 2001-2002) made the following targets for production, exports and imports of bulk drugs and formulations:-

(Rs. in crores)

YEAR	BULK DRUGS				FORMULATIONS		
	Production	Export	Import		Production	Export	Import
			Landed	Cif value			
1996-97	2186	1318	2096	1456	10494	1363	2-3% of total requirement
1997-98	2623	1581	2349	1631	12068	1499	
1998-99	3148	1897	2631	1827	13878	1649	
1999-00	3777	2277	3943	2044	15860	1814	
2000-01	4533	2732	3286	2282	18354	1995	
2001-02	5439	3278	3664	2544	21104	2195	

3.4 The Working Group has worked out future growth rate as follows:

(i) Growth rate for domestic consumption of formulations as 15%;

(ii) Growth rate for exports of formulations as 10%.

(iii) Growth rate for exports of bulk drugs as 20%.

(iv) Growth rate for bulk drugs production as 20%.

(v) Imports of bulk drugs (CIF value) be restricted to 12% of the total value of bulk drug requirement;

(vi) Growth rate for the total bulk drug requirement for exports and formulation activity (for both domestic consumption and exports) as 16%;

(vii) The ratio of value of consumption of bulk drugs for production of formulations to the value of formulation produced as 1:4.

3.5 During the course of examination the Committee observed that Working Group had projected the same quantity of several common medicines as was done for the previous Plan and wanted to know the reasons for such projections. The Department of Chemicals and Petrochemicals submitted the following justification:-

"The Working Group for IX Plan period has adjudged the compound annual growth rate for each drug taking into account the following factors:-

(1) Past trend of consumption.
(2) Disease pattern.
(3) Objectives of National Health Programme.
(4) Likely obsolescence of existing drugs.
(5) Emergence of newer and more effective substitutes.
(6) Trends in growth of newer combinations.
(7) Veterinary usages.

The Working Group has noted that in some cases of therapeutic groups new drugs were emerging leading to obsolescence, of existing drugs and hence zero growth was projected."

3.6 The following table shows the value of production of bulk drugs and formulations from 1990-91 to 1999-00:-

(Rs. in crores)

Year	**Bulk Drugs**	**Formulations**
1990-91	730.00	3840.00
1991-92	900.00	4800.00
1992-93	1150.00	6000.00
1993-94	1320.00	6900.00
1994-95	1518.00	7935.00
1995-96	1922.00	9125.00
1996-97	2186.00	10494.00
1997-98	2623.00	12068.00
1998-99 *	3148.00	13878.00
1999-00 *	3777.00	15860.00

**** Working Group estimates***

3.7 The Committee wanted to know about the specific steps being undertaken for the growth of the drug industry to meet production/investment requirements for the Ninth Five Year Plan, the Department of Chemicals & Petrochemicals submitted the following facts in a written reply:-

"……..to encourage production/investment in Drug Industry the following steps have been taken:-

(a) Almost the entire Drug Industry has been delincensed.

(b) Price control mechanism has been simplified. Drugs having high turnover but no market competition and drugs having monopoly have been kept under price control.

(c) To encourage R&D, drugs produced for the first time and not produced any where are kept outside price control for 10 years and drugs whose process has been developed through indigenous R&D are also considered for exemption from price control in favour of the company which undertakes R&D.

(d) To meet the requirement of highly trained and skilled technical man power Government has established National Institute of Pharmaceutical Education and Research (NIPER) and the functions of Institute are:-

(i) to nurture and promote quality and excellence in pharmaceutical education and research;

(ii) to collect and maintain world literature on pharmaceutical and related sciences and technology so as to develop an information centre of its own kind for other institutions within the country and in the developing world;

(iii) to create a central faculty of pharmaceutical instrumentation and analysis for use by the researchers within and outside the Institute.

(iv) to develop a multi-disciplinary approach in carrying out research and training of pharmaceutical manpower so that the larger interest of the profession, academia and pharmaceutical industry are better served and a pharmaceutical work culture is evolved which is in tune with the changing world trends and pattern of pharmaceutical education and research;

(v) to pay due attention to studies on the distribution and usage of drugs by the rural masses, taking into account the socio-economic spectrum in the country."

3.8 From the very beginning certain bulk drugs were exclusively reserved for production by the Public Sector. In 1978 Drug Policy, 17 bulk drugs were reserved for Public Sector. The 1986 Drug Policy also recognised the need for the Public Sector to have an important role particularly in production of basic bulk drugs, which are essential to the need of National Health Programme and 15 drugs were continued in the list of bulk drugs reserved for Public Sector. In the "Modifications in the Drug Policy 1986", announced in September, 1994 only 5 drugs were reserved for production by the Public Sector and ultimately the reservation for public sector has been abolished completely.

3.9 In response to the specific query of the Committee about the reasons for reducing the number of drugs reserved for PSUs and also about their production position of the de-reserved drugs, the Department of Chemicals and Petrochemicals stated in a note:-

"The reason for reducing the number of bulk drugs reserved for Public Sector is because continued reservation had lost relevance in the context of actual production programme of the PSUs. This is clearly stated at para 6 of "Modifications in the Drug Policy, 1986" which was discussed in the Parliament before being finalised. Dereservation was for increasing availability and increasing market competition.

From the 15 drugs in 1986 the number of bulk drugs reserved for the Public Sector was brought down to 5 in the "Modifications in Drug Policy, 1986" announced in September, 1994. Hence, 10 drugs were de-reserved. Their present position is:-

(i) Streptomycin and Analgin-being produced in the country in sufficient quantity and there is negligible imports.

(ii) Sulpadimethoxine and Sulphamethoxypyridazine obsolete Drugs and new generation drugs are being produced in the their place.

(iii) Morphine- Is being manufactured by the two Government factories in the country under the administrative control of the Department of Revenue.

(iv) Quinine Sulphate- being manufactured by State undertakings in West Bengal and Tamil Nadu.

(v) The rest four i.e. Gentamycin, Sulphaguanidine, Sulphadimidine and Phenobarbitone are not being produced mainly because their cost of production is not economical.

The notified price of the two products i.e. Streptomycin and Analgin which are being produced in the country and is also under price control is Rs. 2381 (Streptomycin Sulphate as base) per Kg and Rs. 378 per Kg respectively.

The five bulk drugs viz.Vit.B1, Vit B2, Folic Acid,Tetracycline,Oxytetracycline which were kept reserved for public sector in the 'Modification in Drug Policy, 1986'announced in 1994 have since been de-reserved and open for manufacture by the private sector companies ."

3.10 When the Committee wanted to know about the share of Private and Public Sector Undertakings in production of drugs and formulations, the Department of Chemicals & Petrochemicals informed that all the Central Public Sector Undertakings in the Pharmaceutical Sector namely, IDPL, HAL, BCPL, BIL and SSPL have been declared sick by BIFR and contribution of these units in production is negligible at present.

(C) Imports and Exports of Drugs/Pharmaceuticals & self-sufficiency

3.11 In accordance with the information available from Directorate General of Commercial Intelligence and Statistics (D.G.C.I.S.), Ministry of Commerce, imports of medicinal and pharmaceutical products for the last three years have been as under:-

Year	**Import of medicinal & pharmaceutical products (Rs. Crores)**
1996-97	1039.18
1997-98	1447.12
1998-99	1446.83
1999-2000	1502.30

Imports of drugs and pharmaceuticals are allowed freely, excepting those in the restricted list of import under the current EXIM Policy, which can be imported under an import licence. In view of these steps, no shortage of medicines is likely to occur. Import can take place from any part of the World, there being no general restrictions. Drugs and Pharmaceuticals are being imported mainly from China, USA, Germany, U.K., France, Switzerland, Belgium, Republic of Korea, Netherlands, Italy, Japan, Denmark, Sweden, Russia and Ireland.

3.12 The Committee specifically wanted to know about the availability of Vitamin B1 and its derivatives in view of decimal production from PSUs and wanted to know the future policy in this matter. The Department of Chemicals and Petrochemicals clarified the position in a written reply:-

"The estimated demand for Vitamin B1 during 1998-99 is 133 MT. Since Vit. B1 was reserved for manufacture by the Public Sector Undertakings and they have closed production, the demand in the country is being fulfilled by allowing imports on case to case basis. Manufacture of Vitamin B1 has since been de-reserved in February, 1999 and it can now be manufactured by any one. Vitamin B1 is a scheduled bulk drug under DPCO,1995. The estimated

demand for this bulk drug for the year 1999-2000 was 146 MT as per the report of the working group on Drugs and Pharmaceutical for the Ninth Five Year Plan period. Production of Vitamin B1 during the year 1999-00 was 6.42 MT as per the Monthly Progress Reports of M/s. Romeda Chemicals Ltd.,Mumbai, the only company submitting returns on the bulk drug. M/s. IDPL has not been submitting returns on the bulk drug since 1996-97, as they have stopped production of the items. As per provisional data available from Directorate General of Health Services (DGHS), the import of Vitamin B1 during 1999-00 was 92.33 MT {consisting of 46.46 MT of Vitamin B1 (Thiamine HCL) and 45.87 MT of Vitamin B1 Mono (Thiamine Mononitrate)}."

3.13 The details of the exports of Drugs, Pharmaceuticals & Fine Chemicals during the last three years are as under:

Year	**Value of Exports of Drugs, Pharmaceuticals and fine chemicals (Rs. In Crores)**
1996-97	4341.80
1997-98	5419.32
1998-99	6256.06
1999-2000	6631.45

From a meagre Rs. 46 crores worth of pharmaceuticals exports in 1980-81, the exports have risen to Approx. Rs. 6631 Crores in 1999-2000.The exports from India are mainly to USA, Russia, Germany, Hong Kong, U.K., Nigeria, Singapore, Netherlands, Iran, Brazil, Vietnam and China.

3.14 Explaining the performance and importance of Drugs and Pharmaceutical sector for the purpose of export Secretary, Ministry of Commerce stated during evidence:-

"Drugs and pharmaceutical sector is one of the very fast growing export sector in our country. It gives us in terms of foreign exchange earning, in terms of employment, enormous benefits. In fact this sector is giving us approximately Rs. 4000 crore of foreign exchange earning. That, of course, is also income to the country.

Apart from the enormous benefits by way of foreign exchange earning, there are a lot of other benefits from this particular sector. One is, it is enhancing our image in the world. Earlier, India used to be known for commodities and traditional goods like textile, etc. For the first time, this particular sector which is a hi-tech sector is giving us an image that India is becoming an importance source of hi-tech sophisticated products because drugs and pharmaceuticals are one sector where a lot of quality control is exercised and a lot of care is taken about the quality of the product which is sold. Another great advantage of the export thrust which has been given is that this has enabled a large number of drug

companies in India to become not only well off but to concentrate on development of basic drugs. Earlier, they were probably only trying to copy the drugs which were already developed but today they are also spending a lot of money on research and development and developing their own new molecules. In fact, India is also now going to become an important source of development of new medicines. This has come about because of the strength they have derived through the advantage of export and earnings etc."

3.15 About the performance of Indian companies he elaborated further:-

"A number of companies have become quite famous in the world and because of that there is a lot of demand for these companies to set up formulation plants all over the world. In fact, this is one sector where a lot of joint ventures are coming up abroad and this is also enhancing the image of India. There are very few countries outside the developed world which can compete with us. We have become a very cost-effective source of drugs and pharmaceuticals and because of this particular advantage which we have got over most of the countries with further help, the sector can really grow enormously. It can provide us a lot of employment and provide all the basic drugs required for our own requirement and also for earning foreign exchange. So, this is one sector which requires enormous help and backing. This will really give not only in terms of export income employment but a very good image of the country."

3.16 While going into the details of exports, the Committee observed that bulk drugs of more value are being exported and wanted to know the reasons for exporting drugs in such huge quantity particularly when the country is not self-sufficient in their production. The Department of Chemicals & Petrochemicals explained the position as under:-

"In an environment of liberation and free trade it is not possible to co-relate exports, production, imports etc. of bulk drugs and formulations, more so, since these are guided by the availability of opportunities and relative cost benefits. Formulation sector is low investment are and therefore many countries have self-sufficiency. Also, in case of formulations regulatory procedures involving approval of drugs, batch-wise inspection etc. stand in the way. However, small countries cannot produce bulk drugs economically and therefore, it would continue to be major item of exports. Export has taken place in case of those bulk drugs where the country has cost advantage and capacities in excess generally of domestic demand."

3.17 When the Committee wanted a categorical reply of the Government regarding steps being taken to make India self-sufficient in Pharmaceuticals, the Department of Chemicals & Petrochemicals elaborated as under:-

"The following steps have been taken to make India self-sufficient in Pharmaceuticals:-

(i) Almost entire drug industry has been de-licensed except for a few items.
(ii) Automatic approval of foreign investment upto 74% (since raised to 100%)
(iii) Automatic approval for technology agreements.
(iv) Most of the items are allowed for imports under OGL.
(v) Higher margin to basic stage manufacturers.

After announcement of Modification in Drug Policy in September, 1994 an amount of Rs. 2040 crores has been approved by the FIPB for foreign direct investments so far. The FDI approved FIPB during the last three years. Year-wise detail is given below:-

Year	**Rs. in crores**
1998	187.00
1999	215.00
2000	1464.00

3.18 While clarifying the level of self-reliance, the Ministry explained that as the value of exports in respect of both bulk drugs and formulations is higher than the imports, the drug sector has a positive balance of trade indicating satisfactory position in terms of self-reliance. It may also be mentioned that since there is greater obsolescence in this sector and newer products are being introduced world wide all the time imports are necessary to get the benefit of latest drugs. They have a view that as such, no country can be fully self-reliant at any given point of time in so far as availability of medicine is concerned.

CHAPTER-IV

AVAILABILITY OF DRUGS & PHARMACEUTICALS

4.1 The basic intention of Government policy in regulating the drugs and pharmaceutical industry has been to ensure adequate availability of quality medicines at reasonable prices. This has been the stated objective in all policy statements since March, 1978. Reportedly , only 26% of the Indian population and that too mostly in urban areas have the access to the modern medicines.

4.2 For ensuring availability of drugs at reasonable prices, the Government has been promulgating Drugs (Prices Control) Order under Essential Commodities Act, 1955 from time to time. The current order known as Drugs (Prices Control) Order, 1995 was promulgated on 6th January, 1995. At present 74 drugs along with their formulations identified by the application of criteria in para 22.7.2 of 'Modifications in Drug Policy, 1986' are under price control.

4.3 During the course of examination the Committee specifically wanted to know the details of the present Government Policy in regard to availability of essential drugs in the country. The Department of Chemicals & Petrochemicals stated that in order to ensure increased availability of drugs in the country the Government has taken the following policy measures:-

(A) Almost the entire Drug Industry has been de-licensed.

(B) Price Control mechanism has been simplified. Drugs having high turnover but no market competition and drugs having low turnover and having monopoly have been kept under price control.

(C) To encourage R&D, drugs produced for the first time and not produced anywhere else are kept outside price control for 10 years and drugs whose process has been developed through indigenous R&D are also considered for exemption from price control in favour of the company which undertakes the R&D.

4.4 In response to specific query of the Committee about the Government policy regarding supply of medicines required for public health, the Ministry of Health and Family Welfare submitted as under:-

> "The supply of Medicines required for Government Hospitals and Institutions are restricted by the budget available for this purpose. The Government is not committed to meet the entire requirements of drugs and medicines for the patients attending government institutions. The budget provided for the purchase of drugs and medicines are not even adequate for all

patients admitted to the hospitals, and the supply of drugs to out-patients is very nominal. The plan budgets aim to create
more centres and treatment facilities but there are no proposals to supply all drugs from government funds even to the members of the economically weaker sections of the society. The actual responsibility of supplying drugs to the patients attending the government hospitals and institutions is with the supplementing the efforts of the states with several National Programmes to control/eradicate certain communicable diseases e.g. malaria, leprosy, tuberculosis etc., and to prevent those communicable diseases for which vaccines are available and which are real public health problems viz., diphtheria, tetanus, pertussis, measles, polio and tuberculosis. The Central Government supplies drugs/vaccines to the states who are responsible for running the programmes.

There is no monitoring mechanism for the production of such drugs/vaccines within the DGHS of the Ministry of Health."

4.5 The Committee further enquired about the actual mechanism available with the Government to assess the demand and supply of the medicines in public hospitals including CGHS and the measures taken to overt the problem of short supply. The Ministry of Health & Family Welfare elaborated further:-

"The normal pattern of assessing the requirement of drugs in Central Government hospitals/institutions is to use the trend of consumption in the previous year as the basis for such assessment. In the CGHS, the trend of consumption of the previous 3 years is taken into account. In addition to this, hospitals also take into consideration requirements indicated by heads of various specialities and prescriptions obtained from patient care areas. Purchase of drugs is done by each institution/hospital, after it has made an assessment of its requirement of drugs. In the case of AIIMS, restricted tenders are placed as per recommendations of the Hospital Drug Selection Committee and medicines are purchased from time to time, keeping in view the availability of drugs. Similar procedure is followed in the case of PGI, Chandigarh also. In the case of hospitals like Dr. R.M.L. Hospital, S.J. Hospital, LHMC and Smt. S.K. Hospital as well as JIMPER, Pondichery, purchase is done through the rate contract of the DGS&D, the Medical Stores Organisation (MSO) as well as through open tender. In cases where certain medicines are not available, limited tender system is also resorted to. Similarly in the case of CGHS, purchase is done primarily through the MSO. In case there is still an urgent necessity for any drug, there is also the provision available to all these institutions to resort to local purchase. Hence there is no reason for any occurrence of shortfall in the availability of drugs under any hospitals/institutions under the Central Government. Adequate provision is made available in the budget to take care of this requirement."

4.6 In view of their indirect control of the Government over the private sector, the Committee wanted to know the way in which they ensure the availability of medicines in all parts of the country. The Department of Chemicals and Petrochemicals replied as under:-

> "As and when shortages are reported by the State Governments, availability of medicines is ensured by asking concerned manufacturers to rush the stocks. It has been experienced that in most of the cases, the equivalent brand/therapeutic substitutes are available."

4.7 When the Committee wanted to know about the views of the Government regarding region-wise requirements and supply position and short supply etc. of medicines, Department of Chemicals and Petrochemicals clarified the position as under:-

> "Most of the drugs required for the treatment of the common diseases are available in the country. In the liberalised import regime, except for few specified newer drugs and medicines, most drugs are allowed to be imported. No assessment of region- wise requirement and supply position of the medicines is kept. Demand/supply is largely regulated by prevailing disease pattern and market forces. However, the State Medical Departments purchase essential pharmaceutical drugs in bulk for supply to needy people free of cost through the network of hospitals dispensaries under the National Health Programme of the Ministry of Health and Family Welfare."

Explaining it further, the Department stated:-

> "Availability of drugs is monitored by the State Drug Controllers. Whenever there is a shortage, the State Drug Controller concerned sends reports on the same to the Government of India. It has been experienced that in most of the cases, the equivalent brand / therapeutic substitutes of medicines are available.
>
> NPPA has not received any report on general shortage of medicines from the State Drug Controllers. However, reports on shortage of some specific formulations/ brand for treatment of cancer was received from the Drug Controller of Delhi during November 2000. NPPA directed the concerned manufacturers for ensuring speedy availability of the medicines in the areas concerned."

4.8 In response to the Committee's specific query whether the Government maintain any buffer stock etc. of medicines to face the seasonal sudden spurt of diseases, Ministry of Health and Family Welfare submitted the following information:-

> "Ministry of Health procure certain essential drugs under National Health Programme for the treatment of Tuberculosis, Malaria and Leprosy. However, it may be stated that each State Government and other Government Agencies do purchase medicines and keep a buffer stock to avoid shortages during seasonal/sudden spurt of disease. Government Medical Store Depots under DGHS in the Ministry of Health also keeps buffers stocks of essential drugs."

4.9 The Committee observed that the Central Government as well as the State Governments are responsible for availability of medicines and their coordination is required at each stage. In view of this fact, the Committee wanted to know the type of coordination between Central Government and the State Government machinery to ensure the quality drugs to the people. Ministry of Health and Family Welfare submitted in a written reply:-

> "The State Drugs Control Organisations are responsible under Chapter IV of the Drugs & Cosmetics Act to ensure manufacture of quality drugs through a system of licensing. Monitoring problems that come in the way are regularly discussed every year in the meeting of Drugs Consultative Committee (DCC) consisting of all State Drug Controllers as member of the Committee under the Chairmanship of DCG(I). Based on these deliberations, rules are amended, Schedules to the Rules are added, such as Schedule M laying down various norms towards Good Manufacturing Practices (GMPs) and Good Laboratory Testing Practices, validation of equipment, skilled manpower, management of batch record, distribution records, quality control testing etc. Policy guidelines are also framed on various technical matters. Follow up actions, dissemination of important information, administrative guidelines and joint inspections etc. are carried out through four zonal offices and sub-zonal offices of CDSCO to coordinate with the State Drugs Controllers of the respective zones to achieve the objective of ensuring the availability of quality drugs.
>
> Similarly, provisions are also available under chapter 3 of the Drugs and Cosmetics Act to ensure quality of imported drugs. While quality control at the point of import is enforced by the CDSCO, the enforcement at the marketing level is done by the State Drugs Authorities."

4.10 During the course of examination the Committee tried to understand the actual problems relating to drug availability and accessibility and discussed the matter with representatives of large and small Drug Manufacturer's Association and Voluntary Health Organisations. After discussions, the following facts/ suggestions emerged:-

(i) Modern medicines reach only 26% of Indian population and mostly in urban areas.

(ii) The industry has developed comprehensive network of distribution agents, stockiest, wholesalers and retailers but the difficulties regarding distribution of medicines in interior rural areas still persist due to poor road network.

(iii) The real problem is not just availability of medicines but also access to medicines with good quality at reasonable prices. The true issue of concern is that access is limited. The main barriers to access are shortages of financial resources, absence of even rudimentary health care in rural areas.

(iv) The Public Undertakings IDPL, HAL, BCPL and BIL have had manufacturing capacities. The capacities should be fully utilised to produce generic drugs for weaker sections.

(v) Safe and effective medicines can be descheduled and can be made available(over the counter medicines).

(vi) Enforcement of Drugs and Cosmetic Act should be uniform in all over the country because of indiscriminate sanction of drug manufacturing licences, there are about 20,000. Manufacturers; many of them do not conform to Good Manufacturing Processes.

(vii) Government should enlarge the scope of Sarvapriya Scheme to include supply of essential drugs through Public Distribution System (PDS). This will expand the ambit of access to modern medicine to 90 per cent of population by 2005. The Scheme will benefit over 30 crore people below poverty line as they will have access to quality drugs at affordable prices. There may be dispensed from primary Health Centres.

CHAPTER-V

QUALITY CONTROL & RATIONAL USE OF MEDICINES

(a) Monitoring the Quality of Drugs and Pharmaceuticals

5.1 While Indian Pharmaceutical Industry has been capable of production of quality drugs, there have been cases of poor quality drugs being sold. The country is manufacturing most of the requirements of drugs and is also in a position to export a significant quantity of medicines of internationally acceptable quality to many countries including those of developed world. The rules made there under the Drugs and Cosmetics Act, 1940 provide in Schedule 'M' the Good Manufacturing Practices (GMPs) which a manufacturer is obliged to follow. A drug is of acceptable quality under the Act not only if it meets the finished product specifications but also more importantly it is manufactured in a plant complying with GMPs. The responsibility for enforcement of GMPs in respect of newer drugs rests with the state drug control authorities.

5.2 During the course of examination when the Committee wanted a complete information about the machinery to monitor the quality of the drugs manufactured and supplied in the country, the Ministry of Health and Family Welfare submitted the following facts in a written reply:-

> "The Central Government controls the quality of imported drugs. The port officers of the Central Drugs Standard Control Organisation (CDSCO) inspect and draw samples for testing by the Government approved laboratories. After the test reports confirm the quality of the drugs, they are permitted to be released by the CDSCO which are located in Calcutta, Chennai, Delhi, Cochin, Mumbai and Nhava Sheba. The staff and facilities available in such offices have not kept pace with the development of trade and import of drugs. The testing capacity in the Government laboratories is also not adequate to test all the samples.
>
> The CDSCO is responsible for approving the licenses issued to the Blood Banks and for the manufacture of blood products, large volume parenterals, and antisera and vaccines. The No. of Drug Inspectors with CDSCO is 32 and is not adequate to inspect regularly all the institutions under the scheme of Central licensing. The Drug rules require that all licensed premises shall be inspected twice a year. There are approximately 1400 establishments and the capacity of each Drug inspector is 72 inspections annually. The number is grossly inadequate to undertake other important activities like inspection of manufacturing premises for Good Manufacturing Practices (GMP), WHO certification for international commerce and to undertake additional responsibilities envisaged under the Drug Policy, 1994.

The quality control of drugs manufactured and sold in the country is the responsibility of State Licensing authorities. Every state and Union territory in the country has a drug control machinery to license the manufactures, wholesalers and retailers dealing in drugs. The main responsibility in this area is with the Drug Inspector (DI) who inspects the premises for licensing, and to check that the conditions of licenses 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 prosecution of the offenders.

The Staffing pattern has not kept pace with the growth of the drug manufacturing in the country. There are approximately 9000 manufacturing establishments, and 3 lakhs sales outlets with a turnover of drugs crossing Rs. 10000 crores in 1997-98. The number of DIs in all the states have remained around 1100 which is inadequate to carry out even one inspection of each licensed premises per year. There are 16 drug-testing laboratories in 14 states with the rest having to depend on the central laboratories. The total testing capacity for the state and central laboratories is only 35000 samples per year against a need for around 100,000 samples per year.

The paucity of DIs and testing facilities have been largely responsible for the lack of any serious effort to check spurious and adulterated drugs in the country, and to make a reasonable estimate of the actual problem.

To update the facilities and strengthen the central and state enforcement machinery and augment the testing capacity, the Central Government is negotiating for funding a project with the World Bank. This project, to be implemented in five years will considerably improve the functioning of the drug control organisations in the country. As only 14 states are participating in the project an improvement all over the country is not likely after the project is completed."

5.3 During the course of evidence the Committee went into the details of the same issue and tried to understand the problems being faced by the Ministry of Health and Family Welfare in implementation of the Drugs and Cosmetics Act, 1940 and Rules made thereunder, the Additional Secretary, Ministry Health and Family Welfare submitted before the Committee:-

"The Drugs and Cosmetics Act, 1940 and the Rules, 1945 have been in force in this country for a very long time and for the last so many decades. Basically, under the Act, the quality control and licensing of all manufacturing and sale units are the responsibilities which have been given to the State Governments. The Central Government has to fulfil five basic responsibilities:-

(i) They have to see that new drugs and imported drugs are checked for quality.

(ii) They have to see that the kind of regulations which are introduced in are shared with the States and they keep in touch with the States to see that that kind of enforcement is carried out.

(iii) Validation, calibration and other norms which are set out are to be shared with the States.

(iv) The Central Government has licensing authority for blood banks. This is the only area where the Inspectors of the Central Drug Organisation actually go into the licensing area.

(v) They see to it that the drugs which are imported into the country are quality tested. For biologicals it is done at the CRI, Kasoli and for other drugs it is done at COL, Calcutta. These are the primary responsibilities. This work is done in the Ministry through the DGHS. The DGHS has got two technical committees set up under the Act. They are statutory Committees and they function under the Chairmanship of the DGHS. All the Centre-State issues regarding quality control, norms, regulations and standards are discussed there and a consensus is arrived at. After that the matter is sent to the Drug and Technical Advisory Board which is another very high level Committee on which we have certain ex-officio members and also some non-officials. This Committee deliberates on the suggestions made by the DCC. Then, it is passed on to the Directorate General of Health Services (DGHS). The DGHS takes the draft notification modifying, amending, changing and nulling whatever the relevant rules may be. Thereafter, it comes before the Government that is at the Minister's level. Then, it is approved for inviting public objections. Two to four months' time is given for obtaining public objections. Then, those objections are considered."

5.4 About the problems being faced in monitoring the quality of the drugs and pharmaceuticals and problems in formation of National Drug Authority, the witness stated:-

"The biggest problems in quality control is the number of inspectors that we ought to be having in our country which is far short of anything which could be considered even the bench mark level. Second problem is that we have not been able to expand and upgrade our laboratories either in the Central Sector or in the State sector. Thirdly, the National Drug Authority was to be set up. This decision was taken in 1994. Till date we have not been able to do that because of the fact that we do not have the infrastructure. Without infrastructure, we would not be in a position just to set up an authority. There would be a marked improvement if that authority is set up. It is because the inter-State commerce would be regulated and there would be inter-State registration of organisations. The Drug Controller of India would regulate it. In US, they have got 14 smaller units looking into specific things, be it quality control, be it cosmetics or veterinary drugs. We are not doing that today. Our difficulty in getting this kind

of infrastructure upgradation has been, as usual, the paucity of funds. We do not have that kind of money. I have the figures with me. The kind of Budget the Drug Control Department receives is somewhere in the region of Rs. 25 crore in the area of non-Plan expenditure and hardly Rs. 10 crore for planned expenditure. With this kind of Budget, it is impossible to do anything."

5.5 About the coordination with States, the Additional Secretary elaborated as under:-

"As far as the States are concerned, it is far worse. I am sorry to say that the Drug Controllers do not have even fax facility. To rectify this, we put together a project seeking the World Bank assistance. We brought all the States, particularly those States which have large manufacturing capacity, to put together a project which would cost Rs. 151 crore. Essentially, it tries to do the following. It tries to strengthen the existing laboratories. There are four Central laboratories at Calcutta, Ghaziabad, Chennai and Mumbai. Those would be strengthened. The number of tests would go up from 30,000 to almost 1,00,000 a year. Four laboratories at Belgaum, Chandigarh, Hyderabad and Guwahati would be set up. These would be brand new laboratories. The land has been taken over. The State Governments have given up these lands. We expect to strengthen the State analytical laboratories. At the moment they do not have the capacity to do this kind of work. We would help them to expand as well as to get the necessary equipments. The Central Drug Controller has only 32 inspectors. We expect to give them 300 and odd inspectors through this project. At the State level there are only 1,040 inspectors through out the country. We expect that we can augment them by about 500. The difficulty with this project has been that there has been a feeling that if we create so many posts, whether we would be able to sustain this once the World Bank project is over. The World Bank naturally will give loan only for five years. To overcome that we have called all the State Governments to Delhi and we have written to all the Chief Secretaries. They have given their commitment that they would sustain this project once the World Bank phase is over. The project is in the very advanced stage of formulation. We do feel that if we have support of the Ministry of Finance, the Departments of Expenditure and Economic Affairs, we would be able to get these resources through the World Bank. The project is not only for drugs but also for other 14 sub-components like food subsidy, national pharmaceutical research. The NIPER which is an institution in the Ministry of Chemicals would also get some assistance so that they can help train our drug inspectors and staff. Tremendous amount of work has gone into this project.

We do not lack in terms of monographs that are being brought out. Our pharmacopoeia is on par with British pharmacopoeia. But certainly the standard leaves a lot to be desired for the reasons, which I have just told you. There are about 4,000 of these units in the manufacturing sector. Out of these, hardly 20 per cent are in the organized sector. They account for 145. The rest are in the small scale sector."

5.6 The witness further accepted the difficulty in monitoring the small sector and submitted as under:-

> "It is very difficult to monitor the small scale sector because we do not have firstly, the inspectorate staff and secondly, they will to see that this kind of a thing is not allowed. So, the number of prosecutions which have been launched throughout the last five years are on a plateau. They are more or less the same. The number of cases of sub-standard drugs etc. coming to notice is about 11 per cent and even that is on a plateau. If one looks at the statutory responsibility for inspecting the manufacturing and the sale units, what we are doing certainly falls short of what we ought to be doing even if we were to follow the Act."

5.7 The Committee went into the details of the purview of Drug Inspectors and wanted to know whether DIs also test the drugs supplied under CGHS scheme, Government hospitals and dispensaries also. The Ministry of Health and Family Welfare submitted in a note as under:-

> "Samples of drugs supplied under CGHS Scheme, Govt. Hospitals and dispensaries are also drawn from time to time by DI's. However, the MSO, which procures and supplies drugs to CGHS and various hospitals, undertakes testing of every consignment at various approved labs as well as their own labs. The DI's while drawing a sample from dispensary or hospitals follow the statutory method as prescribed under Section 23 of the Act. The sample is divided in four portions and sealed. One portion of sample is sent to laboratory for testing. One portion is kept with DI for sending it to supplier of drug in case the drug is found to be not of standard quality. One sample portion is kept by DI for producing it in the Court if the need so arises and one portion is kept at concerned hospital store or dispensary."

5.8 The Committee further wanted to know whether the provisions of Drugs and Cosmetics Act were adequate for maintenance/enforcement of drug standards in the country. The Ministry of Health & Family Welfare replied that the provisions were adequate. However, uniform status of its implementation over drug manufacturing activity was possible only if licences for drugs sold in inter-state commerce were issued and enforced by a Central agency.

5.9 When enquired whether the Ministry of Ministry of Health and Family Welfare had taken steps to persuade the States to appoint more DIs or establish more labs, the Ministry clarified :-

> "Various committees appointed by Govt. of India to review functioning of Drug Control System in the country had recommended for adequate enforcement

staff and testing facilities in states. This subject has been discussed in the meetings of the Central Council of Health (attended by the Health Ministers, Health Secretaries and Directors of Health Services of the States and the Central Ministry of Health and Family Welfare and DGHS officials). Substantial financial assistance has been provided to states to augment their testing facilities. A capacity building plan with World Bank assistance to augment the drug testing facilities in states in respect of equipments, technical staff and building is also being pursued by Deptt. of Health. 17 States have submitted their requirements in this regard."

5.10 During the course of evidence, the Secretary in the Department of Indian Systems of Medicine accepted the fact that there were no standards fixed for Ayurveda, Unani, Sidha or Homoeopathy drugs and informed that the Government have set up different Pharmacopoeia Committees for each system. The Secretary further informed:-

"The work of evolving of standards is going on. In this work, we are backed up by two laboratories, that is, the Pharmacopoeia Laboratory for Indian Medicines is taking care of ayurvedic, sidha and unani medicines and the other one is the Homeopathic Pharmacopoeia Laboratory. Both of them are located at Ghaziabad. They are very small and are engaged mostly in helping the pharmacopoeia committees in evolving the standards for these drugs. So, not much of testing is done there. But wherever it is by court orders or some emergencies, they do undertake testing of other samples. As far as Homoeopathic Laboratory is concerned, it is already declared as a Central Drug Testing Laboratory and so, they do undertake the testing of homeopathic medicines. We need to strengthen these two laboratories and we have separately provided for funds in the budget of our Department. At the same time, our project is also a part of the capacity-building project of the Health Department. Our project is worth about Rs. 19 crore and we are hopeful that it will be accepted because it is part of the major project. If that comes through, we will be able to strengthen these two laboratories because we already have separate land allocated for this purpose."

(b) Quality Control of imported Drugs

5.11 The Committee were informed that the Quality of Imported Drugs is monitored by Central Drugs Standard Control Organisation (CDSCO), under the administrative control of Ministry of Health and Family Welfare . The objectives of CDSCO and the main functions performed by it are as under :-

"(1) Controlling the quality of imported drugs and cosmetics.
(2) Laying down regulatory measures through amendments of the Drugs and Cosmetics Act and Rules made thereunder.
(3) Laying down standards of drugs, by bringing out and updating Indian Pharmacopoeia.
(4) Granting permission for clinical trials and approval of new drugs proposed to be imported or manufactured in the country.

(5) Weeding out of irrational formulations moving in the market licensed by the State Licensing Authorities.
(6) Coordinating the activities of the States and advising them on matters relating to the uniform administration of the Act.
(7) Arranging meetings of two statutory bodies, namely Drugs Technical Advisory Board (DTAB) and the Drugs Consultative Committee (DCC) and follow up actions.
(8) To provide facilities of Appellate Laboratories in respect of different categories of drugs and to assist States in drug testing.
(9) Participation in WHO GMP certification scheme by way of joint inspection as CLAA.
(10) To approve licences as CLAA to approve licences for manufacture of certain categories of drugs, i.e. Sera & Vaccine, LVP, Blood Banks.
(11) Conducting training programme for DI's and Drug Analysts."

5.12 When the Committee wanted to know about the manpower requirement and actual strength of CDSCO and also whether CDSCO was able to handle and keep pace with the development trade and import of drugs, the Ministry of Health and Family Welfare replied:-

"The Development of trade in drugs is the responsibility of the states and CDSCO has traditionally adopted the role of adviser in technical matters and to provide standards for manufacture, storage and distribution of drugs.

The import of drugs has been looked after with the limited staff sanctioned by the Govt. The major bottleneck of testing the samples of increased number of consignments has been largely attended by utilising the services of competent private drug testing laboratories for the pharmacopeial drugs and formulations.

However, the existing manpower of CDSCO is much lesser than the sanctioned staff as more than 50 percent posts at supervisory level have lapsed in the last 7 years. We have requested Ministry of Finance to restore the lapsed posts and to create 60 technical posts at different level."

5.13 The Department of Indian System of Medicines has informed that the Department is enlarging the scope of formulating the safety and efficacy of medicinal plants along with quality control of Ayurvedic and Unani drugs through Ayurvedic and Unani formulations in consultation with the Central Drugs Standard Control Organisation (CDSCO). Department of Indian systems of Medicine is in the process of developing Good Manufacturing Practices for the manufacture of Ayurvedic Medicine in consultation with the CDSCO under the Department of Health.

(c) Irrational Drugs

5.14 The Committee felt that there were numerous irrational drugs in the market and wanted to know about the steps being taken by the Government to weed out those medicines. The Ministry of Health and Family Welfare replied in a note:-

> "So far 57 categories of harmful/irrational combinations have been weeded out. This is a continuous process. The drugs moving in the market are identified as harmful or irrational by practising doctors, academicians, NGOs and reported by WHO and are examined by a Committee of experts. As per procedure suggested by the Supreme Court, the manufacturers are given an opportunity to present evidence and make their recommendations. Such recommendations are to be approved by the Drug Technical Advisory Board, a statutory body under the D&C Act, before any drug can be banned by notification in the Government Gazette. A core group was appointed by the Supreme Court to examine the drugs currently available in the market and identified by Common Cause (an NGO), Voluntary Health Association of India and others in a public interest petition filed in the Supreme Court in 1993. This group has completed the scrutiny of all pending items before the Supreme Court and action is being taken against their recommendations by the Government."

5.15 The Committee drew the attention of the Ministry towards the public complaints regarding availability of irrational and expiry dated drugs in Government hospitals and wanted to know the reaction of the Government along with the steps being taken to minimise distribution levels. The Ministry of Health and Family Welfare submitted:-

> "Supplies of drugs to Government hospitals take place from
> (a) The Medical Stores Organisation,
> (b) Through open or limited tenders or,
> (c) Through local purchase.
>
> In the case of MSOs, when there is urgent need to cover any shortfall, purchase is done of only those drugs listed in the vocabulary of the Medical Stores Book and the CGHS Formulary, both of which are approved by Government for a given period. Hence these lists include only those drugs which are approved for manufacture and marketing by the DCG (I) whereas Drugs which are established as irrational are either banned or phased out by the DCG (I). Hence the question of any drug, established as irrational, being supplied to Government hospitals does not arise.
>
> Similarly each medical depot takes care that shelf life of a drug has not crossed $1/6^{th}$ of its shelf life from the date of manufacture at the time when the drugs are offered by manufacturers for inspection before supply. Care is also

taken to ensure that there is adequate shelf life for any drug which is supplied to hospitals. Similarly precaution is taken to ensure that drugs beyond the expiry date are not supplied to hospitals by ensuring that existing stocks are taken into consideration when making fresh purchases and also by ensuring that supplies are also made keeping in view chronological order of stocks in the MSO."

5.16 The Committee observed that there were several medicines which were banned in other countries and in India also and wanted to know about the specific steps being taken to ensure that banned medicines were not marketed in the country. The Ministry of Health and Family Welfare informed that this was the concern of DCG(I) in the Ministry. Explaining it further the Ministry stated:-

"Under the D&C Act and Rules, drugs include all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals. Substances intended for use as components of a drug including empty gelatin capsules are also defined as drugs. At present no law in the country is available to enforce that only essential formulations are produced. However, drugs which are reported to be harmful or which lack adequate therapeutic justification, are being prohibited under the powers acquired by Central Government under Section 26A of the Act. This is thereafter enforced and monitored through the State Drug Authorities.

To ensure that banned medicines are not sold out in market, a proposal to the Ministry of Health to provide computerized network and necessary sites for all CDSCO zonal offices and offices of all State Drug Controllers in the country is under consideration."

CHAPTER – VI

PRICING AND PRICE CONTROL OF DRUGS AND PHARMACEUTICALS

(a) Price Control and Pricing Mechanism

6.1 Price control has been an essential feature of Drug Policy since early 70's. the purpose behind controlling the prices of drugs was to ensure that no undue profitability is made in these essential items and that drugs are available at reasonable prices to the common man. The Drugs (Prices Control) Order promulgated first in 1979 (DPCO, 79) was replaced by a new DPCO in 1987. It was recognised that only adequate production could lead to abundant availability of drug at a reasonable price. It was felt that the product- wise price control was cumbersome, time consuming and also very difficult to administer. DPCO, 87 was replaced by new DPCO, 95 to fulfil the objectives of new Drug Policy announced in September, 1994. Under DPCO, 95, 74 drugs and their derivatives are regulated by Deptt. of Chemicals and Petrochemicals. Pharmaceuticals industry is the only industry which is subjected to a three tier price control viz. Control of prices of bulk drugs, control on prices of formulations and control on overall profitability. Total indirect tax burden on consumer by way of Customs Duty, Excise Duty, Sales Tax and Octori etc. works out to around 37% of the final price.

6.2 While going into the details of pricing of various drugs and formulations the Committee specifically wanted to know the present method of price fixation. Department of Chemicals and Petrochemicals informed that the price fixation of various bulk drugs and formulation was being done as per provisions of Drugs (Prices Control) Order, 1995.

6.3 Regarding the exact method of fixation of prices of bulk drugs, the Department informed that prices were fixed from time to time by notification in the official gazette and the following steps are involved in fixation/ revision of bulk drug prices:-

"(1) collection of data by issuing questionnaire/ Form-I of DPCO, 1995 /cost audit report etc.
(2) Verification of data by plant visits, if required.
(3) Preparation of actual cost statement.
(4) Preparation of technical parameters to be adopted for working out fair price of the bulk drug.
(5) Preparation of estimated cost based on actual cost and technical parameters. Fair price is calculated by providing returns as

specified in Sub-para (2), para-3 of DPCO, 1995 as opted by the individual manufacturer.

(6) Fixation of fair price of bulk drug by considering weighted average cost, 2/3rd cut-off level of production..

(7) Notification of bulk drug price in official Gazette.

(8) The fair prices may be further revised, if asked for by the manufacturers, based on escalation formula for change in major raw
materials and utilities rates."

6.4 About the Pricing of Formulations, the Department informed as under:-

"Applications received from manufacturers and importers in Forms-III and IV (as prescribed under DPCO, 1995) are considered for price fixation/ revision. The retail price of indigenously produced formulations are worked out as per the formula given in para-7 of the DPCO, 1995. For indigenously manufactured formulations, the Maximum Allowable Post-manufacturing Expenses (MAPE) is allowed upto 100% and in the case of imported formulations, the margin to cover selling and distribution expenses including interest and importer's profit is allowed upto 50% on the basis of landed cost as provided in the DPCO, 1995."

6.5 When the Committee wanted to know specifically about the variation in prices from State to State the Department of Chemicals and Petrochemicals informed:-

"In the case of each bulk drug, which is under price control a single maximum selling price is fixed that is applicable throughout the country. While arriving at the maximum sale price, the raw materials cost considered takes into account transportation, sales tax and other related factors.

Similarly, in the case of commonly marketed pack sizes of scheduled formulations also, a ceiling price is worked out and notified for the entire country. For indigenously manufactured scheduled formulations, a Maximum Allowable Post Manufacturing Expenses (MAPE) upto 100%, and in respect of imported formulations margin upto 50% are provided for meeting the transport cost, post-manufacturing expenses, etc. the Maximum Retail Price (MRP) of drugs and formulations are exclusive of local taxes, therefore, the prices vary from state to state depending on the rate of local taxes (Sales Tax, Octroi, etc.)."

6.6 The prices of the controlled medicines (except where ceiling prices have been fixed)manufactured by small scale industries are permitted to be fixed by the manufactures themselves the prices on their own. In accordance with the provisions of the DPCO, 95 manufacturers of bulk drugs and formulations are required to submit price

lists to the Government. In case of controlled category price rise is examined to see where the increase is due to the increase effected by the Government or due to violation of the DPCO by the company as per para 10 (b) and (c) of DPCO, 95 Government have the powers to fix the price even for a non scheduled formulation and a bulk drug respectively.

6.7 It is generally said that prices of medicines are very high and beyond the reach of common man . According to OPPI the prices of medicines in India are the lowest in the world. The market competition has induced price stabilisation and even price reduction in few cases. To justify the fact they have submitted a table giving comparisons of some essential medicines in India and U.K.:-

	Molecules	**Strength**	**UK Price (Rs.)**	**Indian Price (Rs.)**
1	Erythromycin	250 mg Caps	9.25	3.57
2	Cephxlexin	250 mg Caps	10.40	6.45
3	Cefixime	200 mg Caps	116.96	45.00
4	Betamethasone	0.50 mg Tabs	2.18	0.37
5	Ciprofloxacin	250 mg Tabs	51.00	5.05
6	Diclofenee	50 mg Tabs	10.95	0.79
7	Amoxycillin	250 mg Caps	13.06	3.60
8	Ranitidine	150 mg Tabs	31.62	0.71
9	Rifampicin	300 + 150 mg Caps	51.95	8.65
10	Norfloxacin	400 mg Tabs	32.64	4.70

6.8 ORG-MARG report (April 2000) reveals that the overall price increase during the period 1995-1999 on year over year basis is modest and below the Wholesale Price Index for all commodities. Even in the case of decontrolled formulations, the price increase is not excessive. The reports show the following trend in terms of price increase during 1995 to 1999:-

Year	**Overall Price Increase (%)**	**Price Increase in Decontrolled Formulations (%)**	**Increase in Wholesale Price Index (%)**
1995 over 1994	2.4	2.8	7.7
1996 over 1995	3.6	4.2	6.4
1997 over 1996	3.2	4.7	5.4
1998 over 1997	2.1	3.9	7.0
1999 over 1998	3.2	4.0	3.5

6.9 There is a great competition in pharmaceutical sector due to availability of a large number of brands of the same medicine in the market. The following table (prepared on the basis of brands sold only by 265 companies reflected by ORG) shows the actual position in regard to common/essential medicines used by Indian population:-

Name of Bulk Drug	**No. of Brands**
Ciprofloxacin	98
Amoxycillin	109
Ampicillin	82
Rifampicin	35
Cephalexin	47
Ibuprofen	105
Paracetamol	174
Ranitidine	41
Amlodipine	34
Atenolol	45

6.10 While replying the specific query of the Committee about the drug price control systems in other countries, the Department of Chemicals and Petrochemicals submitted the following details in a written note:-

"Price control in one or other form is exercised in all the countries. In the developed countries it is exercised through reimbursement scheme and through Insurance Scheme. The feature of the various methods used are as follows:-

a. Cost Plus:

The cost plus method bases permitted rise on the cost of production, allowance being made for marketing and R&D expenditure. The low ratio of direct cost to total cost in the pharmaceutical industry makes the cost plus pricing method potentially a difficult technique to apply without any bias.

b. Internal Comparison:

In this system prices are fixed by reference to comparable drugs already on the national market, concessions being made to innovative products with therapeutic advantages. This means that similar products will be similarly priced leaving little room for price competition. In this system the prescribing freedom of the Doctors is not compromised. The prices of new drugs in which there is no equivalent on the national market may be determined by using the price in another country. Spain, Luxembourg and Portugal follow this system.

c. External Comparison:

In external comparison the price of a particular medicine in other countries is taken as the standard. In Ireland, for example, external comparison is used by linking local prices to a Five-country formula.

In most of the member states of the European community, pharmaceutical expenditure is also controlled by one means or the other. Two principal ways of curbing expenditure is by reimbursement control or cost containment. The methodologies used are as under:-

(a) Positive List:

A positive list contains those drugs for which reimbursement is being made partly or wholly by the Government. In countries with product-by-product price control, a positive list is a integral part of the price control.

(b) Negative List:

A negative list is a list of those drugs which are not reimbursed at all. An inclusion of any drug under this list automatically results in non-prescription of this drug.

(c) Reference Prices:

In this method the reimbursement limit for a group of identical or equivalent products is fixed. Reimbursement is made only on the basis of the reference price and any higher price has to be borne by the patient.

(d) Volume related price:

Under this method, practiced in France, in order to tackle new mega priced drugs, a sales volume is fixed. Should actual sales exceed the forecaste sales volume, the price will have to be reduced through negotiations between the authorities and the manufacturer.

(e) Promotional Expenditure Control:

Through this method an attempt is made to keep the promotional expenditure under control either by imposing a tax on such expenditure or by restricting the amount that can be spent on promotion expenditure.

(f) Transfer to OTC status:

This is an alternate to the negative list because once a drug is specified as an OTC drug, the consumer has to meet the entire cost.

(g) Economical prescribing habits:

In some countries the authorities have tried to promote economical prescribing habits in order to encourage pricing of cheap, safe and effective drugs.

This is achieved by publishing an essential drug list or by prescribing disincentives for Doctors who are found to be exceeding the average prices for drugs prescribed.

(h) Percentage of co-payment:

In a number of EC countries, the patient is obliged to pay a percentage of the cost of the drugs prescribed. In some countries the percentage is linked to the financial and medical condition of the patient.

6.11 The Department has submitted a statement showing the drug price control systems in European countries as under:-

Country	**Individual drug price control**	**Basis**
Belgium	Yes	Internal comparison (cost-plus)
Denmark	No	Reimbursement control-reference price system
France	Yes	Internal comparison
Germany	No	Reimbursement control-reference price system
Greece	Yes	Cost-plus for locally produced, external comparison for new drugs
Ireland	Yes	External comparison
Italy	Yes	Internal comparison, (cost-plus)
Luxembourg	Yes	External comparison (Belgium)
Netherlands	No	Reimbursement control-reference price system
Portugal	Yes	External Comparison
Spain	Yes	External comparison but control of profit company-by-company
UK	No	Rate of return fixed company-by-company through negotiations with the D/o Health, U.K.
Austria	Yes	External comparison (cost-plus)
Finland	Yes	External comparison, (cost-plus)
Sweden	Yes	External comparison, (cost-plus) profit margins

6.12 While analysing some prominent pricing systems the Department submitted the following details:-

"The Japenese drug pricing system has to be viewed in the background of the existing medical insurance system. The National Health Insurance Drug Price

list is an itemised list of pharmaceutical products which can be used for insurance of medical care. Based on surveys the list is revised periodically. The list contains approximately 13, 500 drugs and the Drug Price Calculation method is laid down by the Chuikyo (The Central Social Insurance Medical Council).

China follows the cost plus system for fixing prices of drugs. The State Administration of Prices analyses the cost of production of a particular drug as conveyed by the factory which manufactures it and adds an acceptable level of profit margin to it to arrive at a fair price. This fair price is conveyed to the State Administration of Pharmaceuticals and to the sub-office of the State Administration of Pharmaceuticals, who specifically deal with the price of a drug. The official price of each drug is finalised after the approval has been obtained from the State Administration of Pharmaceuticals which is an independent office under the State Council.

Canada has set up the Patented Medicine Prices Review Board which ensures that the prices of patented medicines are not excessive. The board is an independent autonomous and quasi-judicial body and the Government has no powers to direct it. The board determines if the price is excessive by applying the reasonable relationship test, the therapeutic class comparison test, the international prices comparison test or by comparing the change in prices with the change in the consumer price index over a specified period."

6.13 When the Committee enquired about the criteria for deciding the drugs to be included under price control or keeping them out of it, the Department of chemicals and Petrochemicals submitted the following details:-

"The criteria are;-

(i) The criterion of including drugs under price control will be the minimum annual turnover of Rs. 400 lakhs.

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

(iii) Drugs in which there is sufficient market competition viz. at least 5 bulk drug producers and at least 10 formulators and none having more than 40% market share in the Retail Trade (as per ORG) may be kept outside the price control. However, a strict watch would be kept on the movement of prices as it is expected that their prices would be kept in check by the forces of market competition. The Government may determine the ceiling levels beyond which increase in price would not be permissible.

(iv) Government will keep a close watch on the prices of medicines which are taken out of price control. In case, the prices of these medicines rise unreasonably, the government would take appropriate measures, including reclamping of price control.

(v) For applying the above criteria, to start with, the basis would be the data upto 31st march, 1990 collected for the exercise of the Review of the Drug Policy. The updating of the data will be done by the National Pharmaceutical Pricing Authority.

(vi) Genetically engineered drugs produced by recombinant DNA technology and specific cell/tissue targeted drug formulations will not be under price control for 5 years from the date of manufacture in India.

Manufacturers of price control drugs are allowed a post tax return of 14% on net worth or a return of 22% on capital employed or in respect of new plant an internal rate of return of 12% based on long term marginal costing depending upon their option."

6.14 In view of the continuous demand of Druggists and Chemists the Committee wanted to know about the difficulties in deciding the maximum retail price of drugs after inclusion of all taxes as being done in case of several other items. Department of Chemicals and Petrochemicals submitted the following justification:-

"Although, it is desirable to have a single uniform price (MRP) inclusive of all taxes) throughout the country, it is difficult due to the statewise variation in local taxes including sales tax, octroi, purchase tax, entry tax etc. it is not possible to account for state variations in local taxes in the present system of working out reasonable prices under DPCO."

6.15 When the Committee pointed out towards the complaints regarding sale of medicines violating maximum fixed prices and wanted to know about the steps being taken against the persons found responsible in such cases, the Department of Chemicals informed as under:-

"As and when overcharging cases come to the notice of the Government, necessary action to recover the overcharged amount under provisions of DPCO, 95 is initiated against the defaulter. The Government did not receive any complaint from the public. However, the Government has detected about 12 cases of overcharging which are presently being handled by the NPPA. Recently NPPA has received two complaints of overcharging which are also being looked into by them."

6.16 Government has constituted a Committee namely Drug Prices Liabilities Review Committee (DPLRC) whose job is to review cases of overcharges/ excess charges. The Department of Chemicals & Petrochemicals refers cases to this Committee for assessment.So far the Department has referred 72 assessment cases involving an amount of Rs. 220 crores to DPLRC who in turn has put into motion the process of hearing concerned parties. The Committee has, till date, furnished its Reports in 48 cases to the Department. Concerned companies adopt delaying tactics and obtain stays from the Courts.

6.17 Organisation of Pharmaceutical Producers of India (OPPI) has specifically pointed out in their Memorandum that Pharmaceutical Industry is the only industry which is subjected to a three tier control viz. Control of prices on bulk drug, control on prices of formulations and control on overall profitability. There is perhaps no other country where a three-tier control is imposed on the Pharmaceutical industry. It has been subjected to rigid administrative control for more than 30 years. According to them, such controls are outdated in the era of market economy competition is the best regulator of prices.

6.18 OPPI has further submitted that the present system of price control alongwith its administrative mechanism is burdensome for :-

"(1) Investment needed for growth is inhibited because of the uncertainty of administered pricing and non-remunerative prices.

(2) 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 Letters of Intent. However, if Industrial Entrepreneur Memoranda are accounted for the investment amounts to hardly 1% of total industrial investment.

(3) Quality which is the hallmark of the Pharmaceutical Industry is not appropriately recognised and the standards are driven to the lowest common denominator level.

(4) Consumer suffers because of the natural tendency to "sell-up" to a more costly treatment of decontrolled formulations and cheaper price controlled remedies go off the market.

(5) "cost plus" prices are not linked to the value of drug therapy. As such, they cause distortions, sometimes harmful, in prescription practices."

6.19 All India Organisation of Chemists and Druggists have a strong view that the tax structure in the country is very complicated due to 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 are put to unnecessary harassment by consumers with litigation in consumer courts and other forums. They have desired that the Government should fix the Retail prices of the medicines as 'MRP inclusive of all Taxes' to avoid confusion. They have also suggested that a fix margin of 10% and 20% should be given the wholesalers and retailers on the end price inclusive of all taxes only.

6.20 In a reply to unstarred question No. 240 on 21.11.2000 in Lok Sabha the Ministry of Chemicals and Fertilisers replied that the Government have examined the issue relating to implementation of common MRP in consultation with AIOCD and Industry Associations from time to time. In February, 2000 a Working Group consisting of members from the industry, Consumer organisations and representatives of AIOCD, was constituted to go into all aspects related to the issue. The Working Group has since submitted its report to the Government.

6.21 Drug producers have a view that the process of phased decontrol as in the past, should be continued and accelerated and there should be no additions to the existing list of price controlled drugs. They have an assumption that, if the rigours of price control are reduced, availability of medicines in all parts of the country can be vastly improved. They have also advised that the process of gradual decontrol should be based on transparency and predictability. They have suggested that a shift of focus from control to monitoring will be beneficial to both Government and the industry in as much as it will save considerable time and energy of both the parties towards more creative and forward looking endeavours for the overall growth of this industry.

6.22 Chemists and Druggists have an opinion that prices of all drugs including the imported drugs should be fixed by the Government classifying the products in therapeutic segments and allowing higher margins for the manufacturers to encourage production of essential drugs for the treatment of Tuberculosis, Cancer, AIDS, Malaria, Cardiac etc.

6.23 The Committee drew the attention of the Government towards the demand of the drug companies to fix the prices on actual costs and not the normative cost and wanted to know the reaction of the Government. Department of Chemicals and Petrochemicals replied that as per existing practice actual cost were studied and then normated. The normation of cost has to be done to ensure fixation of fair and reasonable prices, and to discourage inefficiency and reward efficiency.

6.24 All India Small Scale Pharmaceutical Manufacturer's Associations in their Memorandum have submitted that drugs have not become costlier rather costlier drugs have come in the market. The common drugs are being substituted by the new molecules which are not covered under the DPCO, 95. MNCs and Indian MNCs are charging exhorbitantly high prices by way of introducing new molecules. According to them 100% margin provided by NPPA forces the manufacturers to adopt such practices in this industry. They have also demanded that all SSI units must be brought under the orbit of DPCO.

6.25 The Committee pointed out towards the current Maximum Allowing Post Manufacturing Expenses (MAPE) of 100% for indigenously manufactured schedule formulations and 50% of landed cost in case of imported formulations and wanted to know about the measures being taken to ensure that the companies may not use this limit in their favour just by improving/spending a little amount for certain purpose as ex-factory cost. The Department of Chemicals and Petrochemicals replied:-

> "All the cost inputs are scrutinised by the NPPA based on verified documents. Superfluous expenses, if any, are excluded in arriving at the ex-factory cost. Since norms for Conversion Cost, Packing Charges and ceiling for Packing Material are fixed, possibility of any superfluous expenses getting into the pricing is remote."

6.26 When the Committee wanted to know the reaction to the demand of the industry for replacement of 'price control system' with 'price monitoring system', the Department of Chemicals & Petrochemicals submitted that price monitoring system as a concept has been propounded by some section of the industry. Even this system would require some pricing bench mark which in other words would mean price determination.

(*b*) *Role of NPPA in price fixation and the price monitoring system*

6.27 In the new drug policy it was decided to establish an independent body of experts, to be called National Pharmaceutical Pricing Authority (NPPA). NPPA was established on 29th August, 1997. It is an autonomous body within the Department of Chemicals and Petrochemicals and is a price fixing body as well as an apellate authority.

6.28 NPPA has the power to fix prices of 74 controlled drugs, review pricing decisions and decide both on formulations meant to be under its control and out of it. The Government have been empowered to review the pricing decisions. The NPPA is thus under its broader form oversee the provisions of Drug (Prices Control) Order, 1995.

6.29 The NPPA consists of a Chairperson and a Member Secretary. The Resolution published in the Gazette of India dated 29th August, 1997 provides for taking experts as members in the field of pharmaceuticals. The following are the functions and role of NPPA:

(i) Price fixation and revision;

(ii) To assist the Central Government in updating the list of drugs under price control by recommending inclusion and exclusion on the basis of established criteria/guidelines;

(iii) Monitoring of prices of decontrolled drugs and formulations;

(iv) Implementation and enforcement of the provisions of the DPCO in accordance with the powers delegated;

(v) To deal with the legal matters arising out of the decisions of NPPA;

(vi) Monitoring the availability of drugs, identify shortages, taking remedial steps;

(vii) Collection and maintenance of data on production, exports and imports, market share and profitability of companies for bulk drugs and formulations;

(viii) Undertaking and/or sponsoring relevant studies in respect of pricing of drugs/pharmaceuticals;

(ix) Rendering advice to the Central Government on changes/revision in the drug policy;

(x) Rendering assistance to the Central Government in the Parliamentary matters relating to the drug pricing;

(xi) Recruitment/Appointment of the officers and staff members."

6.30 Some of the important actions/ steps taken by NPPA since inception are as under :-

(i) NPPA has revised the prices of 56 scheduled bulk drugs (40 bulk drugs plus 16 derivatives) and 1235 formulations since inception. Out of these the prices of 14 scheduled bulk drugs (12 bulk drugs and 2 derivatives and 883 formulations were fixed/ revised during the period April 2000 to 15th November 2000.

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(ii) NPPA vide its order published in the Gazette of India Extra Ordinary dated 27th January, 1999, has asked the manufacturers of all the Scheduled formulation pack sizes to work out the prices of different pack sizes of the tablets and capsules of the same strengths or composition packed in different strips or blisters on pro-rata basis of the latest ceiling price fixed. This was done to ensure that (I) the manufacturers do not change their pack sizes in a bid to remain out of price control and (ii) manufacturers are not forced to approach the Government/NPPA frequently for price approvals of different pack sizes.

(iii) Compiled the data on production of selected/monitored bulk drugs and imports of bulk drugs for the year 1998-99.

(iv) Analysed price movement between January 1994 and March 1999.

(v) Fixed the prices of three commonly used IV Fluids by exercising the powers available under Para 10(b) of DPCO, 1995. These prices are lower by about 40% than the prices charged earlier by the companies from the consumers.

(vi) To keep a check on the prices of the drugs, besides advising the State Government to enforce the prices of scheduled formulations, NPPA held a meeting at New Delhi with the State Drug Controllers on 25th August 1999.

(vii) NPPA advised the States and Union Territories to nominate/set up nodal officers monitoring cells to enforce/monitor the prices and availability of medicines.

(viii) NPPA notified the norms of conversion cost (CC) packing charges (PC) and process loss (PL) vide S.O. 578 (E) dated 13th July, 1999.

(ix) Overcharging cases were pursued vigorously by NPPA and as a result, an amount of Rs.327 lakhs was recovered from the companies on account of overcharging.

(x) NPPA launched its website on 11th January, 1999. It is accessible at www.nppaindia.com.

(xi) One of the functions of NPPA is to render advice to the Central Government on changes/revisions in the Drug Policy. The Government constituted a Drug Price Review Committee on 18th March, 1999 to review the current Drug Price Control Mechanism and suggest alternative models among other things. Another Committee viz. Pharmaceutical Research and Development Committee was also constituted by the Government on the same date 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. Chairman, NPPA was one of the members of these Committees. NPPA, being an expert body, rendered expert advice to both the Committees, besides providing inputs and various data.

6.31 The drug manufacture and distribution is regulated through a Central Act namely Drugs and Cosmetics Act, 1940 and Rules made thereunder. This Act is administered by the Ministry of Health and Family Welfare through Drug Comptroller General of India who coordinates activities of Drug Comptrollers of various States.

6.32 While going into the details of the functioning of NPPA, the Committee wanted to know about the criterion used for inclusion of drugs under price control list , type of data used for fixation of prices. The Department of Chemicals and Petrochemicals submitted the following details:-

"Price controlled list under DPCO, 1995 has been prepared in accordance with the criteria at para 22.7.2 of "Modifications in Drug Policy, 1986" on the basis of data upto 31st March, 1990 collected for the exercise of review of drug policy. Under para 22.7.4 NPPA is required to update such matters. ORG does not give information of bulk drug production in the country. Updating needs production data from all units for all the drugs. Therefore, it can be done only after this information is made available by the Industry."

They further informed:-

"The Government considered the following criterion for inclusion of these drugs under the DPCO. These criteria are elaborated in Para 22.7.2 of Modifications in Drug Policy, 1986 as published in September, 1994. Briefly they are:-

a) Drugs of mass consumption measured in terms of turnover of bulk drugs.
b) Insufficient market competition measured in terms of (I) number of bulk drugs producers, (ii) number of formulators and (iii) market share of formulators.
c) Monopoly situation in the market.

About the latest position in the market, they submitted as under:-

The Government had constituted an expert Committee in March 1999 to review the current Drug Price Control mechanism with the following terms of reference:-

a) To review the current Drug Price Control mechanism and suggest alternative models, if any ;
b) To suggest the criteria of market competition and monopoly and turnover for inclusion of drugs under price control.
c) To suggest measures for improving quality of products within the drug price control mechanism.
d) To suggest pricing policies for newer generation of drugs, new drug delivery systems and non prescription drugs.

The above Committee has submitted its report in October, 1999 and the same is under examination of the Government."

6.33 When the Committee specifically wanted to know about the exact process of monitoring the price of drugs/ formulations at present and the preventive measures available with the Government to stop the abnormal increases, the Department of Chemicals and Petrochemicals submitted the following details:-

"In accordance with the para-14 and 15 of DPCO, 1995 manufacturers of bulk drugs and formulations are required to submit price lists to the Government. In case of controlled category price rise is examined to see where the increase is due to the increase effected by the Government or due to violation of the DPCO, by the Company. As per para- 10(b) and (c) of DPCO, 1995 Government has the powers to fix the price even for a non scheduled formulation and a bulk drug respectively.

NPPA monitors the prices of decontrolled drugs based on market data available in monthly Retail Store Audit Reports of Pharmaceutical Products

published by ORG-MARG and also based on information available from Form-V of DPCO, 1995 submitted by the companies. Action is taken by NPPA under DPCO, 1995 when price of a decontrolled drug is found to be raised by a manufacturer unreasonably. However, for more effective monitoring and enforcement, NPPA needs to be adequately strengthened.

The prices of medicines under control (scheduled formulations) are fixedby the NPPA/ Government as mentioned above. The same are to be followed by all the manufacturers including the multinational companies. Under the DPCO, no person can sell any formulation (medicine) of price controlled category to any consumer at a price exceeding the price notified/ approved by the NPPA/ Government. In case, any company is found selling at prices higher than the price notified/ approved by the NPPA/ Government, action is taken against them as per the provisions of the DPCO. The following actions are taken in such cases:-

(i) State Drug Controllers are the regulatory/ enforcement agencies for implementation of the notified prices and also monitoring of prices of de-controlled medicines.
(ii) Under para-13 of DPCO'95 NPPA is empowered to direct a company to deposit with Govt. of India the amount overcharged form the public in the sale of scheduled formulations at prices higher than the notified
(iii) In addition, such a company is also liable to pay the interest @ 15% under section 7(A) of E.C. Act, 1955.

The companies can themselves fix the prices of medicines which are out of price control. However, their prices are monitored by NPPA as well as by State Drug Controllers. The prices of de-controlled medicines can be regulated by the Government, if warranted in public interest. When the MRPs of I.V. Fluid (a de-controlled drug) were found to be very high, NPPA has brought down their prices by exercising the provisions of the DPCO and the same were notified vide S.O. 725(E) dated 27th August,1998."

6.34 In response of specific query of the Committee regarding machinery available with the NPPA to obtain the latest data in regard to fixation of prices and inclusion or exclusion drugs in the list of controlled drugs, the Department of C&PC informed:-

"NPPA has Monitoring Division headed by a Director rank Officer for collection and analyzing the data. The work relating to fixation of prices and inclusion of exclusion in the list of price control drugs is looked after by two different Divisions in NPPA which are headed by Director level officers. The data relating to review of list of price control drugs requires information on bulk drug production, imports, exports, and their values, domestic consumption, number of manufacturer of bulk drugs and formulations, sale value of formulations, market share of each company for formulations of a given bulk drug etc. NPPA is in a position to analyse data relating to formulation sales as covered in ORG Reports. ORG Reports, however, do not give data on bulk drug

production. The data on production of bulk drugs is incomplete due to non-submission of the same by a large section of manufacturers.

However, the report submitted by the Drugs Price Review Committee to the Department of Chemicals and Petrochemicals includes the new criteria for identification of drugs under price control. The report is under examination of the Department."

6.35 The Committee wanted to know whether NPPA obtains production and price return regularly. The Department of Chemicals & Petrochemicals informed that with the aim of obtaining data for price fixation it has been provided that manufacturers should submit the data as per para 3 of DPCO, 95 in Form I and also additional data as and when required. However, as reported by the NPPA the response of the Industry is lukewarm.

6.36 When the Committee wanted to know that why could we not put all the Drugs Under Price Control Secretary, C&PC replied:-

"It may not be feasible or practicable with the existing Government machinery to put all the drugs, the entire regime under price control. First of all there are drugs which are not produced in the country, which will continue to be based on the imported price. That is number one. Secondly, there has to be a balance of pragmatism and the social cost of administrating the health system being passed on to the industry. If you have too much price control, it is apprehended that the production pattern may shift.

Today we have a large scale production in the country, too many products and newer products are brought in, the production could be outside and we will just be formulating them. That danger exists. So, one has to strike a balance."

6.37 The Committee pointed out that manufacturing of Ayurvedic drugs was controlled by licenses but the sale of Ayurvedic items were not controlled in any manner. During the course of evidence when the Committee wanted to know about the problems in bringing the Ayurvedic, Homoeopathy, Unani or Sidha system medicines under price control, Secretary, Department of Indian Systems of Medicine System submitted as under:-

"There is no price control on the drugs Ayurveda or Homoeopathy or Unani or Sidha system of medicines. Price control is really a tough job because there are 8000-9000 pharmacies and all these are not in the organised sector as such. This is the first point.

Secondly, it is extremely difficult to decide the price structure for these medicines. It is difficult because there are six lakh practitioners of these medicines and they themselves manufacture and all are not subjected to license. Only those drugs which are manufactured for sale are subject to licence. Those

which are manufactured by hakims or vaidyas at their own residences cater to a few patients but not for sale are not subject to licence. It is rather a difficult thing and we are all in the infant stage. It is not possible for us to go in for price control at this stage."

6.38 Consumers have complaints that pharmaceutical industry's sole objective is maximize its profits. The new products are also introduced with this view in mind. A majority of them were developed by the Chemist's roulette with small modifications in the original molecule with marginal advantage, if any. However, these have been proclaimed as new products and promoted with great hype. Some companies have put in bits of Ayurvedic medicines in these medicines to evade price control and quality control and not for the love of Ayurveda. Doctors are persuaded to prescribe them in order to fill the coffers of the company. In response to these allegations, the Department of Chemicals and Petrochemicals has submitted that all the formulations having one or more scheduled bulk drugs are treated to be under price control irrespective of other constituents.

6.39 The Committee drew the attention of the Ministry towards press reports that once the GATT treaty comes into effect Indian Drug Companies would be forced to import a new drug paying exorbitant prices consistently the retail price of such drugs would be out of the reach of most middle class and lower income group customers and wanted to know the reaction of the Government in this regard. The Department of Chemicals & Petrochemicals expressed their opinion that at no point of time more than 10% of medicine sold in the market would be covered by the product patent. In almost all therapeutic categories generic/non-talented alternatives will be available.

6.40 When the Committee wanted to know the reaction of the Government about the press reports that prices in specific categories have doubled/quadrupled since price control were lifted two years ago. The Department of C&PC submitted the following facts:-

"NPPA has fixed/revised the prices of 1359 formulations packs since inception till 15.12.2000. Of this, 659 packs are based on company's applications and 700 are based on suo-moto. There is no pending application".

About the increase/ decrease in prices, the Deptt. of Chemicals and Petrochemicals submitted the following details:-

(i)	Prices were reduced	671	
(ii)	Prices were increased	458	
	Sub total I	**1129**	
(iii)	Fixed for the first time		199
(iv)	No change was effected	31	
	Sub total II	**230**	
	Total	**1359**	

6.41 It has been reported that several companies charge high prices than the prices fixed by NPPA. In reply to Unstarred question in Rajya Sabha on 24.1.2000, the Government informed the House that NPPA has issued notices to about 100 companies for overcharging under Para 13 of DPCO, 1995 and amount of Rs. 3.43 crores on account of overcharging has been recovered. Show cause notices issued broadly for the following drugs/formulations which were pending as on 30.09.2000:-

1.	Salbutamol Sulphate	2.	Doxycycline	3.	Raicap Tab.
4.	Gramogyl/Gramo neg	5.	Betnelan Tablets	6.	Vent Syrup
7.	Chloroquine Phosphate	8.	Dexatopic Cream	9.	Tricox Tablets
10.	Amoxycilin	11.	Nivafen Tablets	12.	Ethambutol
13.	Analgin Tablets	14.	Altacortfil	15.	Lbucomb Tablets
16.	Altraprim & Atragesic Tablets	17.	Captropill 25 Tablets	18.	Diethyl Carbaziine Citrate
19.	Cloxacillin	20.	Ciprofloxacin	21.	Theophylline
22.	Norfloxacin	23.	Cefadroxil	24.	Trimethoprim + Sulphamethoxazile

Some of the major companies against whose show cause notices for overcharging have been issued are:-

1.	M/s. Cipla Limited	2.	M/s. Ranbaxy Ltd.	3.	M/s. Torrent Pharma
4.	M/s. Nicholas Piramal	5.	M/s. Lupin Labs	6.	M/s. Wockhardt Merind
7.	M/s. Wyeth Lederie	8.	M/s. Glaxo	9.	M/s. Sol Pharma
10.	M/s. Cadila Pharma	11.	M/s. Sun Phrma		

6.42 During the course of examination the Committee specifically wanted to know about the controlling/monitoring machinery available with the Central Government to analyse and guide the State Governments to make available the genuine medicines at prices fixed by NPPA. The Ministry of Health and Family Welfare submitted:-

> "The Central Govt. prescribes quality specifications and brings out monographs of standards of drugs under Indian Pharmacopoeia. The onus of ensuring production of genuine quality drugs rest with states through a system of

licensing and monitoring by State Drugs Controllers (SDCs). State Drug Inspectors are notified under DPCO to monitor prices. NPPA coordinates with State Drugs Control machinery to ensure that drugs are sold at prices fixed by them."

6.43 During the course of discussion with Drug Manufacturer's Associations, Chemists & Druggists Association and Voluntary Associations following important points came out which drew the attention of the Committee:-

"(i) Price control mechanism should continue with some improvement which can be suitable both for consumers and Industry. The system should be simple, less intensive and transparent.

(ii) Prices of drugs should be fixed inclusive of all taxes and margins of profit should increase so that industry can spent more on R&D.

(iii) Production of generic drugs should be promoted.

(iv) Some incidental charges should be given to chemists rendering services in rural areas.

(v) Sale of Ayurvedic items should be controlled by licences as being done for the manufacture of these medicines.

(vi) Some mechanism should be developed to control the prices of medicines of Ayurvedic, Homoeopathic and other systems of medicine.

(vii) All Small Scale units must be brought under DPCO,1995.

(viii) Production of costlier drugs should be observed minutely so that no extra burden is put on consumers by minor alteration in composition.

(ix) Formation of National Drug Authority is essential to facilitate and supervise inter-sectoral coordination in issues related to drugs and pharmaceuticals.

CHAPTER-VII

RESEARCH AND DEVELOPMENT IN PHARMA INDUSTRY

(a) Significance of R&D in Pharmaceutical Industry

7.1 The Indian Pharmaceuticals Industry has achieved global recognition. Leading Indian companies have established marketing and manufacturing activities in over 60 countries including USA and Western Europe. To be globally viable in R&D, high level expertise and adequate human resources as also modern facilities in specified areas of drug developments are required. Investment in Research and Development by industry as a whole in India has been low, only around 0.6% of the turnover. In the Indian Pharmaceutical Industry the average R&D expenditure is around 2% of the turnover contributed by around 50 companies against the 15-20% in Western countries. This is worrying factor because unless India-a signatory to the GATT Treaty by which new product patents will become fully operational by 2005-develops newer drugs; India may be in disadvantageous position vis-a-vis multinational companies. In addition to R&D being done by pharmaceutical companies, R&D activities in drug industry is carried out in publicly funded research organisation mainly by the laboratories of Council of Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR), around 25 universities and a few pharmacy colleges.

7.2 The R&D in Pharmaceutical Industry has broadly 3 aspects:

(a) The development of commercial processes for production of known drugs (and products) referred to as Technological Development;

(b) Development of new formulation and advanced delivery formula of known drugs which contribute directly to the pharmaceutical products; and

(c) Discovery and development of new drugs also called Innovative Drug Research.

7.3 Research and Development was largely concentrated on process development for known bulk drugs albeit through novel and innovative process routes, invariably substituting for expensive imported raw materials enhancing the productivity and efficiency of the process. Besides, research on formulations and known drug delivery systems, India's R&D effort has been in synthetic organic chemistry and process development. A few new drugs, using conventional screening techniques have emerged from the Indian R&D, but none of them have been blockbusters. Not much R&D is being persued in traditional systems of medicines. Even the limited R&D is concentrated on standardisation of raw materials and final products.

7.4 While going into the details of the R&D work being done by various agencies in different Ministries/Departments of the Govt. of India, the Committee specifically wanted to know about the nature of coordination between the Department of Chemicals & Petrochemicals, Department of Science and Technology and Ministry of Health and Family Welfare in regard to encourage the R&D in Drug sector. The Department of Chemicals & Petrochemicals submitted the following details:-

> "Department of Science and Technology (DST) in Ministry of Science and Technology is operating a Plan scheme entitled "Drugs and Pharmaceuticals (D&P) Research Programme" since 1994-95 for promoting R&D in D&P sector. This Programme aims at enhancing capabilities of the Indian drugs and pharmaceuticals industry towards development of new drugs and by synergising the strength of national institutions and drug industry in the country. Project proposals are peer reviewed by an Expert Committee constituted for the purpose and includes representative of Department of Chemicals and Petrochemicals, Indian Council of Medical Research, Ministry of Health and Family Welfare. The recommendations of this Expert Committee is approved by Secretary, DST for implementation. During the past six years, 85 research proposals were received, 39 proposals were recommended by the Expert Committee and approved for funding. Financial outlay for 2000-2001 is Rs. 350 lakhs.
>
> With producers having been streamlined and keeping in view the pact that industry demands it has been decided to authorize the Expert Committee to recommend approval of the project as well from October, 2000 earlier prevalent Apex Committee/ Executive Committee is withdrawn.

7.5 Experts and Drug producers have an uniform opinion that the low investment in R&D is due to the low levels of profitability and comparatively small size of companies. The current rate of profitability (as percentage of sales) of Pharmaceutical Industry in India is hardly 6 to 7 per cent as against 22 to 25 per cent in the Western Countries. The prices and profitability controls act as serious deterrent to expanding the scope of R&D efforts.

(b) Role of CSIR in R&D in Drugs/Pharmaceuticals Sector

7.6 Although the Department of Chemicals and Petrochemicals is responsible for overall policies relating to pharmaceutical sector yet the Department of Science and Technology and Bio-technology are formulating the overall policy relating to R&D in the country. R&D activity in drug industry is the concern of Council of Scientific and Industrial Research (CSIR) in the Ministry of Science and Technology.

7.7 When the Committee specifically wanted to know about the basic features and objectives of R&D being undertaken by CSIR in the field of drugs and pharmaceuticals and their achievement in this field. CSIR submitted the following details:-

"The basic features and objective of research and development being undertaken by CSIR laboratories in the field of drugs and pharmaceuticals are:-

(a) to develop novel process routes for off-patent drugs;

(b) to discover, optimise, protect and market new bioactive therapeutic agents based on plant, fungal and microbial sources, for tropical, metabolic and degenerative diseases;

(c) to assist the traditional system of Indian medicines in improving their processes and products through modern scientific tools;

(d) to help spread the science, knowledge and skills of contemporary drug discovery in India.

Over the years CSIR have developed 30 novel process routes for known drugs, invented 10 new drug molecule and has on hand around 20 promising preliminary leads for new drug activity based on natural products."

7.8 In response to the specific query about contribution of these researches in providing cheap medicines for tropical diseases, CSIR submitted as under:-

"Recognising that multinational pharma companies may not find it commercially rewarding to introduce new drugs for tropical infections (viral, bacterial and parasitic), CSIR has directed its R&D towards developing new effective and efficient therapeutic agents for tropical infections and for fertility regulation.

(j) In the area of fertility regulation, development is for:

- Female contraceptives such as early abortificients and anti-adhesive agents and Antiosteoporotic agents.
- Development of male contraceptives including spermicidal and antispermatogenic agents.

(ii) In the area of bacterial infections, development of:

- New adulticidal, herbal as well as synthetic agents for filariasis;
- Antimalrials to tackle resistant, relapse and cerebral varieties; and
- Vaccine for cholera;

- ❖ Bioenhancer to enable reduction in dosage (and therefore side effects) of antileprosy –anti TB drug rifampicin etc.

(iii) In the area of viral diseases development of more cost-effective process routes for anit-AIDS drugs such as azidothymidine, lamivudine, stavudine and nevirapine etc."

7.9 The Committee went into the details of the functioning of CSIR and wanted to know about nature of coordination with Department of Chemicals and Petrochemicals and Ministry of Health and Family Welfare to encourage R&D in drug sector and to achieve the objectives of National Health Programme. CSIR submitted in a written reply:-

"CSIR is collaborating with Ministry of Health and Family Welfare in the area of fertility regulation. Besides above, Department of Chemicals and Petrochemicals in the Ministry of Chemicals and Fertilisers had nominated Director General CSIR, Dr. R.A. Mashelkar, as the Chairman of the Pharmaceutical Research and Development Committee with a view to recommend measures to strengthen the research and development capability of the pharmaceutical industry in the country. The path setting Report outlines the national strategy to realise India's potential in the area of pharmaceutical research which can help in achieving the national health programme."

7.10 The Committee pointed out that that expenditure on R&D in India was very low and wanted to know from CSIR about the disadvantage of this situation and the way to increase R&D expenditure in this industry. CSIR submitted their views in a written note:-

"Investment in R&D by industry as a whole in India has been low, only around 0.6% of the turnover. In the Indian pharmaceutical industry the average R&D expenditure is around 2 to 2.5% of the turnover contributed by around 150 companies. The low investment in R&D is due to the low levels of profitability and small size of the Indian companies. However, the scenario is now changing. Some pharma companies now spend nearly 5% of their turnover on R&D. Some of the progressive R&D units in industry and a few of the publicly funded laboratories are equipped with sophisticated laboratory equipment, instruments and pilot plant facilities. The R&D manpower is generally highly qualified and proficient in conventional techniques of pharmaceutical R&D.

CSIR has analysed the International research scene. It reveals that there is very limited R&D directed to develop drugs for tropical and other diseases endemic to our country like TB, Leprosy, Filaria, Malaria, Dysentery etc. Thus, it is indeed essential for India to initiate new drug discovery for diseases of relevance to the local population and to the neighbouring countries in Asia and

Africa. Normally new drug discovery and development for such diseases would be neglected even by the Indian Industry whose general profit margins are otherwise threatened by transnationals. The need for Government to support R&D for such diseases. In order to increase the R&D activity in pharmaceutical sector some new ways of funding R&D in pharma industry should be considered such as:

(a) Venture capital funding.
(b) Attracting R&D through partial support towards high cost-low return areas.
(c) Tax holidays and concessions.
(d) Outright grants and soft loans.
(e) Using price control as an incentive for R&D."

(c) ***Role of National Institute of Pharmaceutical Education & Research (NIPER) in R&D relating to Phrama Sector***

7.11 The National Institute of Pharmaceutical Education and Research has been conceived as an institute of excellence and learning in pharmaceutical science and technology and it is the only institute of its kind in the country. NIPER has been declared as an institute of national importance by Act No. 13 of 1998.

7.12 The research activities of the Institute have been started from the year 1997. A number of sponsored projects from the pharmaceutical Industry in different disciplines of Pharmaceutical Sciences have been initiated. These also include some projects sponsored by World Health Organisation. The teaching programmes leading to the Masters and Doctoral Degrees have been initiated since January,1998. In the continuous education programme, the Institute has conducted many seminars and workshops in the filed of Pharmaceutical Sciences for pharmacy teachers and industry personnel. The Institute has published more than 40 research publications in both national and international journals in the past two years.

7.13 While going into the details of R&D activities of NIPER the Committee desired to know about the objectives of R&D work being taken by them and the way in which it is going to facilitate the academia, people and drugs/pharmaceutical Industry. NIPER submitted the following details:-

"In the selection of thrust area for research at NIPER, the Institute has been guided by the national needs in the areas of tuberculosis, malaria and leischmania in which multinational pharmaceutical companies have limited

interest. The emerging multi-drug resistance in these areas has necessitated that concerted efforts be made to find out viable solutions to these potentially serious problems. The Institute is engaged in the development of newer agents of synthetic or natural products origin to combat these diseases.

In order to avoid the development of wide-spread resistance to the current anti-tubercular therapy, the Institute has developed a protocol for carrying out bio-availability studies on the fixed-dose combinations of some anti-tubercular drugs and WHO has accredited NIPER, along with a South African Institute for carrying out such studies. The Institute is routinely carrying out these studies for various industrial houses, helping them maintain quality standards as well as generating revenue for itself. Besides, the following services have been established at the Institute which are being made use of by industry, regulatory authorities as well as academic institutes:

- Central Instrumentation Laboratory
- Computer Centre
- Library and Information Retrieval Centre
- Central Animal Facility
- Bio-availability Centre
- Impurity Profiling and Stability Testing Centre
- Technology Development Centre
- Pharmaceutical and Toxicological Screening Facilities."

7.14 They further informed:-

"The Institute has started a separate department of pharmaceutical technology which besides being engaged in training manpower for industry, also undertakes sponsored projects in the following areas:

(k) Process development of bulk drugs employing chemical or chemoenzymatic routes.

(ii) Development of eco-friendly technologies for currently used bulk pharmaceutical chemicals. The Institute has developed process technologies for artmesinin derivaties and mefloquin which are newer generation antimalarials. These technologies are being transferred to industry.

(iii) Process development of conventional and novel dosage forms.

(iv) Using eco-friendly technologies, it is submitted that process development work will reduce the cost of bulk active substance."

7.15 In response to a query raised by the Committee regarding the difference in R&D work being done by CSIR and NIPER in the field of drugs and pharmaceuticals, NIPER submitted:-

> "Unlike CSIR the basic objective of NIPER is to provide higher education in pharmaceutical sciences and be a center of excellence in this area. Besides imparting higher education NIPER is also involved in basic and applied research in drugs and pharmaceuticals. NIPER has created all the facilities required for new drug discovery particularly in the thrust areas selected by the Institute. NIPER is also collaborating with CSIR in computer aided drug design. The Institute has some very active groups engaged in the development of novel drug delivery systems which can provide drugs with relatively low generation period and without undesirable side effects."

7.16 When the Committee wanted to know about the coordination with the Department of Chemicals and Petrochemicals and Ministry of Health and Family Welfare with a view to encourage R&D and to achieve the objectives of National Health Programme. NIPER submitted:-

> "NIPER has, under the aegis of World Bank, agreed to become the nodal agency for imparting training to regulatory personnel from Ministry of Health and Family Welfare. This has been realized to be essential to ensure the availability of quality drugs and pharmaceuticals under the National Health Programme. This Institute is also working with ISM department in developing agrotechnology of some medicinal plants and preparing monographs for Ayurvedic pharmacopoeia. In coordination with the Department of Chemicals & Petrochemicals NIPER has taken some projects regarding documentation of label composition of all the formulations in the Indian market, codification of all the bulk drugs and knobs for packaging materials."

(d) Mashelkar Committee Report on R&D

7.17 The Pharmaceutical Research and Development Committee (PRDC) was set up under the Chairmanship of Dr. R.A. Mashelkar, Director General, CSIR to study and identify the measures needed to strengthen R&D base of the Indian Pharmaceutical Industry. The Committee submitted their Report in November, 1999. The main features and recommendations of the Committee are enumerated below:-

The Committee enunciated a vision for Indian Pharma R& D as:

> To provide intellectual capital to make available safe, cost-effective, contemporary, quality therapeutics to the people of India to help reduce

percentage of mortality and to emerge as a significant player in the global market place.

In consonance with this vision, a grand dream for production, export and investment in pharma R&D was evolved. This report suggests the measures by which such a dream and vision could be realised. The Committee:

(i) Identified and prioritised areas for Indian pharma R&D. It suggested initiation of new drug development for diseases of relevance to the Indian population, while at the same time seizing opportunities to become a global player by introducing globally competitive products based on new molecules and new delivery systems etc.

(ii) Based on a SWOT analysis, identified unique opportunity for India to become a leading centre for clinical trials. The Committee thus called for basic changes in the legislation allowing import of animals, contract research, and a legal status for institutional animal ethics committee and, establishment operationalisation of a GMP, GLP and GCP monitoring authority.

(iii) Recognising the crucial role played by the Indian systems of medicine in the health care needs of the population, recommended major and specific initiatives to strengthen and modernise the existing infrastructure. Besides, proper scientific documentation of traditional knowledge base in the internationally accepted format and media was suggested.

(iv) Suggested enacting a TRIPs compatible IPR legislation, which protects the interest of the consumers and at the same time allow a platform for the growth of Indian pharma industry. Accordingly, it has suggested detailed measures for strengthening the IPR system with action points specified the Government, judiciary and the legal system, industry, S&T and even for educational systems.

(v) In the backdrop of a strong trend towards globalisation of regulatory and scientific requirement pertaining to safety, efficacy and quality, recommended creation of a professionally managed and efficient regulatory mechanism under the Central Drugs Standard Control Organisation (CDSCO).

(vi) Recognising that the significant areas of healthcare of relevance and value to the Indian populance will not be addressed by the companies in the developed world, has recommended the establishment of Drug Development Promotion Foundation, which will promote such R&D. This foundation will be truly autonomous and independent of the

Government, with a well defined legal structure. The Committee has also detailed the functions, management and financing of the Foundation.

(vii) Suggested several fiscal and non-fiscal measures for funding R&D. Most importantly it felts that an effective venture capital financing environment needs to be created by removing the existing roadblocks.

The Committee had urged the Government to quickly set-up an enabling mechanism under the Department of Chemicals and Petrochemicals to initiate implementation of its recommendations in a time bound manner.

7.18 All the major players of the Drugs Industry reportedly have an unanimous view that the recommendations of the Mashelkar Committee are very specific and detailed and the implementation of the Pharmaceutical Research and Development Committee report must be paramount concern of the Government. By implementation of the recommendations of the report particularly relating to R&D funding will prepare the industry for incentive becoming R&D intensive and to meet the global competition.

CHAPTER-VIII

STRENGTHENING OF INDIAN SYSTEMS OF MEDICINE

8.1 As announced in the Drug Policy, 1995, a separate Department of Indian systems of medicines and Homoeopathy was created in the same year to look after and promote these systems of medicines. They have launched the following schemes for promotion and popularising the Indian system of medicine and Homoeopathy in the country:-

(1) Strengthening of Indian system of Medicine & Homoeopathy, education institutions, financial assistance is given for upgradation of facilities in educational institutions of Indian system of Medicine & Homoeopathy.

(2) Standardisation of Indian System of Medicine & Homoeopathy drugs, setting up of laboratory facilities for the testing of Indian system of Medicine & Homoeopathy drugs.

(3) Re-oreientation training in service teachers, physicians and researchers.

(4) (a) Development and cultivation of medicinal plants used in Indian System of Medicines and Homoeopathy medicines.
(b) Scheme for development of agro-techniques and cultivation of medicinal plants.

(5) Strengthening and establishment of premier institutes in these systems of medicines such as National Institute of Ayurveda, Jaipur, National Institute of Homoeopathy, Calcutta, Institute of Post-graduate Training and Research in Ayurveda, Jamnagar, Rashtriya Ayurveda Vidhyapeeth, Delhi, National Institute of Unani Medicine Bangalore and National Institute of Naturopathy, Pune.

(6) Research in Indian systems of Medicine & Homoeopathy is supported through various Central Councils of Research in Ayurveda, Siddha, Unani, Homoeopathy, Yoga and Naturopathy.

(7) Central Scheme for functioning of Ayurveda, Siddha, Unani, Pharmacopoeia Committees to develop pharmacopoeial standards for ISM drugs, and standardisation of drugs and testing of drugs through the Pharmacopical Laboratory of Indian Medicine and Homoeopathy, pharmacoepia laboratory of Ghaziabad.

(8) Setting up of Indian System of Medicine and Homoeopathy speciality clinics in premier hospitals like Dr. Ram Manohar Lohia Hospital, Safdarjung Hospital. In PGI, Chandigarh and JIPMER, Pondichery the issue is in process.

(9) Information, Education and Communication Cell has been set up in the Department for creating awareness and popularisation among the people about the strength and merit of these systems.

8.2 During the course of evidence the Committee pointed out that the other systems of medicines like Ayurveda, Unani, Siddha and Homoeopathy were remained untapped and wanted to know about the steps being taken by CSIR to explore the full potential of these systems. Director of Central Drug Research Institute submitted:-

"We have immense amount of traditional wealth in this particular area, but so far very little of it has been exploited in real terms. Realising this, the CSIR has taken up this work on a very massive scale. We have been looking into the traditional systems of medicine. There are two types of systems here. One is recorded like Ayurveda and Unani and the other is unrecorded. There are traditional remedies which are not recorded or documented anywhere like tribal medicines. Even in tribal medicines, there is a lot of information, which is not recorded. The CSIR has been trying to tap that knowledge.

We have an in-house project on this whole area for development of new drugs from traditional remedies and other natural resources. The basic objective here is two fold. The first one is to develop new leads for new development and the second one is just to standardise or provide a scientific base to these systems of medicine. Since I head the Drug Research Institute, I can tell you that world over there has been a revolution in drug research. So people are using the latest knowledge for drug development. Somehow or the other, we are lagging behind in this particular area. But still we can win the race in certain aspects because we have immense amount of traditional knowledge available with us and if we come with new leads of these traditional drugs we can race ahead in this field. So, realising this potential, we have taken up a programme and we have already signed an agreement with Ayurvaidyashala, Kottakkal and we have been closely working with them. I am happy to report that several of their preparations have turned out to be fairly active. In a few of them, I have practical experience like their anti-ulcer compound and anti-cancer compound. It is not that we have not gone into this area. We are deeply into this area. Even with Unani medicine system we have signed an agreement and we have submitted to the Government a major project focussing on these aspects. So, we are actively working in this area."

8.3 When the Committee put the same question before NIPER, they submitted the following details in written reply:-

"The Institute has a separate department of Natural Products and this department is involved in natural products research in the following areas.

(i) Standardisation of herbal drugs and products

(ii) Isolation and characterisation of bioactive compounds

(iii) Assay method development based on High performance thin layer chromatography (HPTLC), High performance liquid chromatography (HPLC) and Gas liquid chromatography (GLC)

(iv) Agrotechnology of medicinal plants

(v) Chemical processing technology for natural products

(vi) Development of herbal preparation

(vii) Micropropagation.

The above activities are designed to provide scientific basis of practices in Indian Systems of Medicine e.g. Ayurveda, Unani and Sidha etc."

8.4 On being enquired about the research activities being undertaken by Department of Indian Systems of Medicines under the Ministry of Health and Family Welfare and the expenditure incurred for this purpose since creation of the Deptt. of Indian Systems and Medicines submitted in a written reply:-

"Research is being conducted mainly by the four Research Councils, namely; Central Council for Research in Ayurveda & Siddha (CCRAS), Central Council for Research in Unani Medicine (CCRUM), Central council for Research in Homoeopathy (CCRH), Central Council for Research in Yoga & Naturaopathy (CCRY&N) also expenditure is being incurred on research & research related schemes like Strengthening Pharmacopoeia Committee. Extra Mural Research (EMR) Medicinal Plants and the details of amounts spent through them are as follows:-

(Rs. in lakhs)

Year	Plan	Non-Plan	Total
1995-96	840.00	1158.00	1998.00
1996-97	895.37	1495.67	2391.04
1997-98	1548.23	2328.00	3876.23
1998-99	2510.70	2621.01	5131.71
1999-2000	2515.85	2712.00	5227.85

8.5 During the course of evidence the Committee put stress on implementation of central scheme for development and cultivation of medicinal plants and wanted to know about the various activities undertaken by the Medicinal Plant Cell of Department of ISM&H. The Department of ISM&H submitted the following details in a written reply:-

"The Department is implementing two schemes; namely

Development and cultivation of Medicinal Plants & Development of Agro-techniques & cultivation of medicinal plants.

The objective of Development of Cultivation of medicinal plants is to augment the production of raw herbs of plants origin by providing central assistance for their cultivation and development. As per present pattern of the scheme, central assistance is provided to GovernmentSemi-Government Organisations including Indian Systems of Medicine & Homoeopathy institutions autonomous/statutory bodies (directly controlled by the Govt.).

Central assistance of about Rs. 6.82 crores has been provided for setting up of about 95 Medicinal Plants Gardens in different areas of country since implementation of the Scheme.

Central Scheme for Development of Agro-Techniques and Cultivation of Medicinal Plants used in Ayurveda, Siddha, Unani & Homoeopathy.

The Development of Agro-techniques & cultivation of Medicinal Plants has been launched with the objective of developing agro-techniques of all important Medicinal Plants specifically used in the medicines of ISM&H. The scheme was implemented during the year 1997-98. This Department is implementing projects for developing agro-techniques of about 120 Medicinal Plants through 33 organisations. Under this scheme, central assistance is provided to specialised scientific institutions in Govt./Semi-Govt. Sector like Agriculture/Horticulture Universities, Scientific Institutions etc. Projects sanctioned under the scheme are to continue for 3-4 years depending upon the plants undertaken for the study.

An expenditure of Rs. 111.80 lakhs was incurred during the years 1999-2000 for the above two schemes of Department. There is an allocation of Rs. 300.00 lakhs during the current year for this purpose."

8.6 The Committee went in the details of the R&D activities of ISM&H and wanted to know about the type of coordination with CSIR in this matter. Department of ISM&H submitted the following details:-

"Report of the Pharmaceutical Research & Development Committee set up in November 1999 made several recommendations which *inter-alia,* included (I) establish & operationalise GMP (ii) Strengthening & establishing a tenable system of quality & efficacy of indigenous system of medicine (iii) documentation and digitisation of indigenous knowledge system & (iv) human resources development of new drug discovery of ISM&H.

GMP has since been notified. State Government are to be assisted under a scheme of strengthening of State Drug Testing Laboratories. Private Laboratories

would be recognised for broadening the facilities required for testing of ISM&H products. A TKDL is being developed for Ayurveda. For Siddha & Unani it will be developed at a later date.

This Department is also considering training of research personnel of research councils under ISM&H in modern laboratories to equip them with knowledge and expertise which will reorient them in their research work.

This Department has collaboration with CSIR in developing agro-techniques and evolving pharmacopoeial standards. Their two extra-mural research projects have been assisted by us and two more such requests have been received. There is regular interaction with the technical personnel of CSIR. The areas of cooperation would be broadened."

8.7 The Committee further wanted to know whether there was any proposal to expedite or modify the R&D. Department of ISM&H informed:-

"The Research Councils have been advised to clinically evaluate, the research work being done by them with a view to decide which of them should be taken forward. The Scientific Advisory Committees are being reconstituted keeping in view that the councils get expert advice and directions from the Scientists/Pharmacologists and Researchers for the respective system and modern system. A number of procedures/drugs for identified diseases when the drugs have been found efficacious and promising are being subjected to clinical trials in modern institutes under properly evolved protocols to establish their efficacy without any doubt."

PART-II

RECOMMENDATIONS/CONCLUSIONS OF THE COMMITTEE

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 PSUs 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 medicines.**

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 seem to be on paper only and much has not changed in between the long 7 years. The Committee, therefore desire that Government should furnish specific reply as to how much progress has been achieved in implementing the Committee's recommendation stated above. The Committee's recommendations arising out of the examining the subject afresh are given in the following paragraphs.

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 and 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 licencing 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.

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 had categorised 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 channelise 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.

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 objectives 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 and 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 can not 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.

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 Drugs (Prices Control) Order, 1995 the criteria was related to production monopoly and turn over rather than the essentality 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 feel 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 Drug 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 factor for the Govt. National Essential Drugs List. The Committee also direct that while preparing such a list, the Department of Chemicals and Petrochemicals 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.

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 amend the National Health Policy of 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 indepth/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 synchronises 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 are likely to emerge as new health challenges over the next few decades.

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 and 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.

8. The Committee note that Department of Chemicals and Petrochemicals is responsible for licencing, overall production and pricing aspects and Ministry of Health and Family Welfare is responsible to maintain quality and distribution of drugs. Therefore, there is a paramount need of very close and efficient coordination between the Department of Chemicals and Petrochemicals and Ministry of Health and Family Welfare 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 coordination so that the access to medicines with good quality and reasonable prices improves 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 Governments 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.

9. The Committee recognise 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 a 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 liberlisation and globalisation are squelching the much needed efforts at rationalising the drug production, drug distribution, drug prescription , drug utilisation 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 thirdly, 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 licence is the main reason for this type of growth. The Committee desire that in this age of computers the Government must take all initiatives to centralise the licencing procedure so that indiscriminate licencing procedure is stopped immediately and manufacturers are permitted to produce only better quality and rational/essential drugs.

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 deserved drugs has been stopped either due to their

cost of production is not economical or their place has been taken by 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. These national companies have so far played a very valuable role in producing medicines at 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 ncessary 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 capacilities can be utilised 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 PSUs 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 PSUs.

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.

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 specialised 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 a 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 with a view to restrict /minimise the number of drugs, 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 benchmark regulatory standards matching with those adopted in the developed countries for manufacturing, hormonise standards for clinical testing with global practices and even stream-lining the procedures for speedy evaluation and clearance of new drug applications locally developed.

13. The Committee are dismayed to note that despite of the huge production of medicines in the country, the modern medicines are reaching to 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 concerned State Government for 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 an important 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.

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 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 further desire 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.

15. The Committee note that Section 18 of the Drugs and Cosmetics Act, 1940 require every dealer to take a licence 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 licences. 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 licenced Retial 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 licences to the qualified Doctors or Nursing Home owners also so that they may also be held responsible for every wrongful act done by them.

16. The Committee have noted that under the Drugs and Cosmetics Act, 1940, the sales of Allopathic drugs are regularised through licencing system and a it is also required to employ pharmacist to supervise the sale of drugs. The Licencee has to satisfy the Licencing Authority the conditions regarding experience, qualification etc. of the pharmacist and the minimum area of the shop for which the Licence 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.

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 on 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 subsidised rates as very practical one. They have further

justified their suggestion by informing that the proposed scheme could 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/Assocations 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 Food & Civil Supplies to discuss the modalities of such scheme and bring the scheme in action in a shortest possible time.

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.

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 substandard 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 therefor 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 minimise the problem and improve the quality control.

20. The Committee note that State Drugs Control Organisations are responsible to ensure manufacture of quality drugs through a system of licencing. The main responsibility in this area is with the Drug Inspector who inspects the premises for licencing 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 prosecution of the offenders. But the Committee find that the number of 1100 of DIs in the States 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 workload 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.

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 Drug 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 is 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 60 lakh to 3 crore, some minimum requirement of Good Manufacturing Practices for these units should be fixed to be observed by them.

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 practising 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.

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 licences 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 licencing 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 unorganised manner mainly by Vaidya and Hakims. However, 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.

24. Although Ministry of Chemicals and Fertilisers 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 and Petrochemicals. The Committee strongly recommend that STAC should be constituted immediately. As per the recommendations of 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, upgradation 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.

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 have been, by and 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 others 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 a 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 a to fulfill above mentioned objectives.

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 on 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 organisations like OPPI and address their constraints suitably so that pharmaceutical growth is not hindered.

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. They would not be showing interest in the cases where there is a possibility of lowering of prices. In case of decontrolled drugs the situation is more tough. The prices 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 desire 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.

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 and Petrochemicals/ NPPA. In fact, they are more busy in quality control, control of sale of spurious medicines, granting licences 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 exhorbitant 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 difference between the production costs, 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 NPPA more professional in tune with times and needs of the society.

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 and 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 cost-variations in States can be removed.

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 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 and after implementation of uniform Sales Tax the objective of 'MRP inclusive of all taxes' should also be achieved.

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 is 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 Tripps 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 with 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. 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 Equalisation 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.

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, diarrohoea, 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.

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 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 Indian System of

medicines 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 also urge that 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 also desire that Government should formulate a separate Drug Policy to regulate the various issues relating to the various Indian Systems of Medicines.

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.

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'.

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NEW DELHI
Chairman
August 20, 2001 ***Standing***
Committee on
Sarvana 29, 1923 (Saka) ***Petroleum &***
Chemicals