

REPORT

*Task Force to Explore Options other than Price
Control for Achieving the Objective of Making
Available Life-saving Drugs at Reasonable
Prices*

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Submitted to the
Department of Chemicals & Petrochemicals,
Government of India

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FOREWORD

The National Common Minimum Programme of the Government states:

"The UPA Government will raise public spending on health to at least 2-3 of GDP over the next five years with focus on primary health care. A national scheme for health insurance for poor families will be introduced. The UPA will step up public investment in programmes to control all communicable diseases and also provide leadership to the national AIDS control effort.

The UPA Government will take all steps to ensure availability of life saving drugs at reasonable prices. Special attention will be paid to the poorer sections in the matter of health care. The feasibility of reviving public sector units set up for the manufacture of critical bulk drugs will be re-examined so as to bring down and keep a check on prices of drugs."

In pursuance of the above commitment of the Government, the Department of Chemicals & Petrochemicals constituted this Task Force, comprising of representatives from the Planning Commission, the Department of Chemicals & Petrochemicals and the Department of Health to explore options other than price control for achieving the objective of making available life-saving drugs at reasonable prices. The Drugs Controller General of India (DCG(I) and the Member Secretary, National Pharmaceutical Pricing Authority (NPPA) were also associated intimately as Special Invitees. The composition and terms of reference of this Task Force in annexed .

In carrying out its responsibility, the Task Force has had intensive interaction with all stake-holders involved with drugs and pharmaceuticals, including the industry at all levels, health professionals, academics, international agencies, NGOs, etc. A large number of submissions and representations were also received. This Report of the Task Force attempts to bring together the wisdom received from various quarters to develop a consistent structure of strategies, policies and institutional arrangements which can have the effect of achieving the objective of ensuring the availability of essential and life-saving drugs at reasonable prices, not merely in the immediate future but on a sustained basis. Since, as was expected, the views expressed by different stake-holders during the consultation process were varied, and often contradictory, the Task Force has had to exercise its own judgement while framing this Report.

Balancing conflicting interests is seldom an easy task, and neither is reconciling short run imperatives with long term concerns. Our task was made all the more difficult by the fact that the Indian experience in the pharmaceuticals sector is almost *sui generis*, and there was little international

experience to draw upon. Certainly, the wide variety of strategies that exist in the international domain had to be studied, if for no other reason than to avoid the pitfalls that have been experienced elsewhere, but there were no accepted models which could be drawn upon and applied without the need for further explanation. Therefore, every effort has been made to explain the logic and rationale behind the proposals contained in this Report.

The Task Force would like to acknowledge its deep debt of gratitude to all those who took their valuable time to interact with us, and to provide us with insights and documentation which we otherwise would have been unaware of. In particular, we would like to express our sincere appreciation for the keen interest shown and useful advice rendered by Sh Pratyush Sinha, former Secretary, and Smt. Satwant Reddy, present Secretary, Department of Chemicals and Petrochemicals, Government of India, as well as by Sh Satish Chandra, Chairman, National Pharmaceutical Pricing Authority. We would also like to make a special mention and express profound appreciation for the efforts made by and contributions of Prof. P. Rama Rao, Director, National Institute of Pharmaceutical Education and Research (NIPER) and his team, without whom much of this Report would simply not have been possible. Finally, we would like to express our thanks to the Honourable Minister of Chemicals and Fertilizers for having given us this opportunity to contribute, no matter in how small a manner, to the health and well-being of our country and its economy.

(Pronab Sen)
Chairman

Executive Summary

A Task Force with the following composition was constituted on the 29th November 2004 to explore various options other than price control for achieving the objective of making available life saving drugs at reasonable prices:

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|---|----------|
| (1) Principal Adviser (PP) (Dr. Pronab Sen),
Planning Commission | Chairman |
| (2) Joint Secretary (PI) (Shri G.S. Sandhu)
O/O. C&PC | Member |
| (3) Joint Secretary (Smt. Rita Teatota)
(O/O Health) | Member |

Subsequently in February 2005, the Drugs Controller General of India (Dr. Ashwani Kumar) and Member Secretary, National Pharmaceutical Pricing Authority (Shri Pradip Mehra) were nominated as permanent Special Invitees to the Task Force .

The Task Force held meetings on 9.12.2004, 13.1.2005, 22.2.2005 and 24.3.2005. Separate meetings with Drug Industry Associations were also held on 24.1.2005, 6.7.2005, 16.7.2005,29.7.2005,5.9.2005 and 6.9.2005. A meeting with NGOs was also held on 29.6.2005. Further, the Task Force's draft recommendations were provided to most of the Industry Associations and the same were discussed with them in the meetings chaired by Hon'ble Minister(C&F). During these meetings various issues relating to drug and pharmaceuticals were discussed and on that basis the Task Force has furnished its final report to the Government. The major recommendations are as follow:

1. The Strategic Approach:

The Task Force recommends that price regulation should be on the basis of 'Essentiality' of the drug and it should be applied only to formulations and not to upstream products, such as bulk drugs. No effort should be made to impose a uniform price, and only a ceiling price should be indicated. The ceiling price of essential drugs should normally not be based on cost of production but on readily monitorable market based benchmarks. Other drugs falling into selected therapeutic categories should be brought under a comprehensive price monitoring system with mandatory price negotiations system, if necessary. The regulatory mechanism should be Significantly strengthened both at the Centre and in the States. A process of active promotion of generic drugs should be put in place including mandatory debranding for selected drugs. Public Sector Enterprises (PSEs) involved in the manufacture of drugs should be revived where possible and used as key strategic interventions for addressing both price and availability issues. The drug regulator must maintain a data base of brands and their compositions and no change should be permitted in the composition of a given brand.

There should be bulk purchases of drugs by Government agencies, cooperatives or consumer bodies through public-private partnership and insurance companies should be encouraged to extend health insurance covering medicines.

2. Drugs and Therapeutics (Regulation) Act:

A new legislation viz, Drugs and Therapeutics (Regulation) Act (DATA) should be enacted for price control on drugs. Under DATA Government should be empowered to impose a price or limit the increase in price, and to clearly lay down the principles governing or the reasons leading to imposition of any such price control and to seek or compel disclosure of any information or data relevant to its functioning. The powers and provisions of the DATA would be in addition to those contained in the Drugs and Cosmetics Act, 1940 and Essential Commodities Act, 1955.

3. National Authority on Drugs and Therapeutics:

As a long term objective, the Task Force endorses the proposal made by the Planning Commission in the Mid-term Appraisal of the Tenth Five Year Plan to establish a National Authority on Drugs and Therapeutics (NADT), as an independent regulatory agency integrating the offices of the Drugs Controller General of India, the Central Drugs Standard Control Organisation (COSCO) and the National Pharmaceutical Pricing Authority (NPPA) along with all the powers and functions of these bodies. In the interim, a dual regulatory system comprising of the National Drug Authority (NDA) and the NPPA is proposed with standing arrangements for resolution of over-lapping responsibilities.

4. Other Regulatory Issues:

Consistent with the strengthening of the Central Drug regulatory system, the state's supervisory and regulatory capacity should also be strengthened. The Centre should financially support State Governments to bring their state drug control formations to a threshold level, especially as far as the price monitoring functions are concerned. The recommendations of the Mashelkar Committee 2003 report should be adopted as a blue print for this purpose.

5. Principles of Price Regulation:

The Task Force recommends that the National List of Essential Medicines (NLEM) 2003 should form the basis of drugs for price control/monitoring. To support the process the Government should announce the ceiling price of all drugs contained in the NLEM on the basis of the weighted average price of the top three brands by value of single ingredient formulations prevailing in the market as on 1.4.2005. In cases where there are less than three brands, the average of all existing brands would be taken. The ORG-IMS data can be used for this purpose initially with a retail margin of

20. For drugs which are not reflected in ORG-IMS data, the NPPA should prepare the necessary information based on market data collection. In the case of formulations which involve a combination of more than one drug in the NLEM, the ceiling price would be the weighted average of the applicable ceiling prices of its constituents. Excise duty should continue to be payable on the actual MRP of the individual medicines. In the case of drugs not contained in the NLEM, intensive monitoring should be carried out, for any new formulations based on existing APIs, manufacturer concerned would be required to submit its intended price along with application for marketing approval to the regulator, which would be granted only if the indicated price is consistent with relevant ceiling price .. The NLEM should be revised every three years.

6. Patented Products:

All patented drugs and formulations should compulsorily be brought under price negotiation prior to the grant of marketing approval. The reference price to be used for such negotiations will be the prevailing price of the closest therapeutic equivalent in the domestic market/lowest price at which the drug is marketed internationally.

7 Bulk Procurement

Bulk purchase mechanism should be streamlined to ensure that the current malpractices are curbed so that the prices reflect the true value of quality drugs. In order to reduce the financial burden of public health system it would be appropriate that a lower ceiling price is fixed for the bulk procurement by Government.

8. Promotion of Generics:

Public procurement and distribution of drugs through the public health system should mainly be for generic drugs. Quality certification may be provided free to dedicated generic drug manufacturers and there should be no control on price or distribution margins specified for generic drugs.

9. Access Arrangements:

The low volume high priced drugs such as cancer drugs, anti AIDS/HIV drugs may be exempted from the payment of excise duty, custom duty, octroi and other levies if any. This benefit should be passed on to the patients .

10 Public Sector Undertakings:

The role of PSUs producing drugs should be recognized and all Departments of Central Government must be advised to first procure their drugs from the PSUs at prices approved by NPPA for the drugs covered under the essential category. For other drugs produced by these PSUs,

procurement may be done at prices worked out by a committee constituted for this purpose.

11. Scheme for BPL families:

The Central Government has set up a National Illness Assistance Fund (NIAF) under which assistance to states upto 50 of their share is provided out of this fund in the State illness Fund (SIF) set up by respective states. A BPL patient is provided financial assistance upto Rs.1.50 lakhs. The Task Force feels that there is an imperative need for the states to set up the SIFs and revolving funds in all Government hospitals for making available medicines free of cost to BPL families.

12. Excise Duty Relief:

The Task Force has recommended to reduce the excise duty on all pharmaceutical products from 16 to 8. In order to mitigate the rigors faced by and to provide a level playing field for small scale pharma units to enhance the exemption limit of small scale units from the present Rs.1 crore to RS.5 crore.

13. Research and Development:

Keeping in view the introduction of Product Patent Regime in India the Task Force has recommended that fiscal incentives should be granted over a much longer period of time, say 10 years, rather than the limited period extensions that are being made presently. The corpus of RS.150 crore under the Pharmaceutical Research and Development Support Fund (PRDSF) needs to be sufficiently increased over the next 5 years.

14. Facilitating Schedule M Implementation:

A special fund should be created for providing interest subsidy on borrowings to small scale pharma units adopting Schedule M implementation. This assistance should be in addition to any other financial assistance.

15. Public Awareness:

To create public awareness and to educate the people, a dedicated web site needs to be created in addition to other possible modes of enhancing public awareness like public literatures, booklets, newsletters/magazines etc.

16. Settlement Commission as a Device for funding Certain Activities:

A Settlement Commission on the lines of constituted by the Income Tax Department needs to be constituted for settling the cases of past and future arrears of over charging from the drug companies. All on-going court cases should be brought before the proposed settlement commission and efforts be made to arrive at some workable settlement.

Chapter 1

INTRODUCTION

The availability of medicines at reasonable prices has been the subject matter of intense debate ever since independence of the country, and the Central Government has been taking various steps to meet this objective. From time to time, drug policies have been adopted to strike a balance between the often conflicting interests of industry and consumers in moving towards the objective of greater accessibility and affordability of drugs. The present Government also attaches a high priority to this subject and has declared the objective of raising the public health expenditure and to make available life saving drugs at reasonable prices with special attention to the poorer sections of the society.

During the course of last over one year, the issue of drug prices has been discussed frequently both within and outside Parliament. A major reason for this has been the apprehensions arising from the introduction of the product patent regime in pharmaceuticals in India with effect from 1st January, 2005 in line with our international commitments under WTO/TRIPS agreements. Since Indian Industry has mainly grown as a generics industry on the strength of process patents, this would mean a fundamental shift in the operating environment of the industry in the times to come. There is no doubt that India would continue to benefit from its strong generics production for a long time to come, yet the freedom to reverse-engineer newer molecules would be vastly hampered.

Apprehensions have been expressed that introduction of product patent would lead to steep increase in the prices of medicines, affecting their affordability by the common man. It may be mentioned here that, due to the strong base of generics that has been already established, a majority of the drugs are outside the ambit of product patent and should continue to be available in the future. Prices of these drugs too are not likely to be affected adversely in the immediate future, but the repercussions over the longer term are less predictable. Added to this are the safeguards built into the Patents Act, 1970 at the time of amending it, which will ensure continuous production and availability of most of the existing drugs .

Despite the safeguards in the Patents Act, our strong generics base and comparatively low prices of drugs, there are worries on account of very low purchasing power of the vast segments of the poor population in the country. These concerns get reflected differently owing to different perceptions of different people and organizations. Nevertheless, the point remains that it is very difficult for the Government to ignore the fact that availability of essential drugs must be ensured at affordable prices to the

common man, and extra measures and safeguards may have to be taken for improving accessibility of drugs to the poor people.

1.1 Background of price controls on pharmaceuticals in India

In the early stages of production of pharmaceuticals in India, the industry produced only conventional drugs such as tinctures and other spirituous preparations, vaccines etc. Antibiotics and synthetic drugs were introduced after the Second World War. Soon after the independence of the country, the multinationals and the trading concerns started importing the finished formulations. Subsequently, the production activity was stepped up based on imported bulk drugs. The establishment of public sector units during 1954 to 1961 was an important milestone in the development of pharmaceutical industry in India. By 1965-66 there were about 2000 manufacturing units producing formulations worth Rs. 1,500 million. Production of bulk drugs was also picking up and had reached to the level of Rs. 180 million.

The prices of drugs were brought under statutory control for the first time by Government of India in the wake of the Chinese aggression and the declaration of emergency in 1962. Due to soaring prices of medicines the Drugs (Display of Prices) Order 1962 and the Drugs (Control of Prices) Order 1963 were promulgated under the Defence of India Act. These orders had the effect of freezing the prices of drugs as on 1st April 1963.

The industry was highly critical of the freeze order on the ground that the prices of relevant raw materials were not similarly frozen. As a result, Government took two steps in 1966. Firstly, a system of selective increases was introduced in place of the system of total freeze. Secondly, 18 essential drugs were identified and referred to the Tariff Commission for examining the cost structure and recommending fair selling prices.

According to the Drugs Prices (Display & Control) Order 1966, it was obligatory for the manufacturers to obtain prior approval of Government before increasing the prices of all formulations in their lists as on 30th June 1966 (frozen for all practical purposes at the level of April 1963). By amendment in August 1968, *those which were sold under pharmacopoeial names (nowadays known as Igenerics') were exempted from price approval. Exemption was also made in the case of new drugs, i.e. drugs which have been evolved as a result of original research and intended to be marketed for the first time.*

The Tariff Commission, after studying the cost structure of 18 selected bulk drugs and their formulations and some related matters, submitted its Report to Government in August 1968. Soon after the receipt of the Tariff Commission's Report, the Government initiated action to consider the various recommendations in consonance with the different organizations concerned with the matter.

Drugs (Prices Control) Order 1970

The Drugs (Prices Control) Order 1970 was promulgated on 16th May, 1970 under the Essential Commodities Act 1955 (ECA). The principal objective of the order was to affect a measure of rationalization in the prices of drugs and to build up a rational system of price control. This Order also provided for an alternative scheme of pricing, wherein some flexibility in fixation of prices, subject to certain conditions relating to mark up applicable to essential and other formulations and overall profitability not exceeding 15 per cent on sales turnover, was permissible.

The operation of the control, however, had less impact on the structure and level of prices of drugs and formulations than one would have expected in view of the very large proportion of items in respect of which reductions in prices were affected. While the price reduction covered nearly 45 of the formulations in terms of numbers, in terms of the total of sales of the 110 companies, the proportion was less than 30. Similarly, in the case of more than 1/3rd of the formulations, prices were allowed to be kept at the earlier levels. Rigid control on prices of drugs and formulations had to be modified, and selective increase in prices permitted on the merits of each case to take account of any substantial variations in costs of materials including packing material.

Patent Act 1970

Another Significant development was promulgation of *Patent Act 1970*, which provided for process patent in case of drugs and pharmaceuticals, as against the product patent that had existed earlier. This measure was to have far-reaching implications for the development of the pharmaceuticals industry in India in coming years.

The Hathi Committee

In the context of large-scale expansion of the drugs and pharmaceuticals industry, with a view to ensuring the regulated and rapid growth of drug manufacture and further with a view to ensuring that all essential drugs are made available to the consumers at reasonable prices, Government constituted a Committee in February, 1974 under the Chairmanship of Shri Jaisukhlal Hathi, which had Members of Parliament along with officials and non-officials as members, to enquire into various facets of the drugs industry in India. The terms of reference included progress made and status achieved by the industry, role of public sector, growth of indigenous industry, including the small scale, technological requirements, quality control measures, pricing of drugs etc. Almost all the aspects of the drugs and pharmaceutical industry were critically examined by

Hathi Committee with a view to achieve self-sufficiency and to serve the national interest.

Hathi Committee submitted its report in April 1975. The report contained 224 recommendations spread over 8 chapters on various aspects of Pharmaceutical Industry. The thrust of recommendations related to reemphasizing the *leading role for the public' sector, setting up of National Drug Authority, preference to Indian Sector over the foreign sector, indigenous production of raw materials, selective price control on prices of drugs etc.*

Drug Policy. 1978 and opca. 1979

It was on the basis of the Hathi Committee report that the first Drug Policy covering all the aspects was formulated in 1978. Under this policy, preference was given to Indian manufacturing units - public sector units being assigned a key role in selected areas, and the role of units with foreign holding was confined to high technology areas. Price control was imposed on 347 bulk drugs that were used in the formulations listed for price control under three categories with different mark-ups. Formulations considered most essential were given a lower mark-up so as to keep their prices low. Accordingly, the Drugs (Prices Control) Order 1970 was replaced by a new Drugs (Prices Control) Order 1979.

As compared to Drugs (Prices Control) Order 1970, the Drugs (Prices Control) Order 1979, based on the Drug Policy 1978, included many new features, which were as follows:

- (1) In place of essential bulk drugs listed in DPCa 1970 for price fixation, opca 1979 contained the provision for fixation of price of indigenously produced bulk drugs as specified therein numbering 347.
- (2) In order to encourage indigenous production from various manufacturers who may not be equally efficient, the concept of retention price for individual manufacturer and that of common selling price based on weighted average retention prices for the purpose of determining price of formulations was introduced.
- (3) Provision was also made for fixing prices of imported bulk drugs and concept of retention price and pooled price (i.e., common selling price for a drug which was imported as well as produced in the country) was introduced as in the case of totally indigenously produced bulk drugs.
- (4) Drug Prices Equalization Account (OPEA) was set up for depositing excess amounts by companies if they utilized a bulk drug procured

at a lower price than the price allowed in the price of their formulations .

- (5) Fixation of leader prices to be followed by all manufacturers of such packs.
- (6) Specified maximum limits ranging between 8-13 of pre-tax return on sales according to size of turnover, manufacturing activity and R&D activity of the company.
- (7) Encouragement to R&D was provided by way of exemption from price control.

The achievements made after the 1978 policy were impressive, although, in case of bulk drugs manufactured from basic stages or through fermentation process, the cost-effectiveness was lacking. Another reason was fragmentation of capacities due to which economies of scale were not available. Indian companies did not take up R&D activity vigorously and were confined to improving upon the existing processes only, while, due to absence of product patent, foreign companies shied away from introducing new molecules. DPEA, set up essentially to encourage domestic production of bulk drugs through the system of retention price, gave rise to intractable administrative problems. Against the above backdrop, the Government initiated a review of the policy and came out with a new policy in 1986.

Drug Policy 1986 and OpeD, 1987

New measures, announced in December 1986 and now known as Drug Policy 1986, aimed at:

- (a) ensuring abundant availability, at reasonable prices, of essential 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 encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs; and
- (d) strengthening the indigenous capability for production of drugs.

Accordingly, the Policy laid down matters related to rational use of drugs, quality control, pricing, licensing and duty rationalization.

It was proposed that a body to be called the National Drugs and Pharmaceutical Authority be established at the Central level, with a permanent secretariat, for registration of new formulations and rationalization of existing formulations. Standardization of packaging, monitoring of adverse reaction and *promotion of use of generic name* were also pursued along with strengthening infrastructural facilities for quality control and giving statutory effect to good manufacturing practices. Loan licensing system under

Drugs and Cosmetic Act was proposed to be abolished in a phased manner. It may be noted here that the above mentioned proposed authority was not same in character as the National Drug Authority envisaged by the Hathi Committee

As regards Licensing, the list of items reserved for the public sector was pruned keeping in view their performance and the requirement in the country. Indian private sector, however, continued to be given favourable treatment as compared to units having foreign holding. In order to have the desired result from the measures in the areas of licensing and pricing policies, it was necessary to have appropriate fiscal policy measures. Therefore, duty incidence on raw materials, drug intermediates and drugs was recommended to be structured in a graded way so as to make indigenous production viable.

The Drugs (Prices Control) Order, 1987 was promulgated under which the system of retention and pooled pricing was given up and, therefore, the Drug Prices Equalization Account stood abolished. Price fixation for imported bulk drugs was done away with. *In case of formulations, the concept of leader price was replaced with the concept of ceiling price to be followed by all.* Provision was made to recover the amount accrued due to charging of prices higher than those fixed or notified by the Government. Ceilings for maximum pre-tax return were retained as before. A total of 142 drugs and their formulations were brought under price control against 347 drugs under earlier DPCO 1979.

Since 1986, the Drug Industry grew significantly, in terms of production of bulk drugs and formulations. In many cases, manufacture of bulk drugs was also established from the desired basic stage. It was estimated that in case of bulk drug production the contribution of small-scale sector was approximately 30 per cent of the total production in the country. The Indian Pharmaceutical sector was able to carve a special niche for itself in the international market as a dependable exporter of bulk drugs.

Drug Policy of 1994 and Drugs (Prices Control) Order, 1995

Government announced further modifications in the Drug Policy 1986 in September 1994, followed by a OPCO in 1995. The salient features of these modifications were as follow:

(a) Industrial Licensing was abolished except for drugs produced through biotechnological processes and for drugs reserved for production by public sector units.

(b) For encouraging production of drugs from basic stage, a tariff mechanism was proposed to be used along with providing for rate of return higher by 4 over the existing rates.

(c) Only 5 drugs in regard to which public sector units had made huge investment were reserved for production by them with the provision to review the situation after 3 years.

40. (d) Foreign investment limit was raised to 51 from the then existing

(e) *To give encouragement to research and development effort, provision was made to exempt new drugs from price control for a period of 10 years.*

(f) Price control system was proposed to be operated through a single list of drugs based on criteria laid down in the policy and formulations based on these drugs were allowed 100 MAPE.

(g) Drugs having turnover of Rs. 400 lakh or more having no market competition as per laid down parameters and drugs having turnover less than Rs. 400 lakh but not less than Rs. 100 lakh having monopoly situation were kept under price control. In this way, the number of drugs under price control was 76 (presently 74) as against 142 earlier.

(h) Task of price fixation/revision and related matter were proposed to be entrusted to an independent body of experts to be called National Pharmaceutical Pricing Authority, while the Government retained the power of review. Another step towards simplification and streamlining was providing for time frame of two months for formulation pricing and four months for bulk drug pricing.

(i) *Ceiling prices were proposed to be fixed for commonly marketed standard pack sizes and were made obligatory for all, including small-scale units, to follow.*

(j) *National Drug Authority under the Ministry of Health and Family Welfare was proposed to be set up to look after the quality control aspects, rational use of drugs and related matters.*

Post 1994 Situation

As already noted, the process of liberalization was set in motion in 1991, which considerably reduced the scope of industrial licensing and abolished many non-tariff barriers to imports. This process of liberalization and opening up of economy was reflected in changes effected in the policies from time to time. Foreign direct investment through automatic route was raised from 51 to 74 in March 2000 and subsequently to 100. Public Sector units had to face competition from imports and fell sick. Reservation of 5 bulk drugs production exclusively by public sector was abolished in order to meet the demand in the country.

The pharmaceutical industry in India achieved global recognition as a low cost producer and supplier of quality bulk drugs and formulations to the world. In 2004-5, drugs and pharmaceutical production in the country stood at over Rs 35,000 crores, out of which exports accounted for Rs 16,000 crores. Industry started questioning the meaning of terms like 'turnover', 'market share', etc. and many writ petitions were filed in various High Courts. Majority of the cases were at Delhi and Mumbai. The latter ruled in favour of industry and an appeal was filed in Supreme Court which referred the case back to Mumbai High Court. However, the petitioner companies adopted the strategy of appealing/filing cases in other High Courts also on different issues. To sum up, the industry, which has been averse to price control, has

been taking shelter under legal wrangling and thereby trying to thwart the implementation of Drugs (Prices Control) Order. Meanwhile, two major issues surfaced on account of globalization and implementation of our obligations under TRIPs, which impact on the long-term competitiveness of Indian industry.

Recommendations of PRDC and DPCRC

In order to strengthen the pharmaceutical industry's research and development capabilities and to identify the support required by Indian pharmaceutical companies to undertake domestic R&D, a Committee was set up in 1999 by the Department of Chemicals & Petrochemicals by the name of Pharmaceutical Research and Development Committee (PRDC) under the Chairmanship of Director General of CSIR.

Also, in order to review the drug price control mechanism, with the objective, *inter-alia*, of reducing the rigours of price control, where they had become counter-productive, a committee called the Drug Price Control Review Committee (DPCRC). under the Chairmanship of Secretary, Department of Chemicals & Petrochemicals was set up in 1999 .

It emerged from the report of DPCRC that the domestic drugs and pharmaceuticals industry needs reorientation in order to meet the challenges and harness opportunities arising out of the liberalization of the economy and the impending advent of the product patent regime and, therefore, the span of price control over drugs and pharmaceuticals ought to be reduced substantially. However, keeping in view the interest of the weaker sections of the society, it was proposed that the Government should retain the power to intervene comprehensively in cases where prices behave abnormally. Thus, it was felt that there is need to establish effective monitoring systems so as to make a smooth transition from "controlled regime" to "monitoring regime" in a medium and long term perspective.

Action points recommended by PRDC were as follows:-

8.No.	Action Point
1 .	Establish a Drug Development Promotion Foundation.
2.	Revamp and modernize the CDSCO
3.	Not!_ & establish Pharmaceutical R&D SU.....!2Q_ort Fund.
4.	Establish & operationalise GMP/GLP/GCP Monitoring Authority
5.	Amend the Indian Patent Act.
6.	Notify and amend IT Act for tax exemptions on: (a) royalty and licensing from abroad. J..bl Export of pharma R&D.
7.	Amend the customs duty structure to exempt imports for pharma R&D from custom duty.

8.	Modify/amend legislation/rules/guidelines for contract research use and import of animal for pharma R&D.
9.	Strengthening & establishing a tenable system of quality
10.	Strengthening & establishing a tenable system of quality assurance of indigenous system of medicines.
11.	Documentation & digitization of indigenous knowledge systems.
12.	Human Resources Development for New Drug Discovery and ISM.

Pharmaceutical Policy 2002

Based on the recommendations of DPCRC , PRDC and feedback from others, the Pharmaceutical Policy 2002 was formulated. As regards pricing, the basket for selection of drugs for price control was decided to be National Essential Drugs List ,1996 and other drugs considered by the Ministry of Health and Family Welfare to be important in view of their use in various Health Programmes, emergency care etc. The criterion for selection was MAT value as reflected in ORG data. If the MAT value was Rs. 25 crore or more and one manufacturer holds 50 or more share, and if MAT value was less than Rs 25 crore but more than Rs. 10 crore and one manufacturer holds 90 or more, such drugs should be kept under price control. However, *if the cost per day of the medicine did not exceed Rs. 2/- per day, the drug was kept exempt from price control. Besides, new patented drug developed through indigenous R&D drugs produced through new patented process and for formulations involving new delivery system also were exempted from price control.*

Decisions re-affirmed the continuation of delicensing of drug industry, allowing automatically foreign investment upto 100 as well as foreign technology agreements and imports in accordance with the EXIM Policy in force. However, a centralized system of registration was decided to be introduced under the Drugs and Cosmetics Act and Rules made there under for imports of bulk drugs and formulations .

For encouragement to R&D, it was decided to establish a Pharmaceuticals Research and Development Support Fund (PRDSF) and constitution of Drug Development Promotion Board to administer PRDSF under the Department of Science and Technology. It was also decided that appropriate fiscal incentives would be given to facilitate R&D while making yearly budget proposals .

However, a public interest litigation was filed in Karnataka High Court saying that all essential drugs should be under price control in the interest of public, which was substantially accepted by the said court. A special leave petition (SLP) was filed by the Government in the Supreme Court against the

order of Karnataka High Court. The Supreme Court, while staying the order of Karnataka High Court, has directed the Government to evolve such criteria that essential and life-saving drugs do not fall outside price control. The Supreme Court order is given in Annexure-2.

Due to the changing production scenario, ongoing litigation by drug companies and the Supreme Court Order, the Government considered it proper to constitute a committee under Joint Secretary (Pharmaceuticals), Department of Chemicals and Petrochemicals, Government of India in August 2004 (Sandhu Committee). The terms of reference given to the Committee was to review the span of price control in the light of Supreme Court orders and to suggest reasonable trade margins on the sale of drugs. The Committee examined the issues and submitted its interim report to Government in November, 2004. A summary of these recommendations is enclosed at Annexure-3.

Inference Drawn from the Past Policies

Evolution of Drug Policies and Price Control Orders, as mentioned above, reveals that the first comprehensive Drug Policy of 1978 and thereafter the Policy of 1986, along with the Patent Act of 1970, successfully paved the way for development of indigenous pharmaceutical industry. During the period from 1978 to 1990, the domestic industry acquired a respectable status in terms of size, product range and market share. Multinational companies were marginalized and only a few made their presence felt. On the other hand, indigenous R&D was confined to process development/innovation for existing molecules only.

As regards pricing, the span of control, inclusion/exclusion of drugs under price control, methodologies adopted etc. continued to be controversial. First, industry has basically been averse to price control. Secondly, the number of drugs has been ever-growing, and the administrative set-up was never adequate to cope with the mammoth task, giving rise to discontent and leading to litigation. Even in 1978, it was recognized by Hathi Committee that there is no need to control the prices of all the drugs and that there has to be some sort of selectivity. *The Government developed principles of selectivity, from time to time, to keep the price control system manageable and focused, as would be observed from declining trend in number of drugs under price control.* In 1970, almost all drugs were under price control, it got reduced to select 347 bulk drugs, in 1979, to 142 bulk drugs in 1987 and finally to 76 in 1995 (presently 74). It would have reduced further under the Pharmaceutical Policy 2002; however, the matter remains unresolved due to the Supreme Court order.

The above inference would very clearly show that there is a strong case for adopting measures other than direct price control - measures which are less regressive and less cumbersome, and yet effective enough to exercise a fair amount of check on the price increases of drugs. As has been the thinking in the past, and as mandated by the Supreme Court, there is

need to focus on the essential medicines as these are the widely used drugs across the country in the public health system.

The opening up of the economy since 1990, and the TRIPs agreement effective from 1995, have resulted in withdrawal of support available from trade and economic policies. These developments necessitate complete reorientation of the aims and objectives of policy, since the international situation has now far greater impact on the domestic market. Therefore, apart from meeting the indigenous requirement of drugs, focus has to be on exploring the export potential also.

1.2 Present status and the need for change

It is a matter of indisputable fact that *India today has some of the lowest drug prices in the World*, not only compared to developed countries but relative to other developing countries as well. A price comparison of a limited sample of drugs given in Table-1 illustrates this point forcefully. Even if allowance is made for selectivity in the choice of drugs and the brands whose prices have been picked up for comparison purposes, there can be no doubt that drug prices in India are on the average about a half to a third of those prevailing in Pakistan and Indonesia and one-fifth to one-seventh of those in the developed countries.

Table 1: Pharmaceutical Prices in Selected Countries

(Indian rupees)

Drug	India	Pakistan	Indonesia	USA	UK
Cipr_floxacin 500 mg tabs	29.00	423.86	393.00	2352.35	1186.70
Norfloxacin 400 mg tabs	20.70	168.71	130.63	1843.56	804.78
Ofloxacin 200 mg tabs	40.00	249.30	204.34	1973.79	818.30
Cefpodoxime Proxetil 200 mg tabs	114.00	357.32	264.00	1576.58	773.21
Diclofenac Sodium 50 mg tabs	3.50	84.71	59.75	674.77	60.96
Ranitidine 150 mg tabs	6.02	74.09	178.35	863.59	247.16
Omeprazole 30 mg caps	22.50	578.00	290.75	2047.50	870.91
Lansoprazole 30 mg capsules	39.00	684.90	226.15	1909.64	708.08

Source: Joint submission made by Indian Drug Manufacturers Association (IDMA) and Organisation of Pharmaceutical Producers of India (OPPI)

It also has, for the most part, a highly competitive market structure, with nearly 10,000 companies engaged in the production of bulk drugs and formulations as per the Mashelkar Committee. Of these, nearly 350 are in the organized sector and may be capable of independent marketing of their products. Nevertheless, *there is evidence of market concentration*. For the Indian pharmaceutical sector as a whole, the share of the top 10 companies is around 30 per cent, which is not significantly different from the 35 per cent market share of the top 10 global pharmaceutical companies in the total world market. The situation is considerably worse in some

therapeutic areas where the top two or three companies alone account for more than 50 per cent of the market share.

However, it has not always been the case that India has had a low priced competitive market structure. In fact until the early 1970s, there were relatively few drug companies in the country, and drug prices in India were nearly at par with international prices. In purchasing power terms, therefore, India was considerably worse off than most other countries. There are three main policy interventions, other than the various drug policies discussed above, which took place in the early 1970s that are responsible for the present competitive structure and low prices:

- Shift away from product patent to process patent allowing new Indian drug producers to emerge.
- FERA and MRTP Acts restricting expansion of large firms, especially MNCs, thereby creating space for new entrants.
- Pervasive price controls reducing cross-subsidisation by multi-product large firms, and thereby preventing predatory behaviour leading to market dominance.

There is a tendency to ascribe the emergence of the Indian pharmaceutical sector only to the shift from product to process patent. However, review of the international experience shows that India was by no means unique in adopting this measure, and a large number of developing and developed countries had done so at roughly the same time, but with nowhere near India's success in terms of developing domestic manufacturing capabilities. Nor is it the case that the low purchasing power in India was instrumental in drug prices being kept lower than in higher income countries. Our own experience in the pre-1970 period and the high prices that continue to prevail in other developing countries with comparable levels of per capita income are sufficient proof that *pharmaceutical companies do not necessarily tailor-make their pricing strategies to suit the purchasing power of their potential clientele* defined in its widest sense. It appears, therefore, that what distinguishes the Indian experience from that of other countries is the collateral policies which were adopted at around the same time.

It is ironic that some of the ostensibly most anti-competitive policies actually led to the emergence of a highly competitive domestic industry and to the enviable position that India enjoys internationally in terms of pharmaceutical prices. The reason for this is that the pharmaceutical industry by its very nature is non-competitive, and requires active public intervention to ensure competitive outcomes. Furthermore, it also has to be recognized that Indian prices reflect the barriers to trade faced by Indian pharmaceutical companies in accessing external markets until very recently, which forced them to adjust to the domestic market conditions. Thus, anti-competitive behaviour prevailing in international markets has proven to be a blessing in disguise for the Indian consumer - yet another irony.

However, none of the above three conditions obtain today. The country has shifted back to a product patent regime. FERA and MRTP have effectively been scrapped. And pervasive price controls are becoming increasingly more difficult to administer. It is, therefore, very *likely that the Indian pharmaceutical sector will gradually acquire market characteristics similar to those obtaining in other countries - namely, high degree of market concentration across the industry. with correspondingly higher prices.* While it is no doubt true that with the coming of age of large Indian pharmaceutical companies, the dominance of the MNCs may not be re-established to the same degree as earlier, but this may be cold comfort to the consumers. As Indian companies steadily establish their presence in the international market, there is likely to be a certain degree of convergence between their domestic and export prices, to the detriment of the lower income groups in the country. Only companies who see their future as being inextricably linked to the domestic market will retain sensitivity to the affordability issue.

Such an eventuality can have disastrous consequences in the Indian context. Unlike in most other countries, where public healthcare and other forms of subsidized or prepaid coverage account for nearly 80 per cent of healthcare spend, out of pocket expenditures on health are close to 80 per cent in India. Therefore, any increase in any component of healthcare costs tends to fall across a very wide cross-section of our people, who have no fallback options. This is one of the principal reasons why international experiences and price control models are not readily adaptable to our situation.

It is, therefore, necessary to evolve a strategy which would meet the twin objectives of ensuring that the relative price of drugs does not deviate sharply from the pattern and growth of purchasing power in country, on the one hand, and the Indian pharmaceutical industry continues to maintain its robust growth path, on the other. This does not mean that the need to provide institutional healthcare support to the relatively poor, whether through public or private means, is obviated. It merely reflects a recognition that such interventions may take time to establish and become effective. Devising such a strategy requires an understanding of the nature of the market for pharmaceuticals and the dynamics of price and output formation.

Chapter 2

ISSUES AND STRATEGIC APPROACH

2.1 Characteristics of the pharmaceutical market

The single most important characteristic of the pharmaceutical sector is that it is perhaps the only class of products in which the consumer - i.e. the patient - has virtually no choice that he/she can meaningfully exercise. The decision on what medicine must be taken is made by the doctor or, in some circumstances, the druggist/pharmacist. Thus, *the normal dimensions of consumer choice - product, price and quality - simply do not exist*. The only available choice is whether to take the prescribed medicine or not.

The 'choice maker' in this case, whether the doctor or the pharmacist, has no incentive to be price-sensitive, and indeed may have perverse incentive structures. The doctor's decision at the most ethical level would be based on the best treatment of his/her patient, and he/she should neither be expected to know or even care about the cost of treatment, except in cases where the patient's economic condition patently rules out a specific course of treatment. Even in such situations, the choice is not likely to be between alternative brands of the same active pharmaceutical ingredient (API), but between alternative APIs within the therapeutic category. It is not reasonable to expect that the doctor will, or even should, be aware of the various brands of the same API available in the market, let alone keep himself/herself updated on the market prices of the huge range of formulations across the various therapeutic categories. In this situation of limited information, it is rational to expect prescriptions to be driven by the promotional efforts of the drug companies, whether ethical or not. Since the intensity of such promotions is resource-driven, they are likely to be positively correlated to the price of the drug or to the resource base of the company.

However, there is evidence that in India there is distinct market segmentation between different brands of the same API, usually on a locational basis, with prescription behaviour in terms of brand selection being driven by the economic status of the patients in the catchment area. Although there is no rigorous research which conclusively proves a positive correlation between average incomes and the price of the most commonly prescribed brand, there is sufficient anecdotal evidence. This makes perfect economic sense since *new companies coming into a particular API are likely to position themselves to address a target population which has been excluded by the incumbents*. Indeed, there is also evidence that the same company may market more than one brand of the same API at very different price points. This kind of behaviour, whether by incumbents or by new

players, in essence transfers the bulk of the "consumer's surplus" to the producers or marketers.

This, in itself, is not necessarily a bad thing, since first of all it provides space for new entrants. Second, it ensures that a drug is available to a much wider range of patients than would have been the case if only a single price point were to be used in all markets across the country. The available data suggests that the range of prices within which different brands of the same API are currently marketed can be anywhere between 2: 1 and 10: 1. However, the downside is that such segmentation can never be perfect, and consequently it may well be the case that a large number of poor patients may be prescribed a drug which is either beyond their economic capacity or therapeutically inferior. It is, therefore, of the highest importance that *doctors are provided with information support systems which will enable them to prescribe in the most case-sensitive manner possible*. Whether they do or not would of course depend upon their ethical standards, but lack of information should not be the cause.

As far as the pharmacist is concerned, who is expected to know the prices of different brands, the incentive structure is actually perverse since it is rational to push brands which have higher margins. Even in the case where retail margins are fixed as percentage of the price, a higher price will be associated with a higher absolute margin. *Thus, controls on retail margins are unlikely to serve the purpose of moderating prices, and may in fact push lower priced products out of the market*. This is not a phenomenon peculiar to drugs, and a retail margin-driven marketing strategy has been effectively used in a range of products where quality differentiation is an important factor in consumer choice. However, in most cases where consumer sovereignty exists, such strategies tend to be short-lived since there are other equally, if not more, effective ways of affecting consumer behaviour. In the case of drugs, such alternatives are not available and, therefore, there is a tendency for such strategies to be perpetuated for extended periods of time.

Secondly, the prevailing system for drug certification is completely opaque as far as the therapeutic quality and effectiveness of different brands are concerned, certainly for the patient and also possibly for doctors. The Indian Pharmacopoeia (IP) certification, or its equivalent in other countries, only attests to the quality of the API in most cases, and not to the 'quality' of the formulation, which is what the patient actually purchases. In fact, the Significance of the IP mark is lost to all but the most discerning due to the lack of any active consumer awareness programme. However, since different formulations of the same API are perceived to have different levels of effectiveness, perhaps quite rightly since there are usually differences in the excipients or the drug delivery technology, the lack of adequate information and awareness may lead to *'adverse selection' behaviour, whereby a higher price is associated with better 'quality'*. Active brand promotion by the drug companies contributes to this process in no small measure, and the government has done practically nothing in this regard. The introduction of

good manufacturing practices (GMP) through Schedule M is eminently desirable in itself as it addresses the issue of consistency and assurance of quality. However, the level of regulatory enforcement of GMP through intensive GMP audits as well as the level of competence of GMP inspectors varies considerably in the country. Its main focus is also consistency rather than assurance of therapeutic effectiveness.

The reduction in prices of drugs observed over time appears to arise partly from price competition between alternative brands of the same API, but also from two other sources. First, competition between alternative APIs within the same therapeutic category, whereby the emergence of newer, more 'effective' alternatives force drug companies to reposition their older products to cater to a lower income category. Second, growth in incomes can possibly change the price elasticity of demand sufficiently to justify addressing a larger market segment by lowering of prices. It should be noted, however, that the latter effect depends critically upon the distribution of income growth between different income segments. In fact, if growth leads to an increase in income disparities, drug prices may go up rather than down. In the Indian context, for instance, historically there has been a reduction in income inequalities, which may have been a major cause of the observed low drug prices in the country. In recent years, however, there is evidence that the trend has changed, and income distributions are worsening. *The rapid growth in the size and incomes of the Indian middle-class in recent years permits significant increase in drug prices without running into affordability and market size issues, which existed in the past.*

The role of the introduction and diffusion of newer and better drugs as perhaps one of the prime mover in lowering drug prices has implications which need to be considered carefully in the Indian context. Until now, in the absence of product patents, new drugs could be introduced at considerably lower prices, which then had strong knock-on effects on the prices of existing APIs in the same therapeutic class. In the future, this process is likely to be much weaker since the newer patented drugs should be expected to follow market skimming strategies, which has been the trend in the rest of the world. Consequently, the prices of existing drugs may not experience the kind of pressure as earlier unless the entry point price is pitched at an appropriate level. Although drug companies are expected to be sensitive to price-income considerations prevailing in the specific market, the likelihood of an affordable entry price will depend largely upon whether the company concerned already has a significant presence in that particular therapeutic category. In all probability, *new APIs will be introduced by relatively large, multi-product firms, which will not be inclined to poach on their existing client base and will, therefore, tend to follow a high price-low volume approach, at least initially.* This would be particularly true of MNCs, which would have to be sensitive to their international reference price and third country repercussions.

On the other hand, the impetus given to domestic research and development (R&D) by the product patent regime may accelerate the pace of

discovery and introduction of new molecules by companies which do not need to worry about the international dimensions of their pricing strategy, but this is likely to take time and cannot entirely be relied upon, since the innovator may perceive the external market as being more important to his interest than the domestic. Nevertheless, in this context, the processes for grant of patents and for drug approvals in the country are of the highest importance, and it is necessary that these be streamlined to minimize time delays. In fact, the immediate danger is that most Indian companies may come under severe pressure and their resource availability for R&D may get eroded until such time as they reconfigure their product portfolios. It is, therefore, important to ensure that *the pricing and marketing regime consciously takes into account both R&D needs as well as the transitional arrangements* that may be necessary.

The diffusion of new drugs, or even new formulations, is as important as their introduction, and requires considerable expenditure in educating the medical fraternity about the product characteristics and points of differentiation from existing alternatives. It is quite natural, therefore, that the promotional expenditures of drug companies are significantly higher than that of most other products, and which serve a very important function. However, there is a very thin line between legitimate promotion, on the one hand, and market manipulation or anti-competitive behaviour, on the other.

It should be clear, therefore, that in the market for drugs and pharmaceuticals, consumer sovereignty, which is at the heart of all competition-based policy, simply does not exist and the role of price competition is, therefore, very limited indeed. In this respect, if no other, the pharmaceuticals sector is completely different from practically all other commodities, and thus the strategies and policies normally used to promote industrial activity in other sectors simply do not apply in this context. It is little wonder then that almost all countries, at one time or another, have found overt price controls to be the most attractive, and indeed the most effective, method for ensuring the availability of drugs at affordable prices. There is no doubt that a well designed price control mechanism can not only moderate the prices of critical drugs, but actually increase their supply as well. Nevertheless, price controls appear to have fallen out of favour in recent years due to the increasing complexity of the pharmaceuticals sector and the need to provide drug companies the flexibility to meet emerging market challenges.

However, it needs to be recognized that intense competition in the Indian Pharma sector, which is basically multi-source in nature, has in the past responded to the general paying capacity of Indian population, with the consequence that the prices of drugs manufactured and marketed in India have remained among the lowest in the world. Although this may change in the coming years, for reasons that have already been discussed in the preceding chapter, the strategy to moderate drug prices in the country would have to take cognizance of this fact.

2.2 The Strategic Approach

Arising from the above discussion, the broad strategy for evolving a market-based system which would ensure the availability of drugs at reasonable prices to all sections of the population rests on the following fundamental principles:

1. Domestic production of bulk drugs should be encouraged to the extent possible.
2. Space for the emergence of new pharmaceutical companies should not be curtailed.
3. Focus should only be on 'the prices of formulations, i.e, the products actually used by the consumer .
4. Intra-industry transactions should not be distorted.
5. All regulations should be transparent and non-discriminatory. Choice and exercise of consumer sovereignty should be promoted, Provision
6. should exist for strategic interventions.
7. Interests of the economically weaker sections should be protected.
- 8.

There are three broad options available to moderate the price of drugs and to subserve the above principles without resorting to overt price controls:

- (a) Price regulations, involving monitoring and negotiations.
- (b) Creating conditions for a competitive market structure in which the existence of choice and exercise of consumer sovereignty can lead to price competition.
- (c) Encouraging emergence of countervailing forces on the demand side.

In the Indian context, as in many other countries, a combination of all three options will have to be evolved, given the wide variations in disease conditions in different parts of the country and the disparate nature of the people in terms of income and awareness. These options are discussed in detail in the following chapters.

Chapter 3

REGULATION OF PRICES

There is a legitimate fear that with the introduction of product patents in India, the prices of existing drugs which get covered under patents will tend to rise sharply. In the case of new patented drugs, the prices are likely to be high *ab initio*. In addition, essential drugs which are not covered under the Drugs Prices Control Order (OPCO) could also display rising prices if market dominance exists or comes into existence over time. It is, therefore, imperative that a *mechanism be established whereby the government can monitor the prices of drugs on an on-going basis and either impose price control or call the manufacturers in for negotiations* if there are any untoward or unjustified price increases. There is a point of view that holds that price regulations are not necessary for drugs and that competition should be able to provide the necessary discipline. The Task Force does not entirely agree with this point of view on the grounds that any sector in which consumer sovereignty is abridged for any reason needs to be regulated. As has been argued in the previous chapter, there is little, if any, consumer sovereignty in the pharmaceuticals sector.

The first, and most important, point that needs to be noted in this connection is that *no. price negotiation mechanism can be effective unless there is a credible threat of price controls being imposed and enforced*. Therefore, the OPCO or its equivalent must continue to exist with adequate provision for imposing price control as and when deemed necessary in public interest. It is also essential that the principles underlying price controls and/or negotiations be clearly articulated and benchmarks established.

3.1 Shortcomings of the Existing Price Control Mechanism

In so far as price control legislation is concerned, the present situation is far from satisfactory. Since the DPCO is issued under the Essential Commodities Act (ECA), the only real penal provision available under it is prosecution leading to imprisonment. While criminal action and imprisonment is appropriate for controlling production and sale of spurious and sub-standard drugs or for deliberate hoarding, it is excessively draconian for pricing issues. On the other hand, it is not even entirely clear whether this provision can at all be applied to corporates, since a body corporate cannot be imprisoned and neither can its functionaries unless specific provisions to this effect exist in the law.

Moreover, the provisions requiring manufacturers to provide their pricing data for regular monitoring under the ECA, or the OPCO, are not effective. Although the DPCa does provide for regular submission of price

lists and other details, it is mainly observed in the breach. Consequently, monitoring compliance of price control orders involves market surveys, which are both tardy and expensive.

The present basis and methodology for imposition of direct price controls also need to be considered afresh. The existing system is based on criteria relating to turnover and market dominance in specific APIs, and is implemented through detailed examination of cost structures of manufacturers. Both these need to be reconsidered.

In the first instance, it is not clear how much distortion is caused by selecting individual APIs for price control from within a wider therapeutic segment rather than the therapeutic class itself. Second, the choice of the API on the basis of turnover is questionable since, as has been argued, it simply ignores market dynamics, on the one hand, and may not reflect the 'essentiality' of the drug, on the other. As things stand, for instance, of the 74 drugs presently under price control (about 10 of total APIs in the country), only 15 are present in the National List of Essential Medicines (NLEM), which is just over 4 of the total number of drugs in the NLEM. It is not clear, therefore, what purpose is being served by such price controls, except to hold down the prices of a few drugs.

An effective drug price control system should be more strategic in nature. *It should select APIs which are essential in some sense and will have the maximum cascading effect on the entire therapeutic class.* More often than not, these will be the newer drugs on the market which may not, and in fact probably will not, have the highest turnover, but will display high degree of market concentration.

Fixing prices on the basis of costs is both intrusive as well as prone to manipulation. Often this may be inescapable, but a preferable alternative would be to *determine controlled prices on the basis of benchmarks.* The price of the closest therapeutic alternative existing in the market readily suggests itself as an option, and the main consideration then becomes the extent of the margin that would be permitted. This of course presumes that therapeutic equivalence has been established, and systems would need to be in place for doing so. There WOULD, however, be a problem with 'blockbuster' drugs for which no therapeutic equivalent may be available.

The main weaknesses of the current DPCO, however, lie elsewhere. First, it is overly focused on the bulk drug, for which detailed costing and price fixation is done. The prices of formulations are determined on a more *ad hoc* basis based on the price fixed for the bulk drug. As a consequence, its impact falls disproportionately on the bulk drug manufacturer, and there is evidence of several *bulk drugs going out of production because of such price controls.* This is detrimental to the interests of all stake-holders. Equally importantly, since the bulk drug manufacturer is constrained to sell at a fixed price, he is likely to always give preference to an existing buyer rather than to a potential new entrant. This *constrains the emergence of new companies*

and formulations in the price-controlled segment and is inherently anti-competitive.

Second, since the controlled prices of formulations of a particular API are determined on a "lowest common denominator" basis, they tend to be clustered within a narrow band. This allows virtually no space for a new entrant to come in at an uncovered price point. As a result, *production activity and competition in the product segment tend to stagnate.*

Third, the experience in recent years has been that *circumventing price controls is extremely easy* through non-standard combinations, strengths, and other such innovations. In addition, there is a tendency for prescriptions to move away from controlled drugs to non-controlled drugs in the same therapeutic class. The consequence on the quality of treatment is not known, but it is almost certain that the consumers end up buying higher priced products.

On the positive side, para 10(b) of the *DPCO, 1995 empowers the government to impose price controls even on non-scheduled drugs*, which has been used quite effectively through a price monitoring system currently in place. The guideline used for this purpose is a permissible price increase of up to 20 on an annualized basis. Although this provision has not really been used, there is evidence that its presence has moderated the pace of price increases in drugs. However, a permissible annual increase of 20 leaves open the possibility of drug prices doubling every 4 years, which is clearly not in the interest of the country.

Thus, in its present form, the *DPCO is not very effective either in its coverage or in subserving its intent*, or in terms of its broader impact on encouraging production of essential drugs and promoting a competitive framework. The only purpose the *OpEO* may serve at present is to *control* the pricing of the scheduled drugs, and to instill a sense of fear which may have a limited impact on the pace of price increases in the drug industry. In such a situation, *there is a compelling case for providing an alternative system and legislation which could serve the purpose without taking recourse to extreme measures.* The objective of such an *alternative* regulatory framework should be to ensure sufficient space for competitive forces to play their role without running the risk of a systemic rise in prices. It is also necessary to reconsider the monitoring and enforcement provisions so that they are effective without being draconian. There are a number of alternative penalties that can be thought of, such as fines, compounding of offences, temporary or permanent withdrawal of production or distribution licences, etc:

3.2 Alternative System of Price Regulation

In the opinion of the Task Force, therefore, direct price control in the sense that it is understood today is neither necessary nor effective. An

alternative system of price regulation is, therefore, proposed, which has the following features:

- Price regulations should be imposed not on the basis of turnover, but on the 'essentiality' of the drug and on strategic considerations regarding the impact of price control on the therapeutic class. This must be a dynamic process.
- Price regulations should be applied only to formulations, i.e. the medicine actually used by the consumer, and not to upstream products such as bulk drugs. In other words, intra-industry transactions should not be controlled unless there are compelling reasons for doing so.
- There should be no attempt to impose uniformity in prices of regulated drugs on a lowest common denominator basis, and only a ceiling should be prescribed. Companies should be free to decide their pricequantity configuration within the prescribed price limit.
- The ceiling prices of regulated drugs should normally not be based on cost of production, but on readily monitorable market-based benchmarks.

The National List of Essential Medicines (NLEM), 2003 should form the basis on which the selection of drugs for active regulation is made. The NLEM contains such medicines that satisfy the priority health needs of the country's population. These are intended to be available within the context of a functioning health system at all times in adequate amounts in the appropriate dosage forms. These medicines have been selected by an Expert Core Committee constituted by the Director General of Health Services (DGHS) out of the WHO model list of essential medicines, Essential Drugs Lists of various States, medicines used in various national health programmes and emergency care drugs. There are two categories of medicines in the NLEM, 2003 - the core medicines and the complementary medicines. The complementary medicines denote those medicines which may be needed when the core medicines are not readily available or they may be required in specific situations or locations for well founded reasons.

Although the NLEM is specified in terms of APIs and a few fixed-dose combinations, no *price regulation should be applied to the APIs themselves, but to all formulations made therefrom*. To start the process, the government should announce the ceiling price of all formulations based on these 354 drugs (APIs and fixed-dose combinations) contained in the NLEM on the basis of the weighted average prices of the top three brands by value of single ingredient formulations prevailing in the market as on the latest date for which market data from ORG-IMS is available *prior* to the announcement of the policy. In cases where there are less than three brands, the average of aU existing brands would be taken. Since the ORG-IMS data relate to dealers' prices, a standard retail mark-up of 20 may be provided as per the existing arrangement in the industry.

The reference product (formulation) should be specified in terms of specific strength and pack size for each product which would form the basis for the ceiling price determination. The price ceiling, however, would be specified on a per dosage basis, such as per tablet/capsule or standard volume of injection.

The ceiling prices of all other strengths and dosages would be determined on the basis of a standard formula, which would be related to the ceiling price of the reference formulation. The suggested formula for this purpose is as follows:

$$P(s) = P^* \cdot [1 + a \cdot \{(s - s^*)/s^*\}]$$

Where: P(s) = price ceiling for strength s
P* = price ceiling for reference strength s*
s = strength in terms of API content
s* = reference strength
a = constant such that 0 < a < 1

The constant 'a' in the above formula recognizes that the cost of production of a tablet or injection decreases as the strength is increased. However, it is also recognized that the other 'costs', such as promotional expenses and profit margins, which constitute a substantial fraction of the price of a formulation, do not exhibit the same behaviour. Therefore, great care needs to be taken to ensure that 'a' is not chosen in a manner that incentivises companies to produce non-standard strengths in order to maximize profits. Preliminary exercises carried out by the Task Force indicate that the appropriate value of 'a' is 0.8 for tablets/capsules and 0.7 for injectibles. These may be used to begin with, and further refinements can be carried out overtime.

Prices of formulations should be allowed to move freely so long as the ceiling prices are not breached. Price relaxations for higher ceilings may be permitted for non-standard delivery systems, packaging and pack sizes through applications to a negotiations committee to be set up for this purpose, which then should become applicable for all similar cases. The NPPA already has standard mark-up norms that are allowed in most such cases, and these should be automatically applied before the case is referred to the negotiations committee.

In the case of formulations which involve a combination of more than one drug in the NLEM, the ceiling price would be the weighted average of the applicable ceiling prices of its constituents. For formulations containing a combination of a drug in the NLEM and any other drug, the ceiling price applicable to the essential drug would be made applicable. However, the company would be free to approach the price negotiations committee for a relaxation of the price on the basis of evidence proving superior therapeutic effectiveness for particular disease conditions.

Although the above may take care of limiting future price increases, it leaves open the question of further moderation of prices of existing essential drugs. It is, therefore, suggested that a *reference price should be derived from the prices quoted in the bulk procurement by government and other agencies*. This is in fact the system which is effectively in operation in countries which have strong and wide-spread public health-care systems. Recognising that such prices are likely to vary from order to order and location to location, an average would need to be used. In addition, a mark-up will need to be allowed to cover trade margins and other distribution costs. An analysis of the available data suggests that a 100 margin should be ample.

However, the Task Force recognizes that the bulk purchase systems prevailing in India leave a lot to be desired, and the prices derived from them may not reflect the true prices of quality drugs. There is considerable evidence that the systems are riddled with all manner of malpractices, such as sub-standard or under-strength drugs and short-supplying. It is, therefore, not possible to use these prices immediately, despite the fact that there are a few notable examples of excellent systems of bulk purchase, such as in Tamil Nadu and Delhi, and in institutions like the Armed Forces, Employees State Insurance (ESI) and some hospitals. Furthermore, it needs to be recognized that any such price monitoring strategy based on bulk purchase data may compromise the tender processes in bulk purchases. As it is, there is evidence of cartelization and other undesirable practices in drug tendering, and these are likely to become worse. It is, therefore, of the highest importance that the benchmarking is not based on a fixed set of bulk purchase tenders, and the tendering systems are properly designed. Suggestions in this regard are given later in this Report. *Until such time there is reasonable assurance that the bulk price systems are reliable and reflect quality drugs, such benchmarking should not be used or should be confined only to such bulk purchases which meet certain minimum standards for tender procedures.*

Since it would take time to streamline the bulk procurement procedures and to generate reliable data on such bulk purchases prices, the *ceiling prices should be allowed to rise on the basis of the wholesale price index for manufactured goods* (this would be a subset of Wholesale Price Index (WPI) and is readily available from the Ministry of Industry). This could be done twice a year on pre-specified dates.

The determination of the ceiling prices and ensuring compliance should not be discretionary and should be completely transparent. The regulator should set up a computer based system which would scan the price data provided by companies against the ceiling prices determined as above and identify formulations which breach the relevant price ceiling. The company manufacturing or marketing such a product would be required to reduce its price or to face penal action.

Companies should be permitted to represent for any price increase on valid grounds and with appropriate documentation, which should be considered by the negotiations committee and then, if accepted, become applicable to the entire class of products.

There are two issues which are left unaddressed by the above proposal. First, the ORG-IMS data at present covers about 246 of the 354 items contained in the NLEM. Of the remaining, about 40 are not directly purchased by individuals and are primarily used in hospitals with little market sales, for which there may be no urgency to announce ceiling prices since they are mostly procured through bulk purchases. The industry has also agreed to make available these items at 50 of the market price to the government. The prevailing market prices of the formulations of the remaining 60 odd drugs would have to be collected immediately through a quick market survey before the policy is put into effect.

Second, 15 of the drugs presently under price control through opo 1995 are also contained in the NLEM, for which free market prices will simply not be available. Since the ceiling prices are to be determined on the basis of existing prices, the present controlled prices will become the ceiling for these drugs. It is recognized that this is iniquitous and may be distortive, but there is little that can be done at present. It is, therefore, suggested that for all such drugs the bulk purchase price, if available, should be immediately examined to consider whether the ceilings should be adjusted upwards.

Finally, it is extremely important that *the NLEM should be revised periodically, say every 5 years*, in order to reflect new drugs and significant changes in pattern of drug sales within the therapeutic categories, for which a permanent arrangement needs to be made by the Department of Health.

3.3 Price Ceiling vs, Price Freeze

During the consultation process, it emerged that the industry would prefer to have a freeze on the existing prices of all formulations produced from APIs in the NLEM with provision of annual escalations rather than the ceiling price that is being recommended by the Task Force. It is claimed that this measure would serve the same purpose as the price ceiling, with one significant advantage - the prices of all formulations would remain stable as against the possibility of increases in the prices of those formulations which are initially below the ceiling price. It has been claimed that aU prices will tend to move up to the ceiling as soon as the government announces the ceiling price.-

The Task Force has considered this proposal in all seriousness, and is of the view that the two proposals are not similar in terms of their impact. In this regard, the following points need to be made:

- There is no reason to believe that under the ceiling price system, aU prices will tend to converge to the ceiling. Each company typically

selects a particular price niche in which it is competitive and is unlikely to change it casually. If it does so, it is likely to lose heavily and will return to its original price point. Moreover, if a particular price point is vacated by an incumbent, it is quite likely that a new company will fill the niche.

- The price freeze proposal is inherently anti-competition since it does not allow any flexibility to the companies to adjust to market dynamics. Thus the market structure for the existing products gets frozen almost permanently.
- A price freeze can apply only to existing products and not to any new product. Therefore, it leaves open the possibility of the freeze being easily circumvented by small changes in the formulations or even in the brand names. Such behaviour could completely negate the intention of the policy.

In view of the above points, the Task Force is of the opinion that *the price freeze proposal has serious drawbacks, and does not provide an acceptable substitute for the price ceiling approach.*

3.4 Price Monitoring and Price Negotiations

There is a legitimate fear that price regulation of only a selected basket of drugs can lead to a switch in production and prescription behaviour away from these drugs towards those which are not covered. This is certainly a possibility since the NLEM is based on specific APIs and not on therapeutic categories. Thus there is ample space for doctors to address disease conditions without necessarily prescribing the drugs under price ceilings. The likelihood of this happening is less under the proposed system than at present since it does not disturb the existing market equilibrium in any significant manner. There is, therefore, no rational reason for companies to change their marketing strategies in the immediate future. Nevertheless, in the longer run, it is possible that the relative profitabilities may alter sufficiently to induce such switching behaviour, and some provision will need to be made.

This aspect can be addressed through a price monitoring mechanism. The key element of any price monitoring system is the benchmark or reference price that is used. There is a suggestion that the current market price of every formulation plus an annual percentage escalation could serve the purpose. The danger in this is that the escalation factor may become the basis for all companies to raise prices on a regular basis, thereby defeating the very purpose of such a mechanism. Cost-based benchmarking too does not recommend itself due to its intrusiveness and the delays that are involved.

In the case of drugs not contained in the NLEM, it is suggested that three separate categories be distinguished:

1. Isomers of APIs in the NLEM - these should be brought under the same ceilings as applicable to the NLEM molecule.
2. Existing drugs falling into a pre-specified list of therapeutic categories - intensive monitoring should be carried out for all formulations in specified therapeutic categories. Any significant variation in the prices (say above 10 per cent annually) would be identified for negotiation. The therapeutic categories which may be considered for such treatment in annexed.
3. All other drugs should be completely free of price regulations, and only regular monitoring should be done. Only in cases where there is evidence of unusual price escalations, significant change in prescription behaviour or public complaints should there be any regulatory action.

The advantage of this method is that normal market behaviour is dynamically taken into account, and to facilitate this, a half-yearly revision of the benchmarks may be considered.

3.5 New and Patented Products

The above suggestions relate mainly to existing formulations, and it is necessary to lay down the guidelines for new drugs. As has already been argued, one of the main pressure points for moderating the price of drugs is the entry of new products. However, for this role to be played effectively, it has to be ensured that the prices of new drugs are not completely out of line with the existing.

Any new formulation based on existing APIs would be required to submit its intended entry price along with application for marketing approval, which would be granted only if the indicated price is consistent with the relevant ceiling price, if applicable. If there are no price ceilings, i.e. the new formulation is not based on an API contained in the NLEM or its isomer, the proposed entry price should be accepted automatically and then subjected to the disciplines indicated above wherever applicable.

All patented drugs and their formulations should compulsorily be brought under price negotiation prior to the grant of marketing approval. Failure of such negotiations should then invite either price control or compulsory licensing. There are a number of alternative ways of ensuring that the price of a patented drug reflects the purchasing power in the country and is not confined only to the highest income groups. The use of purchasing power parity (PPP) indices has been suggested, for instance, and there are other alternatives such as the ratio of per capita incomes. However, it is felt that it would be preferable to benchmark the prices of new patented products to the prices prevailing in the domestic pharmaceuticals market, and not to any general measure of prices or incomes. This is likely to distort the relative prices much less than any other method.

The other dimension of benchmarking is the foreign price that is used for the purpose. The various suggestions that exist at present usually depend upon market prices in selected foreign markets, which may not actually serve the purpose. It is necessary to recall that most other countries have a very substantial proportion of their pharmaceutical usage going through either the public healthcare system or through reimbursements. The prices used in these cases arise either out of negotiations or from bulk purchases. Since much of the work is already done, India should take advantage of this information in its negotiations. Much of this data is not readily available in the public domain, and arrangements will have to be made with selected countries to obtain the requisite information.

It is, therefore, suggested that all applications for marketing of patented drugs should be required to contain comprehensive information on not only the market prices charged in other countries, but more particularly the prices negotiated for reimbursement or bulk purchases. *The reference prices to be used for such negotiations should be based on the premium enjoyed by the drug in the lowest priced market abroad compared to its closest therapeutic equivalent in that same country. This premium can then be applied to the corresponding price of the same therapeutic equivalent prevailing in the domestic market to determine the reasonable price in Indian conditions.* In other words, what is being suggested is that patented drugs should be allowed the premium it commands elsewhere, but applied to the prices prevailing in India.

3.6 Information needs for price regulation

In order to make the proposed system of price regulation effective, a number of collateral measures need to be implemented. First, *regular reporting of prices (MRP) and any changes therein must be made mandatory* for all essential drugs, and eventually for all drugs. At present there is no legal provision for compelling such disclosure from companies, and the experience has been that most companies do not provide such data on a regular basis. It is necessary, therefore, to provide a legal basis for compelling such disclosures with appropriate non-criminal penalties such as temporary revocation of licence. Second, *there must be standardization which will enable meaningful price comparisons.* This has two dimensions: (a) standardization of pack sizes and strengths; and (b) uniform MRP for the entire country. The first will need to be imposed legally so that violations are punishable. The second should be feasible without too much problem since the VAT rates are now more or less common between states.

Mandatory price reporting does not, however, do away with the need to have a well-designed system for *ex-post* price monitoring in the market. In fact, it becomes all the more important, and its periodicity may have to be increased. The present system is too weak and needs to be strengthened significantly.

The availability of the price data should be ensured by the measures described above, but additional information would need to be generated on at least other two dimensions. First, for establishing market dominance or producer behaviour, it would be necessary to *establish a prescription monitoring system* whereby the trends in specific brands or formulations being disproportionately prescribed either nationally or even regionally could be tracked. Second, there would have to be a *system in place to measure the availability of drugs* on an on-going basis in order to assess whether artificial scarcities are being created.

Chapter 4

ESTABLISHING CONSUMER SOVEREIGNTY

The most durable and effective method of ensuring that competition plays the same role in the drug industry as in other sectors is to establish consumer sovereignty by creating conditions for proper exercise of consumer choice. Internationally, this has been attempted through the active promotion of generics by governments. The experience appears to have been mixed. In most countries, even when there has been good governance and active cooperation of the medical profession, generics still occupy a relatively minor share of the drug market. In the Indian context, despite the fact that it is claimed that about 5 of pharmaceuticals sales are generics, the fact is that true generics, i.e. drugs which are sold on the basis of the API name, is practically non-existent.

There is considerable confusion regarding the nomenclature that is used in the pharmaceuticals industry. It is, therefore, important to clearly define some of the terms and the manner in which they are used in this Report.

Generic drugs:

(a) 'Generic' generic: These are single ingredient or fixed-dosage formulations which are marketed using only the name of the active ingredient or the purpose for which it is used (such as oral rehydration therapy (ORT) or vitamin B complex). In this report the term "generic" is used only in this sense unless otherwise qualified.

(b) 'Branded' generic: These are also single ingredient or fixed-dosage formulations of non-patented drugs, but are marketed under a brand name and not the chemical name. This is the sense in which the term 'generic' is used by industry, especially in reference to exports, but in this Report 'branded' generics are treated as part of branded products in general.

Proprietary drugs:

These are branded drugs which are proprietary to the company. There are 3 common bases for distinguishing proprietary drugs:

- (a) Patented drugs, single ingredient or otherwise
- (b) Non-standard combinations
- (c) Non-standard delivery systems

These are the drugs which are actively promoted by the companies and for which normal competitive pressures based on consumer choice simply do not apply.

The distinction that is drawn in India between branded products and generics has more to do with marketing strategies rather than on the nomenclature of the product. The so-called generics in India are pushed directly through retailers rather than through doctor's prescriptions. As a consequence, the generics in India provide high trade margins as opposed to the high promotional costs that are built into the pricing of the branded products. To make matter worse, even the so-called generics typically have specific brand names and the name of the API, although given the prominence required by law under the Drugs & Cosmetics Act, is not popularised in the manner that it should. This state of affairs tends to obscure the fact that true generics have no role to play at present in the Indian drug scene.

4.1 Promotion of Generics

Following international experience, India should also promote generics actively. There is, however, a difference in the manner in which it can do so, since most medicine purchases in India are by individuals as against institutions in other countries. Consequently, the role of public procurement or reimbursement in promotion of generics is relatively limited in the Indian context, and its popularization will have to be more market-oriented. In order to achieve this end, the following measures are proposed.

1. Public procurement and distribution of drugs through the public health system should only be for generic drugs. In this case, however, it may be acceptable to allow procurement of 'branded' generics as well, provided that the tender is based on the chemical composition and not on the brand name, and that the prescription and dispensing must also be in the API name.
2. Quality certification (such as GMP audit) may be provided free to drug manufacturers who produce only 'generic' generics (i.e. do not produce any branded formulation at all). Since generics do not command the kind of profit margins and premium obtained in branded products, the manufacturer's ability to afford such certification is limited, and needs to be augmented.
3. No control on price or distribution margins may be specified for non-patented generic drugs. This is essential since generics cannot rely upon doctor's prescriptions and have to operate through the retail pharmacist in the Indian context. Since there is a remote possibility of this provision being misused in the case of drugs which have a monopoly producer, these may be kept under the price monitoring system.

In order to bring about further consumer choice, it is necessary to consider *establishing the role of true generics through a process of compulsory de-branding of selected drugs*. This proposal may appear to be contrary to the intention of liberalizing the drug market in the country, but in actuality it aims principally towards commoditization of drugs so that brand and product differentiation do not completely obscure the role of price competition. In view of the fact that the reputation of the manufacturer is an important ingredient in quality perceptions, manufacturer identification cannot entirely be done away with. It is therefore proposed that for selected drugs a time bound process of de-branding should be instituted whereby the product shall carry the API nomenclature along with a manufacturer identification. It is recognised that a similar suggestion was made in the Hathi Committee Report, but it could not be implemented because of legal objections. Therefore, legal provisions for enforcing such commoditization and debranding will have to be brought about in order to move effectively in this regard.

Compulsory debranding, however, needs to be done with care, if undue disruptions are to be avoided. It is, therefore, suggested that *debranding should be considered only for prescription drugs* (Schedule H), and not for non-prescriptions. The idea is influence the doctor's prescription behaviour so that the patient can source the lowest price version in the market. Moreover, it is further suggested that this measure should be considered primarily in cases where there is evidence of clear market dominance, such as when 70 or more of the sale of the medicine concerned is accounted for by a single company.

It is sometimes claimed that this measure will: (a) lead to confusion due to the complexity of the chemical names; and (b) shift decisions from the doctor to the pharmacist, which would be detrimental to the patient's interest. The Task Force does not subscribe to this view. In the first place, it is difficult to believe that trained medical professionals would have more problems in remembering a single chemical name than a wide variety of brand names that they have to contend with at the moment. Second, if the quality assurance system is effective, there should not be any problem regardless of the manufacturer of the drug. There is of course always the possibility that the chemist may push the product of the company which gives him the highest margin, a phenomenon that has been noted earlier, but this is hardly an insuperable problem with appropriate consumer education and support from the medical community.

4.2 Control on pharmaceutical brands

In fact, the present system of brand approvals in the country appears inappropriate for the pharmaceutical sector. There are two kinds of problems that are commonly encountered. First, even a casual look at the list of brands existing in the Indian pharmaceutical sector reveals that a number of products have either the same brand name or names which are very similar both phonetically and written. Second, there are a number of recorded instances

where the composition of a particular brand has been changed without any change in the brand name - a phenomenon termed as '*misbranding*'. Both *these have the potential to cause immense harm through mts prescription and/or wrong dispensing.*

At present, brand names of drug products are approved while granting manufacturing licenses by the State authorities, which is not a desirable practice when marketing is done at a national level. It is, therefore, suggested that branding of drugs and other therapeutics should be brought under the central drug regulatory system. The drug regulator must be required to maintain a data base on brands and their compositions, and *all brand registration of drugs must compulsorily be approved by the drug regulator.* In particular, no change should be permitted in the composition of a given brand. In order to do so, the Drugs & Cosmetics Act, 1940 should be amended to provide the government or its deSignated authority the power to approve a brand name for a specific product, to prevent changes in the composition of a product marketed under an approved brand name and to determine the nomenclature under which a product can be marketed, if necessary, for all drugs and therapeutic products.

4.3 Quality assurance

The third issue has to do with quality. In order to provide the highest level of confidence about quality of drugs produced in the country, which is crucially linked to acceptance of generic drugs by consumers in general, the issue of quality and uniformity of enforcement over manufacturer of drugs in the country needs to be tackled on priority as suggested in the Report of the Expert Committee on 'A Comprehensive Examination of Drug Regulatory Issues including the Problem of Spurious Drugs' (Mashelkar Committee, 2003). The issue of sub-standard drugs needs to be tackled at the quality assurance and regulatory level, and not be used as a reason for perpetuating oligopolistic market behaviour.

It has already been mentioned that in India the only assurance of quality that exists in the consumer's mind is the name of the manufacturer. This tends to exclude companies which do not have the financial muscle to build adequate brand equity. In order to get over this problem, it is proposed that *the government should institute a method of widely publicizing GMP certification as a guarantor of quality* of the certified drug, and ensuring that public confidence is maintained through strict and transparent application of GMP audit requirements.

In addition, it is suggested that a quality mark much like the ISI or Agmark approvals may be evolved through industry involvement. Such marks should be awarded only on submission of bioequivalence and bioavailabiJity studies to the DeGI or its successor for approval.

4.4 Enabling price comparisons

The other measure which could improve the proper exercise of consumer choice would be the *establishment of a public website with full data on prices of all formulations by APIs*, which could be accessed not only by doctors and retailers but also by consumers to do a comparative assessment of price variations in the industry. The price monitoring system that has been suggested earlier would easily provide the data for developing such a website. The system should be query-based and API specific, but should not be therapeutic class-based or disease condition-based in order to avoid the danger of self-medication by patients.

4.5 Prevention of abuse of market dominance

In order to maintain the competitive structure of Indian drug industry and to prevent market dominance, the Competition Act has been passed and the Competition Commission of India (CCI) is in the process of being established. This is an extremely important step, especially for the pharmaceuticals industry which internationally has been prone to abuse of market power. It should be noted, however, that *the CCI will not be able to play its designated role without strong support from the drug regulatory system*. In particular, the complexities of the pharmaceuticals market that have been described above would need to be understood and the normal methods of assessing anti-competitive behaviour modified suitably. In addition, information and data support would be critical, which would have to be collected and maintained by the drug regulatory system.

Chapter 5

ENCOURAGING COUNTERVAILING FORCES

The essential idea of a countervailing force in the pharmaceutical sector is the existence of one or more intermediaries between the producers/distributors, on the one hand, and the final consumer, on the other, which has a vested interest in keeping prices as low as possible and sufficient monopsonistic power to do so. Internationally, the strongest countervailing force against the market power of the drug companies has been a strong national public health care system, which procures drugs in bulk for distribution. In recent years, private health insurance has begun to cover outpatients and drug costs as well, which has led to negotiated prices, especially for generics.

In India, neither of these forces exists in any meaningful manner. The public health care system is financially stressed and most patients are required to purchase medicines from the market. Although private hospitals also procure drugs in bulk, the price benefit is rarely passed on to the patients. Health insurance has very little coverage, and even in these cases is usually limited to hospitalization and out-patient costs are almost never covered. Thus, insurance companies have no incentive to control drug prices.

Active encouragement by government for emergence of such countervailing forces is necessary. This could involve all or any of the following:

- Strengthening of public health care system including supply of medicines, especially for the poor.
- Bulk procurement and retailing of medicines by public agencies, cooperatives and consumer organizations.
- Encouraging insurance companies to cover cost of medicines.
- Encouraging private hospitals and doctor's groups to provide group health cover including medicines.

There are a number of excellent examples of the enormous cost savings that can accrue with proper bulk procurement, whether by the public health care system (the Tamil Nadu model) or by government sponsored medicare societies (Rajasthan model). Innovative public health insurance schemes too can make a significant difference to health care costs (Yeshasvini in Karnataka). Detailed recommendations in this regard have been made in the Sandhu Committee Report, and there is no need to cover the ground again. A summary of the Sandhu Committee Report (interim) is annexed. However, these interventions are likely to be partial at best, and a very large number of people, as well as a fairly high proportion of drugs, both essential and otherwise, will have to go through the normal retail channels. Therefore, the other interventions also continue to be necessary.

5.1 Access Arrangements

Most of the standard arrangements will cover drugs which are in common use and are not patented. In the case of low volume high priced drugs or those which are patented and which are nevertheless life saving, such as anti-AIDS/HIV and cancer drugs, the government may consider entering into access arrangements with the manufacturers concerned whereby a lower priced equivalent may be procured and marketed through the government health system or other agencies to be designated by Government. For such arrangements to work effectively, the government should be prepared to enter into relatively long-term agreements. The Department of Chemicals and Petrochemicals, in close conjunction with the Department of Health and other concerned agencies, should initiate this task.

5.2 Scheme for BPL families

A major issue in India has been the accessibility and affordability of medicines by poor families, particularly families below poverty line. Central Government has set up a National Illness Assistance Fund (NIAF). Assistance to States up to 50% of their share is provided in the State Illness Fund (SIF) set up by them. So far assistance of Rs 5402.50 lacs has been provided to various States as Central contribution. A BPL patient is provided financial assistance up to Rs 1.50 lacs. While most States have set up the State Illness Funds, there are 9 States which have not set up these Funds so far. Apart from the Illness Funds, revolving funds have been set up in some of the leading Government hospitals for providing financial assistance to BPL patients up to Rs 50,000. Till date Rs. 550.34 lacs has been released to Government Hospitals for this purpose. The Central Government directly sanctions assistance in cases where estimated expenditure is more than Rs 50,000. A *Rashtriya Arogya Nidhi* has been set up for this purpose. Some States have made good use of this assistance and are providing free health care, including medicines, to BPL families - Rajasthan and MP are the noteworthy examples. There is an imperative need for the States to set up SIFs and revolving funds in all Government Hospitals for making available medicines free of cost to the BPL families. Also there is need to popularize these schemes so that maximum people can take advantage of the initiative taken by government.

Chapter 6

INSTITUTIONAL AND OTHER ISSUES

The various suggestions made in the preceding chapters require a number of legal and institutional changes for them to become effective. In particular, there is a pressing need to bring drug prices under a new legislation instead of being governed by an order passed under the Essential Commodities Act. Equally, if not more, important is the need to strengthen and reorganize the drug regulatory system, both at the Centre and the States. In fact, the present state of drug regulatory institutions leaves much to be desired not just from the pricing angle, but from the drug approval and quality enforcement dimensions as well.

6.1 Drugs and Therapeutics (Regulation) Act

It is suggested that the Drugs (Prices) Control Order (DPeO), which is presently an order under the Essential Commodities Act (ECA), should be converted to a legislative enactment - The Drugs and Therapeutics (Regulation) Act (DATA). The main features of this Act are as follow:

1. Empowering government or its designated authority to impose a price or limit the increase in the price or control the price in any other manner of any individual, class or category of drug or therapeutic product for any period of time it deems appropriate in public interest.
2. Requiring the government or its designated authority to clearly lay down the principles governing or the reasons leading to imposition of any such price control or any deviations permitted therefrom.
3. Authorizing the government or its designated authority to seek or compel disclosure of any information or data relevant to its functioning from all manufacturers, marketers, distributors or retailers of drugs and therapeutic products.
4. Requiring all companies involved in the manufacture or marketing of drugs and therapeutic products to submit authenticated price lists of all their products along with other relevant details to government or its designated authority on a regular basis with a frequency to be specified by the latter.
5. Granting the government or its designated authority the power to approve a brand name for a specific product, to prevent changes in the composition of a product marketed under an approved brand name and to determine the nomenclature under which a product can be marketed, if necessary, for all drugs and therapeutic products.

6. Providing penalties, for violation or non-compliance with the provisions of the Act or the Rules framed and orders issues under the Act. These penalties could be graded - fines, temporary withdrawal of marketing approval, withholding of marketing approval, compounding of offences, etc:
7. The powers and provisions of the DATA would be in addition to those contained in the Drugs and Cosmetics Act and the Essential Commodities Act.

6.2. Central Drug Regulatory System

The Task Force considered two alternative structures for the central drug regulatory system. The first envisages a separation of functions between two central agencies - one dealing with all matters relating to drug approvals and quality assurance, and the other dealing with all matters related to market behaviour, including pricing and availability. This essentially involves the conversion of the office of the Drugs Controller General of India (DCGI) to form an autonomous National Drug Authority (NDA), on the one hand, and strengthening of the National Pharmaceutical Pricing Authority (NPPA), on the other. The second is based on the proposal made by the Planning Commission in the Mid-term Appraisal of the Tenth Five Year Plan to establish a National Authority on Drugs and Therapeutics (NADT), which would integrate the offices of DCGI, CDSCO and the NPPA, along with all the powers and functions of these bodies.

There is something to be said for both these alternatives. As far as the first is concerned, the Ministry of Health & Family Welfare favours this structure on the grounds that the two functions are completely distinct, require distinct skill sets, and have separate obligations. Current global practices also distinctly separate the regulatory and price administration of the pharmaceutical sector. Moreover, the separation of powers ensures that the NDA remains relatively insulated from the pulls and pressures emanating from the commercial aspects of the drug industry, and can therefore focus on therapeutic and quality issues. This avoidance of conflicts of interest is the most powerful argument in favour of this option, especially in the context of the levels of governance existing in the country at present. It also involves minimum changes in the existing institutional structures, and is thus relatively easy to implement. The Mashelkar Committee 2003 has also endorsed such a system.

On the other hand, there are distinct drawbacks as well. In the first place, the NPPA simply does not have any field formation which can carry out the enforcement functions. This role is presently being played by the State drug control agencies, which are jurisdictionally under the DeG!. This arrangement not only reduces the effectiveness of the price regulation mechanism, but also does not meet the attribute of separation of powers and functions at the operating level. Second, the presence of multiple regulatory

authorities enables drug companies to engage in 'forum shopping', i.e. exploit the presence of a multiplicity of agencies without adequate coordination to their own advantage. Third, and most importantly, it should be clear from the preceding chapter that the nature of price regulation that is being proposed in this Report involves close linkage between the therapeutic aspects of drugs and the price regulation regime. It would, therefore, be inefficient to operate this system through two separate agencies. The integrated regulatory system envisaged by the NADT obviates the above problems, but it does involve the creation of a super regulator, with the possible problems of conflict of interest.

Keeping in view the above considerations, therefore, it is felt that creation of the NADT may be kept as a long run objective towards which the central drug regulatory system should evolve. For the interim, however, the dual structure may be implemented with the following additional dimensions:

- In order to strengthen the price and market regulatory system, separate dedicated cells may be created in the State drug control agencies for undertaking these functions under the direction of the NPPA. If necessary, these may be funded by the Central Government.
- The manpower, skill set and technical capabilities of the NPPA may be suitably enhanced to take care of the additional responsibilities.
- The revamped NPPA and the NDA must set up standing arrangements for addressing over-lapping issues such as price negotiations and brand approvals in a coordinated manner.

6.3 National Authority on Drugs and Therapeutics

As has already been mentioned, all things considered, in the long run a merger of the NDA and the NPPA appears desirable and should be worked towards. The Drugs and Cosmetics Act would have to be amended for this purpose. The NADT would also be the designated authority of the government for implementation of DATA.

Ideally the NADT should be an independent regulatory agency under the Ministry of Health & Family Welfare with appropriate statutory backing from DATA, but for the immediate future it may be set up as an attached office through the issue of the necessary government orders.

The NADT should constitute two Expert Committees which would be responsible for: (a) Regular updating and revision of the National List of Essential Medicines (NLEM); and (b) Price negotiations as prescribed under the Rules framed under DATA. These Committees should be chaired by the Chairman, NADT, and comprise primarily of outside experts drawn from government Ministries/Departments, ICMR, health professional. pharmacologists, civil society organizations, etc:

The NADT should not only carry out all the regulatory functions, but also be responsible for the promotional activities which are mentioned in this Report, such as quality certification and marking, promotion of generic drugs, maintenance of the public web-site/data base on drug prices, etc:

The functions proposed to be assigned to the NADT will require a significant enhancement in both the manpower and the skill sets available in the existing organizations which are proposed to be merged. In particular, there is need to develop strong capabilities in pharmacoeconomics, which is completely absent at present. The Mashelkar Committee Report (2003) has detailed the requirements for the Drug Controller's office, which should be adopted as the initial blue-print. A summary of the Mashelkar Committee Report is annexed. In addition, a suitable manpower and training requirement plan should be drawn up for it to effectively carry out the other functions that have been indicated.

A suitable mechanism for financing the NADT will need to be evolved, especially if it is to be made into an independent regulator. The Planning Commission has suggested a cess for this purpose, which could be a possible solution.

6.4 Other Regulatory Issues

Since the NADT will be wielding considerably greater powers and authority than any existing organization, there is need to consider the establishment of an appellate body, and provisions will have to be made in the Rules framed under the various concerned Acts.

Consistent with the strengthening of the Central drug regulatory system, the state supervisory and regulatory capacity should also be strengthened. The Centre should financially support state governments to bring their state drug control formations to a minimum level. The recommendations of the Mashelkar Committee should be adopted as a blueprint for this purpose. A beginning has been made by the Ministry of Health which has already undertaken a Capacity Building Project through World Bank assistance to support the State Governments to augment their regulatory capacities. This should be continued with even greater vigour in order to ensure a world-class regulatory system.

Since these institutional changes are likely to take time, the various functions and authority needed to give effect to the recommendations of this Report will need to be clearly demarcated between the existing regulatory bodies until they are eventually merged. It is suggested that all matters relating to pricing should vest in the NPPA, and all other functions, including brand regulation, be carried out by the NDA. As far as the NPPA is concerned, the following changes are recommended:

- a) Review the present structure and staffing pattern and strength of NPPA to make it more effective

- b) The tenure of Chairman should be minimum for 2 years
- c) Strengthen the monitoring system of NPPA through appropriate computerization and software
- d) Establish a live linkage of NPPA with the State Drug Controllers through a dedicated Drug Price Monitoring Cell in each of the major States. The full cost of these Cells should be funded by Central Government for a period of at least 5 years

6.5 Bulk procurement procedures

Since the long-term operation of the proposed price regulatory mechanism is depending upon the prices prevailing in bulk procurement activities, it is imperative that the bulk purchase mechanism be streamlined to ensure that the current malpractices are curbed so that the prices reflect the true value of quality drugs. Since bulk purchases are a valuable method for enabling smaller companies to diversify and grow, care should be taken to ensure that the bulk purchase orders are not so large as to exclude smaller manufacturers if they qualify otherwise.

It is suggested that the following conditions should be considered as minimum criteria for evaluating bulk purchase operations for inclusion in the reference price computations:

- (a) Procurement only from pre-qualified manufacturers and not from middle-men or traders.
- (b) GMP compliance of the manufacturer. Although this is now legally required, it needs to be specified as pre-qualification and enforced.
- (c) Minimum three years of track record in sustained production of the concerned drug. Balance sheets of past three years may be obtained to assess the installed manufacturing capacity and financial strength of the manufacturer
- (d) Post-award inspection of manufacturing facilities
- (e) Procurement of preferably generic drugs only.

Bulk procurement systems not conforming to the above requirements should not be taken into account for working out reference prices.

In order to ensure that bulk purchase data is available from a variety of sources, the government should consider specifying the above requirements as a condition for any financial support to States and other designated agencies for procurement of drugs for distribution through the public health care system.

6.6 Role of Public Sector Undertakings (PSUs)

It is well recognized that PSUs can play a significant role in ensuring availability and keeping a check on the prices of drugs produced by them. Whether it was the earthquake in Latur or in Kutch or the recent floods in Mumbai the PSUs when called upon have come to the forefront in supplying some of the essential drugs urgently required in such emergencies. The need to have vibrant public sector pharma enterprises has become all the more pertinent in the era of product patents where, in order to meet a public health crisis, they can be awarded compulsory licences to make patented medicines. In addition, PSUs can also be an important source of information on costs of production, if it becomes necessary for price regulation purposes. Finally, the PSUs can be used for strategic intervention in price formation processes for drugs which may not be under price regulation.

The existing PSUs have huge installed capacities and operationalising it in its entirety may not be worthwhile. There is, however, need to revive them to a limited extent (keeping in view their viability) and to provide them an assured market in the public health system. It is suggested that all departments of Central Government may be advised to first procure their drugs from these PSUs at prices approved by NPPA for the drugs covered under the essential category. For other drugs produced by these enterprises, procurement can be done through the normal tendering process. Another system can be to have a common Pricing and Supply Committee for all the Central pharmaceutical PSUs, which can determine the prices of drugs produced by them and also the list of drugs which must be necessarily produced for the public health system.

6.7 Excise Duties

One of the most glaring anomalies in policy is that while the government has laid great emphasis on moderating the prices of drugs, it continues to tax pharmaceutical products at the same rate as any other consumer non-durable, namely at 16. This issue has become particularly visible since the State governments reduced the applicable VAT rate to 4 in recognition of the essential nature of pharmaceutical products. It is suggested, therefore, that *the excise duty rate on pharmaceuticals should be reduced to 8*. Ideally, this reduction should be applicable only to the essential drugs and their formulations, but in view of the complexity of monitoring and enforcement, it is suggested that it be applied across the board. At most, the loss to the exchequer on this account would be less than Rs. 1,000 crore.

To make matters worse, the government issued a notification on 7th January, 2005 vide which it levied excise duty on drugs on the MRP. An abatement of 40 in the MRP was given to allow for marketing and other expenses. This means that excise duty is to be levied on 60 of the MRP. This has brought about a sharp reaction from the small scale pharmaceutical industry due to the sudden increase in tax burden which created a big

anomaly owing to the tax free areas of Himachal Pradesh, Uttaranchal and J&K. There has been a very intense and vocal demand from industry for giving relief to these units. On the basis of the experience of the last few months, the impact of this measure on the small scale pharmaceutical units reveal that there are both positive and negative effects. These are as follow:

Positive Effects:

a) The biggest positive effect has been on the working and practices of the small units. It has brought about the much needed discipline in terms of reasonableness in the costing and prices of drugs produced by them which are mostly branded generics. There is a pressure to keep the prices low to avoid a proportionate increase in the excise duty burden. This was absent earlier.

b) There has been a downward trend in prices of most of the branded generic drugs produced by small scale units as the incidence of excise duty on 60 of the MRP becomes Significantly higher than what it was on the exfactory price .In order to keep the burden low the MRP has been reduced in most cases

Negative Effects:

a) The major negative effect has been the wide disparity created in the tax burden between the units established in the zero-duty areas and rest of the country .The small scale units in other parts of the country find it difficult to compete with their counterparts in these areas and face the threat of closure unless they also shift to those areas or are provided some relief.

b) Possible loss of revenue to the government due to large scale movement of new/established units into zero duty areas and tendency to pay lower duty by units in other areas due to evasion as a result of very high tax incidence (on 60 percent of MRP as compared to ex-factory price earlier)

c) Another adverse effect has been on the implementation of Schedule M of the Drugs and Cosmetics Act,1940. It is estimated that about 10 percent of the small units have already implemented it while another 10 percent were in the process of doing so. Due to the uncertainty and higher tax burden leading to reduced capacity to finance the high cost involved in the implementation of Schedule M its implementation by these units has reportedly been stopped midway.

On balance, it can be concluded that the MRP based excise is in the long term interest of industry and should stay. However to mitigate its rigours and to provide a level playing field for small units it is essential that *the exemption limit of small scale units is enhanced from the present Rs. 1 crores to Rs. 5 crores.*

Both these steps, namely the reduction in the excise duty rate and the enhancement of the exemption limit, are likely to provide the much needed relief to the small scale units leading to their survival, improved quality and better tax compliance, which would have a positive effect on the revenues of Government. In any event, the loss to the exchequer is not likely to be large.

Encouraging R&D

The introduction of product patent regime in India has made it imperative for augmenting resources for greater R&D in pharmaceutical sector. The present level of R&D in this sector is quite low as compared to most of the developed countries. While the pharmaceutical companies need to step up their expenditure on R&D it is necessary on the part of Government to provide liberal incentives and resources for activities related to drug discovery and drug development.

The following incentives are available for R&D purposes in the pharmaceutical sector:

- a) Section 80-1 B(8A) of Income Tax Act: Any company carrying on Scientific R&D, deduction of 100 of Profits and Gains of such business for a period of 10 consecutive assessment years, beginning from the assessment year.
- b) Section 35(2AB)(1) of Income Tax Act: A company engaged in the business of biotechnology, drugs, pharmaceuticals, etc. incurring any expenditure on scientific research (excluding cost of land or building) on in-house R&D facility, a deduction of a sum equal to 150 of expenditure so incurred is allowed
- c) A corpus fund of Rs. 150 crores to fund R&D projects.

It has been suggested that domestic R&D activity should be encouraged through relaxations being made in price regulations which would otherwise be applicable. The Task Force, however, does not favour this approach since most such suggestions are bad in law and can also lead to unforeseen distortions in the regulatory system. It is felt that a better method would be to provide a more liberal fiscal regime for domestic R&D. Some suggestions in this regard are as follow:

- The benefit of 150 weighted exemption under section 35(2AB) may be increased to 200.
- Section 35(2AB) may be extended to depreciation on investment made in land and building for dedicated research facilities, expenditure incurred for obtaining regulatory approvals and filing of patents abroad.

- It should also be examined as to whether the expenditure made on clinical trials by the Indian companies should be made eligible for the purpose of above mentioned incentives.
- The fiscal incentives are at present only available up to 31st March, 2007. Since R&D activity has to be carried over long periods of time, fiscal incentives should be granted over a much longer period, say 10 years, rather than the limited period extensions that are being made presently.

At present, the Pharmaceutical Research and Development Support Fund (PRDSF) corpus of Rs. 150 crores (where only interest income is available for spending) is utilized for funding R&D projects of Research Institutions and industry. It is not sufficient to meet the present day and the emerging requirements of this sector. It needs to be sufficiently augmented over the next five years. Immediately it should be converted into an annual grant of Rs. 150 crores, and thereafter it should be suitably increased in a phased manner over a period of next five years

The recommendations made by the Pharmaceutical Research & Development Committee (headed by Dr. R. A Mashelkar) in 1999 on promotion of R&D should be reexamined by the Department of Chemicals and Petrochemicals -to see as to whether any of these are still applicable (in original or revised form) and can be adopted in the new policy.

Chapter 7

RECOMMENDATIONS

1. The Strategic Approach

1.1 In the opinion of the Task Force, no price regulatory mechanism can be effective unless there is a credible threat of price controls being imposed and enforced. However, it is also felt that the present price control system is inappropriate, inadequate, cumbersome and time consuming.

1.2 Price controls should be imposed not on the basis of turnover, but on the 'essentiality' of the drug and on strategic considerations regarding the impact of price control on the therapeutic class. This must be a dynamic process.

1.3 Price controls should be applied only to formulations, i.e. the medicine actually used by the consumer, and not to bulk drugs. Intra-industry transactions should not be controlled unless there are compelling reasons for doing so.

1.4 There should be no attempt to impose uniformity in prices of controlled drugs on a lowest common denominator basis, and only a ceiling should be prescribed. Companies should be free to decide their price-quantity configuration within the prescribed price limit.

1.5 The ceiling prices of controlled drugs should normally not be based on cost of production, but on readily monitorable market-based benchmarks.

1.6 All other drugs should be brought under a comprehensive price monitoring system with appropriate market-based reference prices and with mandatory price negotiations, if necessary.

1.7 Licensing and marketing approval of drugs should be centralized and tightened. In particular, no combination drug should be approved unless there is a demonstrated therapeutic advantage.

1.8 The regulatory mechanism should be significantly strengthened both at the Centre and in the States. Since quality, quantity and price are to be addressed in an integrated manner, there should be a unified regulatory structure covering all aspects:

1.9 A process of active promotion of generic drugs should be put in place, including mandatory debranding for selected drugs.

1.10 All public health facilities should be required to prescribe and dispense generic drugs, except in cases where no generic alternative exists.

1.11 In the case of proprietary drugs, particularly anti-HIV/AIDS and Cancer drugs, the government should actively pursue access programmes in collaboration with drug companies with differential pricing and alternative packaging, if necessary .

1.12 Public Sector Enterprises (PSEs) involved in the manufacture of drugs should be revived where possible and used as key strategic interventions for addressing both price and availability issues. Arrangements may need to be made to ensure their continuing viability.

1.13 Fiscal incentives should be provided on a long-term assured basis to research and development activities in drugs.

1.14 The government should institute a programme for strict enforcement of Schedule M compliance, and should promote and publicize such quality marking strongly.

1.15 The government should consider providing financial support to dedicated generic manufacturers and small-scale units for achieving Schedule M compliance. For this, the Department of Chemicals & Petrochemicals should formulate a separate Plan scheme to be funded through the Budget.

1.16 The government should create and maintain a public website with complete data on prices of all formulations by APIs and therapeutic categories which can be used by medical practitioners, and perhaps even consumers, for price comparison purposes.

1.17 The drug regulator must maintain a data base on brands and their compositions, and all brand registration of drugs must compulsorily be approved by the drug regulator. In particular, no change should be permitted in the composition of a given brand.

1.18 Availability of essential medicines through public health facilities should be ensured both through bulk purchases by government agencies, cooperatives or consumer bodies, through public-private partnerships if necessary.

1.19 Insurance companies should be encouraged to extend health insurance to cover medicines. Public-private partnerships for providing health care services, including insurance and group health plans, should be actively encouraged. The Department of Health should take up this matter in conjunction with the IRDA

2. Drugs and Therapeutics (Regulation) Act

2.1 The Drugs Prices (Control) Order (DPCO), which is presently an order under the Essential Commodities Act (ECA), 1955 should be converted into a legislative enactment - The Drugs and Therapeutics (Regulation) Act (DATA). The main features of this Act are outlined in the following paragraphs.

2.2 Empowering government or its designated authority to impose a price or limit the increase in the price or control the price in any other manner of any individual, class or category of drug or therapeutic product for any period of time it deems appropriate in public interest.

2.3 Requiring the government or its designated authority to clearly lay down the principles governing or the reasons leading to imposition of any such price control or any deviations permitted therefrom.

2.4 Authorizing the government or its designated authority to seek or compel disclosure of any information or data relevant to its functioning from all manufacturers, marketers, distributors or retailers of drugs and therapeutic products.

2.5 Requiring all companies involved in the manufacture or marketing of drugs and therapeutic products to submit authenticated price lists of all their products along with other relevant details to government or its designated authority on a regular basis with a frequency to be specified by the latter.

2.6 Granting the government or its designated authority the power to approve a brand name for a specific product, to prevent changes in the composition of a product marketed under an approved brand name and to determine the nomenclature under which a product can be marketed, if necessary, for all drugs and therapeutic products.

2.7 Providing penalties, for violation or non-compliance with the provisions of the Act or the Rules framed and orders issued under the Act. These penalties could be graded - fines, temporary withdrawal of marketing approval, withholding of marketing approval, sealing of production facilities, compounding of offences, etc:

2.8 Other powers with regard to production and prices as mentioned in the EC Act, 1955 should be incorporated in the Act to the extent possible.

2.9 The powers and provisions of the DATA should be in addition to and in consonance with the provisions of the Drugs and Cosmetics Act and the Essential Commodities Act.

2.10 Greater role and accountability of State Drug Controllers should be specifically provided for under the Act.

3. National Authority on Drugs and Therapeutics

3.1 The Task Force endorses the proposal made by the Planning Commission in the Mid-term Appraisal of the Tenth Five Year Plan to establish a National Authority on Drugs and Therapeutics (NADT) as a long-term objective. This would integrate the offices of the Drug Controller

General of India, the Central Drugs Standard Control Organisation (CDSCO) and the National Pharmaceutical Pricing Authority (NPPA), along with all the powers and functions of these bodies. The Drugs and Cosmetics Act would have to be amended for this purpose. The NADT would also be the designated authority of the government for implementation of DATA

3.2 Ideally the NADT should be an independent regulatory agency with appropriate statutory backing from DATA, but for immediate future it may be set up as an attached office through the issue of the necessary government orders .

3.3 The NADT should constitute two Expert Committees which would be responsible for: (a) Regular updating and revision of the National List of Essential Medicines (NLEM), which may be approved by Government in consultation with the States through a joint Committee of Departments concerned; and (b) Price negotiations as prescribed under the Rules framed under DATA These Committees should be chaired by the Chairman, NADT, and comprise primarily of outside experts drawn from government Ministries/Departments, ICMR, health professionals, pharmacologists, civil society organizations, etc:

3.4 The NADT should not only carry out a/l the regulatory functions implied by para 3.1 above, but also be responsible for the promotional activities which are mentioned in this Report, such as quality certification and marking, promotion of generic drugs, maintenance of the public web-site/data base on drug prices, etc:

3.5 The functions proposed to be assigned to the NADT will require a significant enhancement in both the manpower and the skill sets available in the existing organizations which are proposed to be merged. The Mashelkar Committee Report (2003) has detailed the requirements for the Drug Controller's office, which should be adopted as the initial blue-print. In addition, a suitable manpower and training requirement plan should be drawn up for it to effectively carry out the other functions that have been indicated.

3.6 A suitable mechanism for financing the NADT will need to be evolved, especially if it is to be made into an independent regulator. The Planning Commission has suggested a cess for this purpose, which could be examined.

3.7 Since the constitution of NADT may take time because it will involve resolving several interdepartmental issues and legislative enactments, a dual regulatory system may be implemented immediately. This would be a National Drug Authority (NDA) for safety, quality and efficacy aspects and a revamped NPPA for pricing and market-related issues .

3.8 In view of the increased responsibilities, there is an immediate need to bring about some fundamental changes in NPPA. These are:

- a) Review the present structure of NPPA to make it more effective
- b) The tenure of Chairman should be minimum for 2 years with maximum age limit as 62 years
- c) Strengthen the monitoring system of NPPA through appropriate computerization and software
- d) Establish live linkage of NPPA with the State Drug Controllers through a dedicated Drug Price Monitoring Cell in each of the major States and on-line electronic linkage. The full cost of these Cells and electronic connectivity should be funded by Central Government for a period of at least 5 years

3.9 The revamped NPPA and the NDA must set up standing arrangements for addressing over-lapping issues such as price negotiations and brand approvals in a coordinated manner.

4. Other Regulatory Issues

4.1 Since the NADT will be wielding considerably greater powers and authority than any existing organization, there is need to consider the establishment of an appellate body, and provisions will have to be made in the Rules framed under the various Acts concerned.

4.2 Consistent with the strengthening of the Central drug regulatory system, the state supervisory and regulatory capacity should also be strengthened. The Centre should financially support state governments to bring their state drug control formations to a minimum level. The recommendations of the Mashelkar Committee 2003 report should be adopted as a blue-print for this purpose.

4.3 There are several instances where formulations are changed by companies without changing the brand or misbranding. Such changes are made even in the prescription drugs which fall under Schedule H of the Drugs and Cosmetics Act. Since there is a tendency on the part of Indian pharmacies to sell such drugs without doctor's prescription it puts the patient to a considerable risk.

5. Principles of Price Regulation

5.1 The National List of Essential Medicines (NLEM) should form the basis of drugs to be considered for intensive price monitoring, ceiling prices and for imposition of price controls, if necessary.

5.2 To start the process, the government should announce the ceiling price of all drugs contained in the NLEM on the basis of the weighted average prices of the top three brands by value of single ingredient formulations prevailing in the market as on 01.04.2005. In cases where there are less than three brands, the average of all existing brands would be taken. The Org-IMS data set can be used for this purpose initially with a 20 per cent retail margin

provided. There is, however, a need to improve the available data coverage, which should be taken up with ORG-IMS or any other data provider.

5.3 For drugs which are not reflected in ORG-IMS data, the NPPA should prepare the necessary information based on market data collection.

5.4 During the transition period (Le. till the time ceiling prices are fixed and notified) prices of all essential drugs may be frozen.

5.5 The Government should specify the reference product in terms of strength and pack size for each product which would form the basis for price determination. The price ceiling would be specified on a per dosage basis, such as per tablet/per capsule or standard volume of injection. Where syrups and liquids are sold in bottles the ceiling price may be fixed on individual pack size.

5.6 Price relaxations may be permitted for non-standard delivery systems, packaging and pack sizes through applications to the negotiations committee, which should become applicable for all similar cases.

5.7 In the case of formulations which involve a combination of more than one drug in the NLEM, the ceiling price would be the weighted average of the applicable ceiling prices of its constituents.

5.8 For formulations containing a combination of a drug in the NLEM and any other drug, the ceiling price applicable to the essential drug would be made applicable. However, the company would be free to approach the price negotiations committee for a relaxation of the price on the basis of evidence proving superior therapeutic effectiveness for particular disease conditions.

5.9 In order to determine the reasonableness of the ceiling prices fixed as above, the L 1 prices quoted in bulk procurement by Government and other designated agencies may be examined for use, provided that the system of bulk procurement meets certain minimum prescribed standards. Recognising that retail distribution has costs not reflected in bulk procurement, a mark up of 100 per cent over this reference price is recommended.

5.10 The regulator (initially the NPPA) should set up a computer based system which would scan the price data provided by companies against the ceiling prices determined as above and identify formulations which breach the relevant price ceiling. The company manufacturing or marketing such a product would be required to reduce its price or to face penal action.

5.11 Companies should be permitted to represent for any price increase on valid grounds, which should then become applicable to the entire class of products.

5.12 In the case of drugs not contained in the NLEM, intensive monitoring should be carried out for all drugs falling into a pre-specified list of therapeutic

categories. The reference prices for this purpose would be the ceiling prices of drugs contained in the NLEM, and any significant variation in the relative prices (say above 10 per cent) would be identified for negotiation .

5.13 The NLEM should be revised periodically, say every 5 years, in order to reflect new drugs and significant changes in pattern of drug sales within the therapeutic categories. Till such time as the NADT is formed, the Department of Health may set up a Standing Committee for selecting medicines for inclusion in the NLEM. The first review of NLEM should be undertaken in the year 2008, and thereafter every 5 years. However till the time the new list is finalized the existing list will continue to be valid for the purpose of price control.

5.14 In the case of drugs not contained in the NLEM, intensive monitoring should be carried out of all drugs falling into a pre-specified list of therapeutic categories. Any significant variation in the prices (say above 10 per cent) would be identified for negotiation.

5.15 It is to be emphasized that the MRP should be inclusive of all taxes. Under the provisions of Packaged Commodities Rules, 1977, all commodities sold in prepackaged form are required to have a label declaration of retail sale price in the form of MRP inclusive of all taxes. This should be made applicable in case of medicines also.

6. New and Patented Products

6.1 Any new formulation based on existing APIs would be required to submit its intended entry price along with application for marketing approval, which would be granted only if the indicated price is consistent with the relevant ceiling price, if applicable. If there are no price ceilings, i.e. the new formulation is not based on an API contained in the NLEM or its isomer, the proposed entry price should be accepted automatically and then subjected to the disciplines indicated above wherever applicable.

6.2 All patented drugs and their formulations should compulsorily be brought under price negotiation prior to the grant of marketing approval. Failure of such negotiations should then invite either price control or compulsory licensing. Till such time as the NADT is formed, the Committee may be located in the Department of Chemicals & Petrochemicals and the DCGI (or the equivalent in the NDA) must be a permanent member.

6.3 The reference prices to be used for such negotiations should be based on the premium enjoyed by the drug in the lowest priced market abroad compared to its closest therapeutic equivalent in that same country. This premium can then be applied to the corresponding price of the same therapeutic equivalent prevailing in the domestic market to determine the reasonable price in Indian conditions. In other words, what is being suggested is that patented drugs should be allowed the premium it commands elsewhere, but applied to the prices prevailing in India.

7. Bulk Procurement

7.1 Since the long-term operation of the proposed price regulatory mechanism is depending upon the prices prevailing in bulk procurement activities, it is imperative that the bulk purchase mechanism be streamlined to ensure that the current malpractices are curbed so that the prices reflect the true value of quality drugs.

7.2 It is suggested that the following conditions should be considered as minimum criteria for evaluating bulk purchase operations for inclusion in the reference price computations:

- (a) Procurement only from pre-qualified manufacturers of drugs
- (b) GMP compliance of the manufacturer. Although this is now legally required, it needs to be specified as pre-qualification and enforced.
- (c) Minimum three years of track record in sustained production and/or marketing of the concerned drug. Balance sheets for the previous three years be obtained to make an assessment of the manufacturing and financial capacity of the manufacturer.
- (d) Post-award inspection of manufacturing facilities.
- (e) Procurement preferably in the form of generic drugs.

7.3 Care should be taken to ensure that the bulk purchase orders are not so large as to exclude smaller manufacturers if they qualify otherwise.

7.4 In order to ensure that bulk purchase data is available from a variety of sources, the government should consider financial support to State and other designated agencies for procurement of drugs (only in generic form) for distribution through the public health care system and also for retailing it within the hospitals. Some states like Rajasthan are doing it on a small scale, and such experiments should be increased.

8. Promotion of Generics

8.1 Public procurement and distribution of drugs through the public health system should preferably be for generic drugs.

8.2 Quality certification may be provided free to generic drug manufacturers through an appropriate scheme to be formulated by the Department of Chemicals & Petrochemicals_

8.3 No control on price or distribution margins may be specified for generic drugs, but these may be kept under price monitoring.

9. Access Arrangements

9.1 In the case of low volume high priced drugs which are nevertheless life saving, the government should consider entering into access arrangements with the concerned manufacturers whereby a lower priced medicine would be procured and marketed through the government health system or other agencies to be designated by Government. Department of Chemicals and Petrochemicals should initiate this work in close collaboration with Department of Health and other concerned agencies.

9.2 One of the things which could be considered in case of cancer and anti-AIDS/HIV drugs could be the complete exemption of these drugs from the payment of excise duty, octroi and other levies, if any. This benefit should be passed on to the patients. Manufacturers should be asked to charge lower profit and trade margins on these specific drugs

9.3 Although most of the drugs for cancer and anti-HIV/AIDS are exempted from payment of customs duties this may be reexamined and in case there are any such drugs (bulk and formulations) which still attract customs duties these should be exempted from this levy.

10. Public Sector Undertakings

10.1 It is suggested that all departments of Central Government may be advised to first procure their drugs from these PSUs at prices approved by NPPA for the drugs covered under the essential category. For other drugs produced by these enterprises, procurement can be done through the normal tendering process. Another system can be to have a common Pricing and Supply Committee for all the Central pharmaceutical PSUs, which can determine the prices of drugs produced by them and also the list of drugs which must be necessarily produced for the public health system.

11. Scheme for BPL families

11.1 There is an imperative need to persuade the States to establish the SIFs and for setting up revolving funds in all Government Hospitals for making available medicines free of cost to the BPL families. Also, there is need to give wide publicity to these schemes so that maximum poor people can take advantage of them.

12. Excise duty relief

12.1 In order to have an appropriate excise duty regime, it is essential that the following measures are taken:

- 1) reduce the excise duty on all pharmaceutical products from 16 to 8 percent.

- 2) enhance the exemption limit of small scale units from the present Rs. 1 crores to Rs. 5 crores.

80th these steps are likely to reduce prices and also provide the much needed relief to the small scale units leading to their survival, improved quality and better tax compliance which would have a positive effect on the revenues of Government

13. Research and Development

13.1 It is felt that a more liberal fiscal regime for domestic R&D should be provided. Some suggestions in this regard are as follow:

- The benefit of 150 weighted exemption under section 35(2AB) may be increased to 200.
- Section 35(2AB) may be extended to depreciation on investment made in land and building for dedicated research facilities, expenditure incurred for obtaining regulatory approvals and filing of patents abroad.
- It should also be examined as to whether the expenditure made on clinical trials by the Indian companies should be made eligible for the purpose of above mentioned incentives.
- The fiscal incentives are at present only available up to 31st March, 2007. Since R&D activity has to be carried over long periods of time, fiscal incentives should be granted over a much longer period, say 10 years, rather than the limited period extensions that are being made presently.

13.2 At present, the Pharmaceutical Research and Development Support Fund (PRDSF) corpus of Rs. 150 crores (where only interest income is available for spending) is utilized for funding R&D projects of Research Institutions and industry. It is not sufficient to meet the present day and the emerging requirements of this sector. It needs to be sufficiently augmented over the next five years. Immediately it should be converted into an annual grant of Rs. 150 crores, and thereafter it should be suitably increased in a phased manner over a period of next five years

13.3 The recommendations made by the Pharmaceutical Research & Development Committee (headed by Dr. R. A. Mashelkar) in 1999 on promotion of R&D should be reexamined by the Department of Chemicals and Petrochemicals to see as to whether any of these are still applicable (in original or revised form) and can be adopted in the new policy.

14. Facilitating Schedule M Implementation

14.1 A special fund should be created for providing interest subsidy (5 to 6 percentage points) on borrowings to small scale pharma units going in for

Schedule M implementation. This assistance should be in addition to any other financial assistance that may be available to the SSI pharma units from Central or State Governments. Financial institutions like SIDBI and public sector scheduled banks can be involved in this work. Promotional activity motivating industry to adopt schedule M should also be undertaken from this fund with the active involvement of Department of Health and the States. A plan scheme should be prepared in this regard.

15. Public Awareness

15.1 There is an urgent need to educate the people and create awareness about the alternative available drug formulations and their prices. As has been mentioned earlier a dedicated website need to be created for this purpose which should be regularly updated and publicised. Apart from this other possible modes of enhancing public awareness like publicity literature, booklets, a dedicated news letter/magazine etc should be made use of. In addition to English language other Indian languages should also be used. The state governments should be closely involved with this work. Initially at least for a period of 5 years the expenditure on this should be incurred by the Central Government with states participating to the extent possible. Thereafter the scheme should be reviewed and states and other agencies should also be asked to share the expenditure.

15.2 In order to provide the required focus to this important task it would be desirable that a dedicated agency is set up under the Department of Chemicals and Petrochemicals to undertake this work with an annual budget. This agency may outsource some of the work and also involve the states and other government agencies as much as possible

16. Settlement Commission as a device for funding certain activities

16.1 A large number of cases of overcharging are detected where the overcharged amount is recovered from the companies concerned. Often recovery of the amount is contested by the companies leading to protracted litigation and court stays. In case of some other recoveries like Income -tax arrears Government have constituted Settlement Commission which is authorized to decide the recoverable amount in a summary manner after hearing both sides. This helps in faster recovery of the dues and avoids unnecessary litigation. A similar system needs to be put in place in the case of past and future arrears of overcharging from the companies. All ongoing court cases should be brought before the Settlement Commission and effort made to arrive at some workable settlement.

16.2 Amount so recovered can be utilized to partly fund public awareness programme and also for operating and continuous strengthening of the price monitoring mechanism of NPPA along with online electronic system with the States

16.3 The fund so created should be housed in NPPA but it should be operated by an Empowered Committee headed by Secretary, Chemicals and Petrochemicals. Apart from the areas mentioned here the Committee should be authorized to utilize part of the fund on such incidental activities which may be instrumental in achieving the broader objectives.

16.4 A one time settlement of old dues of Drug Price Equalisation Account (DPEA) under OPCO, 1979 should be announced to settle these cases, most of which are under protracted litigation.

(G.S.Sandhu)
Joint Secretary,
Department of Chemicals & Petrochemicals
Member

(Ms. Rita Teotla)
Joint Secretary,
Department of Health
Member

(Pradip Mehra) Member
Secretary, NPPA Special
Invitee

(Ashwini Kumar)
DCGI, Deptt. of Health
Special Invitee

(Dr. Pronab Sen)
Principal Adviser (PP)
Planning Commission
Chairman

ANNEXURES

1. Order constituting Task Force.
2. Supreme Court Order
3. Drug Price Control Order 1995
4. List of Therapeutic Categories for Intensive Monitoring
5. Summary of Sandhu Committee Report
6. Summary of Mashelkar Committee Report

12/12/2004-PI-I
Government of India
Ministry of Chemicals & Fertilizers
Department of Chemicals & Petrochemicals

Shastri Bhavan, New Delhi
Dated the 29th November 2004

OFFICE MEMORANDUM

Sub ject: Constitution of Task Force

,It has been decided to set up a Task Force to explore various options other than price control for achieving the objective of making available of life-saving drugs at reasonable prices,: The Task Force will comprise the following:

- | | | |
|----|--|----------|
| 1. | Principal Adviser (PP), -
Planning Commission | Chairman |
| 2. | Joint Secretary (PI)
D/o. C&PC} | Member. |
| 3. | Joint Secretary (Deptt. of
Health) | Member |

Shri Gurdeep Singh, Director (PI), D/o. C&PC would act as the Secretary of the Task Force. The Task Force would submit its report within a period of 3 months. The Task Force may seek the opinion/views of any expert on the subject ..

(Gurdeep Singh)
Director Tel:
23382846

Court No. 1----- SECTION IVA
SUPREME COURT OF INDIA

RECORD OF PROCEEDINGS

Petition (s) for Special Leave to Appeal (Civil) NO,3668/2003!
(From the judgment and order dated 1211112002 in WP 21618/2002 of
The HIGH COURT OF KARNATAKA AT BANGAIORE)

UNION OF INDIA

Petitioner
(s)

K. S. GOPINATH & ORS.
(With prayer for interim relief)

Respondent (s)

Date: 10/03/2003 This Petition was called on for hearing today.

CORAM:

HON' BIE THE CHIEF JUSTICE
HON'BIE MR. JUSTICE S.B. SINHA
HON'BIE DR. JUSTICE, AR.
LAKSHMANAN

For Petitioner
(s)

Mr. K.N. Raval, SG
Mr. Sanjay R. Hegde, Adv.
Mr. Satyar Mitra, Adv.
M3. Sushma Suri, Adv .. Mr
B.V. Balaram Das, Adv.

For Respondent (5)

Dr. Ashok Nigam, Sr. Adv.
Mr. C. Aryama Sundaram, Sr.Adv.
Ms. Binu Tamta, Adv

upon hearing counsel the Court made the following

ORDER

Issue notice. - Ms. Binu Tamta, learned counsel, accepts notice on behalf of respondent Nos.1 and 2. She prays for and is allowed two weeks' time to file counter affidavit. Two weeks' time thereafter is granted to file rejoinder affidavit. list after' four weeks

Meanwhile, we suspend the operation of the order to the extent it directs that the Policy dated: 15.2.2002 *shall* not be implemented. However, we direct that the petitioner *shall* consider and formulate appropriate criteria for *ensuring essential and life saving* drugs not to fall out of price, control and further directed to review drugs which are essential and life saving in nature till 2nd May, 2003.

(Alka Dudeja), " , _
11_... I

6
7

.Qk-"
(5. Krishnan)
.Court Master

Drugs (Prices Control) Order, 1995 The
Gazette of India-Extraordinary PART II
Section 3 Sub-Section (11) Ministry of
Chemicals and Fertilizers
Department of Chemicals and Petrochemicals New
Delhi, dated the 6th January, 1995

Annexure - III

S.O.18(E).In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby makes the following Order, namely:

1. Short title and commencement -

- This Order may be called the Drugs (Prices Control) Order, 1995
- It shall come into force on the date of its publication in the Official Gazette

2. Definitions ~ In this Order, unless the context otherwise requires:

- a. "bulk drug" means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in *any* formulation
- b. "capital employed" means net fixed assets plus working capital of a manufacturer in relation to manufacture of bulk drug
- c. "ceiling price" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of paragraph
- d. "dealer" means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and whether or not in conjunction with any other business, and includes his agent e. "distributor" means a distributor of drugs or his agent or a stockiest appointed by a manufacturer or an importer for stocking his drugs for sale to a dealer
- f. "drug" includes:
- (i) all medicines for internal or external use of human beings or animals and 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, including preparations applied on human body for the purpose of repelling insects like mosquitoes
 - (ii) such substances, intended to affect the structure or any function of the human or animal body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Government by notification in the Official Gazette (iii) bulk drugs and formulations
- g. "Form" means a form specified in the Second Schedule
- h. "formulation" means a medicine processed out of, or containing one or more bulk drug or drugs with or without the use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but shall not include:
- (i) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines
 - (ii) any medicine included in the Homeopathic system of medicine
 - (iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply
- i. "free reserve" means a reserve created by appropriation of profits, but does not include reserves

provided for contingent liability, disputed claims, goodwill, revaluation and other similar reserves j.
"Government" means the Central Government

k. "import" with its grammatical variations and cognate expressions means bringing into India from a place outside India, and "importer", in relation to any goods at any time between their importation and consumption, includes any owner or any person holding himself out to be the importer

l. "manufacture" in relation to any drug, includes any process or part of a process for making, altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view its sale and distribution, but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business, and "to manufacture" shall be construed accordingly

m. "manufacturer" means any person who manufactures a drug

n. "net-worth" means the paid-up share capital of a company plus free reserve, if any, and surpluses excluding outside investments which are not readily available for operational activity

o. "non-Scheduled bulk drug" means a bulk drug not specified in the First Schedule

p. "non-Scheduled formulation" means a formulation not containing any bulk drug specified in the First Schedule

q. "pre-tax return" means profits before payment of income-tax and surtax and includes such other expenses as do not form part of the cost of formulation

r. "price list" means a price list referred to in paragraphs 14 and 15 and includes a supplementary price list

s. "retail price" means the retail price of a drug arrived at or fixed in accordance with the provisions of this Order and includes a ceiling price

t. "retailer" means a dealer carrying on the retail business of sale of drugs to customer

u. "Scheduled bulk drugs" means a bulk drug specified in the First Schedule

v. "Scheduled formulation" means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs not specified in the First Schedule except single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name

w. "sale turn-over" means the product of units of formulations sold by a manufacturer or an importer, as the case may be, in an accounting year multiplied by retail price inclusive of sales tax, if any, paid on direct sales by the manufacturer or importer but does not include excise duty and local taxes, if any

x. "Schedule" means a Schedule annexed to this Order

y. "Wholesaler" means a dealer or his agent or a stockiest appointed by a manufacturer or an importer for the sale of his drugs to a retailer, hospital, dispensary, medical, educational or research institution purchasing bulk quantities of drugs

3. Power to fix the maximum sale prices of bulk drugs specified in the First schedule _

[1] The Government may, with a view to regulate the equitable distribution and increasing supplies of a

bulk drug specified in the First Schedule and making it available at a fair price, from different manufacturers, after making such inquiry as it deems fit, fix from time to time, by notification in the Official Gazette, a maximum sale price at which such bulk drug shall be sold

Provided that for the purpose of enquiry, in addition to the information required to be furnished by the manufacturers under this Order, the manufacturers shall provide any such additional information as may be required by the Government, and shall allow for inspection of their manufacturing premises for verification through on the spot study of manufacturing processes and facilities and records thereof, by the Government

(2) While fixing the maximum sale price of a bulk drug under sub-paragraph (1), the Government shall take into consideration a post-tax return of fourteen per cent on net worth or a return of twenty two per cent on capital employed or in respect of a new plant an internal rate of return of twelve per cent based on long term marginal costing depending upon the option for any of the specified rates of return that may be exercised by the manufacturer of a bulk drug

Provided that where the production is from basic stage, the Government shall taken into consideration a post-tax return of eighteen per cent on net worth or a return of twenty six per cent on capital employed
Provided further that the option with regard to the rate of return once exercised by a manufacturer shall be final and no change of rates shall be made without the prior approval of the Government

[3] No person shall sell a bulk drug at a price exceeding the maximum sale price fixed under subparagraph (1) plus local taxes, if any

Provided that until the price of a bulk drug is fixed by the Government under sub-paragraph (1), the price of such bulk drug shall be the price which prevailed immediately before the commencement of this Order and the manufacturer of such bulk drug shall not sell the bulk drug at a price exceeding the price prevailing immediately before the commencement of this Order

[4] Where, after the commencement of this Order, any manufacturer commences production of any bulk drug specified in the First Schedule, he shall within fifteen days of the commencement of production of such bulk drug, furnish the details to the Government in Form I, and any such additional information as may be required by the Government and the Government may after receipt of the information and after making such inquiry as it may deem fit, may fix the maximum sale price of bulk drug by notification in the Official Gazette

[5] Any manufacturer, who desires revision of the maximum sale price of a bulk drug fixed under subparagraph (1) or (4) or as permissible under sub-paragraph (3), as the case may be, shall make an application to the Government in Form I and the Government shall after making such enquiry, as it deems fit within a period of four months from the date of receipt of the complete information, fix a revised price for such bulk drug or reject the application for revision for reasons to be recorded in writing

(4) Information to be furnished by the manufacturer in relation to the Scheduled bulk drugs: Every manufacturer, producing a Scheduled bulk drug shall furnish to the Government:

(a) a list of all Scheduled bulk drugs produced by him within thirty days of the commencement of this Order and indicate the details of the cost of each of such bulk drug in Form I

(b) the details of the cost of each Scheduled bulk drug produced by him, including such bulk drug which has been produced after the commencement of this Order, in Form I by the 30th September, every year

5. Information to be furnished by the manufacturer in relation to the non-Scheduled bulk drugs: • Every manufacturer, producing a non-Scheduled bulk drug shall furnish to the Government

(a) a list of all such bulk drugs produced by him within thirty days of the commencement of this Order and indicate the details of the cost of each of such bulk drugs in Form II

(b) the details of the cost of each non-scheduled bulk drug produced by him, including such bulk drug which has been produced after the commencement of this Order, in Form II

Provided that, for the purpose of this paragraph, the Government, may after making such inquiry as it may deem necessary in public interest, fix or revise the price of any non-Scheduled bulk drug and the manufacturer or importer of such bulk drug shall "give effect to the price so fixed or revised within fifteen days of receipt of the order.

6. Power to direct manufacturers of bulk drugs to sell bulk drugs to other manufacturers of formulations: -

[1] With a view to achieving adequate production and regulating the equitable distribution, the Government may, from time to time, by general or special order, direct any manufacturer of any bulk drug to sell such bulk drug to such other manufacturers of formulations as may be specified in such order

Provided that while making any such order, the Government shall have regard to all or any of the following factors, namely:

(i) the requirement for captive consumption of such manufacturer, and (ii) the requirement of other manufacturers.

[2] For the purpose of making any order under sub-paragraph (1), the Government may call for such information from manufacturer, importer or distributor, of bulk drugs, as it may consider necessary and such manufacturer, importer or distributor shall be bound to furnish such information within such time as may be specified by the Government

7. Calculation of retail price of formulation: - The retail price of a formulation shall be calculated by the Government in accordance with the following formula, namely:

$R. P. = (M.C.+C.C.+P.M.+P.C) \times (1+MAPE/100) + ED.$ where

- o "RP." means retail price
- o "M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf
- o "C.C." means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf
- o "P.M." means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by notification in the Official Gazette in this behalf
- o "P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf
- o "MAPE" (Maximum Allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed One hundred per cent for indigenously manufactured Scheduled formulations
- o "E.D." means excise duty;

Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importers profit which shall not exceed fifty per cent of the landed cost

Explanation - For the purpose of this proviso, "landed cost" means the cost of import of formulation inclusive of customs duty and clearing charges.

8. Power to fix retail price of Scheduled Formulations: •

[1] The Government may, from time to time, by order, fix the retail price of a Scheduled formulation in accordance with the formula laid down in paragraph 7.

[2] Where the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilises such bulk drug in his Scheduled formulations he shall, within thirty days of such fixation or revision, make an application to the Government, in Form-III for price revision of such formulations and the Government may, if it considers necessary, fix or revise the price of such formulation.

[3] The retail price of a formulation once fixed by the Government under sub-paragraphs (1) and (2) shall not be increased by any manufacturer except with the prior approval of the Government.

[4] Any manufacturer, who desires revision of the retail price of a formulation fixed under subparagraph (1), shall make an application to the Government in Form III or Form IV, as the case may be, and the Government shall after making such enquiry, as it deems fit within a period of two months from the date of receipt of the complete information, fix a revised price for such formulation or reject the application for revision for reasons to be recorded in writing.

[5] Notwithstanding anything contained in the foregoing sub-paragraphs, the retail price of a Scheduled formulation, of a manufacturer shall, until the retail price thereof is fixed under the provisions of this Order, be the price which prevailed immediately before the commencement of this Order, and the manufacturer of such formulation shall not sell the formulation at a price exceeding the price prevailing immediately before the commencement of this Order.

[6] No manufacturer or importer shall market a new pack, if not covered under sub-paragraph 3 of para 9, or a new formulation or a new dosage form of his existing Scheduled formulation without obtaining the prior approval of its price from the Government.

[7] No person shall sell or dispose of any imported Scheduled formulation without obtaining the prior approval of its price from the Government.

9. Power to fix ceiling price of Scheduled formulations:-

[1] Notwithstanding anything contained in this Order, the Government may, from time to time, by notification in the Official Gazette fix the ceiling price of a Scheduled formulation in accordance with the formula laid down in paragraph 7, keeping in view the cost or efficiency, or both, of major manufacturers of such formulations and such price shall operate as the ceiling sale price for all such packs including those sold under generic name and for every manufacturer of such formulations.

[2] The Government may, either on its own motion or on application made to it in this behalf by a manufacturer in Form III or Form IV, as the case may be, after calling for such information as it may consider necessary, by notification in the Official Gazette, fix a revised ceiling price for a Scheduled formulation.

[3] With a view to enabling the manufacturers of similar formulations to sell those formulations in pack size different to the pack size for which ceiling price has been notified under the sub-paragraphs (1)

and (2), manufacturers shall work out the price for their respective formulation packs in accordance with such norms, as may be notified by the Government, from time to time, and he, shall intimate the price of formulation pack, so worked out, to the Government and such formulation packs shall be released for sale only after the expiry of sixty days after such intimation.

Provided that the Government may, if it considers necessary, by order revise the price so intimated by the manufacturer and upon, such revision, the manufacturer shall not sell such formulation at a price exceeding the price so revised.

Explanation- For the purpose of this paragraph the "Scheduled formulation" includes single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name .

10. Power to revise price of bulk drugs and formulations:- Notwithstanding anything contained in this order :-

(a) The Government may, after obtaining such information as may be considered necessary from a manufacturer or importer, fix or revise the retail price of one or more formulations marketed by such manufacturer or importer, including a non-Scheduled formulation, in such manner as the pre-tax return on the sales turnover of such manufacturer or importer does not exceed the maximum pre-tax return specified in the Third Schedule;

(b) The Government may, if it considers necessary so to do in public interest, after calling for such information by order fix or revise the retail price of any formulation including a non-Scheduled formulation;

(c) The Government may, if it considers necessary so to do in public interest, by order include any bulk drug in the First Schedule and fix or revise the prices of such a bulk drug and formulations containing such a bulk drug in accordance with the provisions of paragraphs 3, 7, 8 and 9, as the case may be.

11. Fixation of price under certain circumstances:- Where any manufacturer, importer of a bulk drug or formulation fails to submit the application for price fixation or revision, as the case may be, or to furnish information as required under this Order, within the time specified therein, the Government may, on the basis of such information as may be available with it, by order fix a price in respect of such bulk drug or formulation as the case may be.

12. Power to recover dues accrued under the Drugs (Prices Control) Order, 1979 and to deposit the same into the Drug Prices Equalisation Account:- [1J Notwithstanding anything contained in this Order, the Government may by notice, require the manufacturer, importer or distributor, as the case may be, to deposit the amount which has accrued under the provisions of the drugs (Price Control) Order, 1979 on or before the commencement of this Order, into the Drugs Prices Equalisation Account and the manufacturer, importer or distributor, as the case may be, shall deposit the said amount into the said Account within such time as the Government may specify in the said notice.

[2] The existing amount, if any, in the Drugs Prices Equalisation Account on or before the date of commencement of this Order, and the amount deposited under sub-paragraph (1) shall be utilised for, [a] Paying to the manufacturer, importer or distributor, as the case may be, the short-fall between his retention price and the common selling price or, as the case may be, the pooled price for the purpose of increasing the production, or securing the equitable distribution and availability at fair prices, of drugs;

[b] Meeting the expenses incurred by the Government in discharging the functions under this paragraph; and

[c] Promoting higher education and research in Pharmaceutical Sciences and Technology and for the purposes incidental thereto.

13. Power to recover overcharged amount:- Notwithstanding anything contained in this order, the Government shall by notice, require the manufacturers, importers or distributors, as the case may be, to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under the provisions of Drugs (Prices Control) Order, 1987 and under the provisions of this Order.

14. Carrying into effect the price fixed or revised by the Government, its display and proof thereof:-

[1] Every manufacturer or importer shall carry into effect the price of a bulk drug or formulation, as the case may be, as fixed by the Government from time to time, within fifteen days from the date of notification in the Official Gazette or receipt of the order of the Government in this behalf by such manufacturer or importer.

[2] Every manufacturer, importer or distributor of a formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the retail price of that formulation, notified in the Official Gazette or ordered by the Government in this behalf, with the words "retail price not to exceed" preceding it, and "local taxes extra" succeeding it, in the case of Scheduled formulations :

Provided that in the case of a container consisting of smaller saleable packs, the retail price of such smaller pack shall also be displayed on the label of each smaller pack and such price shall not be more than the prorata retail price of the main pack rounded off to the nearest paisa.

[3] Every manufacturer or importer shall issue a price list and supplementary price list, if required, in Form V to the dealers, State Drugs Controllers and the Government indicating reference to such price fixation or revision as covered by the order or Gazette notification issued by the Government, from time to time.

[4] Every retailer and dealer shall display the price list and the supplementary price list, if any, as furnished by the manufacturer or importer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

15. Display of prices of non-Scheduled formulations and price list thereof:-

[1] Every manufacturer, importer or distributor of a non-Scheduled formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale the retail price of that formulation with the words "retail price not to exceed" preceding it and the words "local taxes extra" succeeding it. *(1)

Provided that in the case of a container consisting of smaller saleable packs, the retail price of such smaller pack shall also be displayed on the label of each smaller pack and such price shall not be more than the prorata retail price of the main pack rounded off to the nearest paisa.

[2] Every manufacturer or importer shall issue a price list and supplementary price list, if required, of the non-Scheduled formulations in Form V to the dealers, State Drugs Controllers and the Government indicating changes, from time to time.

[3] Every retailer and dealer shall display the price list and the supplementary price list, if any, as furnished by the manufacturer or importer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

16. Control of sale prices of bulk drugs and formulations:- No person shall sell any bulk drug or formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less, plus all local taxes, if any, payable.*(1)

17. Sale of split quantities of formulations:- No dealer shall sell loose quantity of any formulation at a price which exceeds the pro-rata price of the formulation plus 5 per cent thereof.

18. Manufacturer, distributor or dealer not to refuse sale of drug:- Subject to the provisions of the Drug and Cosmetics Act, 1940 (23 of 1940) and the Rules framed thereunder:-

[a] No manufacturer or distributor shall withhold from sale or refuse to sell to a dealer any drug without good and sufficient reasons;

[b] No dealer shall withhold from sale or refuse to sell any drug available with him to a customer intending to purchase such drug.

19. Price of formulations sold to the dealer:-

[1] A manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of this Order or any order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government (excluding excise duty, if any) minus sixteen per cent thereof in the case of Scheduled drugs.

[2] Notwithstanding anything contained in sub-paragraph (1), the Government may by a general or special order fix, in public interest, the price of formulation sold to the wholesaler or retailer in respect of any formulation the price of which has been fixed or revised under this Order.

(20) Maintenance of records and production thereof for inspection:

[1] Every manufacturer and importer shall maintain in such form as may be specified by the government, records relating to the sales turnover of individual bulk drugs manufactured or imported by him, as the case may be, and the sales turnover of formulations pack-wise and also such other records as may be directed from time to time by the Government and the Government shall have the power to call for such records or to inspect such records at the premises of the manufacturer or importer.

[2] Every manufacturer or importer shall, within six month of the close of the accounting Year, submit to the Government information in respect of turnover and allocation of sales and expenses for that year in Form-VI.

[3] Every dealer, manufacturer or importer shall maintain the cash memo or credit memo, books of account and records of purchase and sale of drugs and shall make available such records for inspection by the Government or any officer authorised in this behalf by the Government.

(21) Power of entry, search and seizure:-

[1] Any Gazetted Officer of the Central Government or of a State Government authorised by a general or special order by the Central Government or, as the case may be, by the State Government in this

behalf may, with a view to securing compliance with this Order or to satisfy himself that the provisions of this Order have been complied with -

[a] Enter and search any place;

[b] Seize any drug, along with the containers, packages or covering in which the drug is found, in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened, and thereafter take all measures necessary for securing production of the drug, containers, packages or covering, so seized, in a court of law and for their safe custody pending such production:

rc] Seize any document, such as, cash memo 'or credit memo books, books of account and records of purchase and sale of the drugs in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened.

[2] The provision of section 100 of the Code of Criminal Procedure, 19/3 (2 of 1974), relating to search and seizure shall, so far as may be, apply to searches and seizures under this Order.

22. Power to review:- Any person aggrieved by any notification issued or order made under paragraphs 3,5,8,9 or 10 may apply to the Government for a review of the notification or order within fifteen days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as the case may be, and the Government may make such order on the application as it may deem proper:

Provided that pending a decision by the Government on the application submitted under the above paragraph, no manufacturer, importer or distributor, as the case may be, shall sell a bulk drug or formulation, as the case may be, at a price exceeding the price fixed by the Government of which a review has been applied for.

(23) Power to issue guidelines and directions:-

(1) The Government, may for the purpose of implementing the provisions of this Order, authorise any Officer, by a general or special order, to inspect the premises of any manufacturer, importer, distributor or dealer and such manufacturer, importer, distributor or dealer shall allow such authorised officer and make available all relevant information required for the purpose.

[2] The Government may, from time to time, issue such guidelines and directions, consistent with the provisions of this order to any manufacturer or importer as may be necessary to carry out the provisions of this Order and such manufacturer or importer shall comply with such guidelines and directions.

24. Penalties:- Any contravention of any of the provisions of this Order shall be punished in a accordance with the provision of the Essential Commodities Act, 1955 (10 of 1955).

25. Power to exempt:-

(1) Government may, having regard to the factors mentioned in sub-paragraph (2) and subject to such conditions as it may specify, by an order in the Official Gazette, exempt any manufacturer from the operation of all or any of the provisions of this Order.

[2] While granting exemption under sub-paragraph (1), the Government shall have regard to all or any of the following factors:-

- a. Number of workers employed
- b. Amount of capital invested
- c. Range/group and type of products manufactured
- d. Sales turnover
- e. Production of bulk drugs from basic stage by a process developed through indigenous research and development, and which is Significantly different from known processes and results in cost reduction
- f. Production of a new drug which has not been produced elsewhere, if developed through indigenous research and development

26. Delegation of powers:- The Government may, by notification in the Official Gazette, direct that all or any of the powers conferred upon it by this order, other than those contained in paragraphs 22, 23, and 25 shall, subject to such restrictions, exceptions and conditions, as may be specified in the direction, be exercisable also by such Officer or authority as may be specified in the notification.

(27) Repeal and saving:-

[1] The Drugs (Prices Control) Order, 1987 is hereby repealed.

[2] Notwithstanding such repeal, anything done or any action taken, including any notification order made, direction given, notice issue or exemption granted under the Drugs (Prices Control) Order 1987, shall, in so far as it is not inconsistent with the provisions of this Order, be deemed to have been done, taken made, given, issued or granted, as the case may be, under the corresponding provisions of this Order.

(Vinoth Vaish) Joint Secretary to the
Government of India
(NO.5(4)/94-PI-If)

ANNEXURE-IV

List of Therapeutic Categories for Intensive Monitoring

1. ANTI-INFECTIVE MEDICINES (including Antihelminthics, Antibacterials, Antileprosy, Antituberculosis, Antifungals, Antivirals, Antiprotozoals).
2. MEDICINES AFFECTING THE BLOOD (Antianaemia medications and medicines affecting coagulation).
3. CARDIOVASCULAR MEDICINES (Antianginal, Antiarrhythmics, Antihypertensives, medicines used in heart failure, Antithrombotic medicines)
4. MEDICINES ACTING ON RESPIRATORY TRACT (Antiasthmatics, Antitussives)
5. HORMONES, OTHER ENDOCRINE MEDICINES, CONTRACEPTIVES
6. IMMUNOLOGICALS (including Sera, Immunoglobulins, and Vaccines)
7. GASTROINTESTINAL MEDICINES (Including Anti-ulcer medicines, Antiemetics, Anti-inflammatory medicines, medicines used in diarrhea)
8. PSYCHOTHERAPEUTIC MEDICINES
9. ANTICONVULSANTS/ANTIEPILEPTICS
10. ANTINEOPLASTIC, IMMUNOSUPPRESSIVES, AND MEDICINES USED IN PALLIATIVE CARE
11. ANALGESICS, ANTIPYRETICS, NSAIDS, MEDICINES USE IN RHEUMATOID DISORDERS
12. ANTIALLERGICS AND MEDICINES USED IN ANAPHYLAXIS
13. BLOOD PRODUCTS AND PLASMA SUBSTITUTES
14. DERMATOLOGICAL MEDICINES
15. DISINFECTANTS AND ANTISEPTICS
16. DIURETICS
17. OPHTHALMOLOGICAL PREPARATIONS
18. VITAMINS AND MINERALS

Sandhu Committee 2004

SUMMARY

The Committee held extensive deliberations on various issues pertaining to life saving drugs and ways to make them available at reasonable prices. On the question of criteria for price control no final decision could be taken as the process of consultations with various stakeholders and experts in the field could not be concluded. Hence, an Interim Report consisting of various other recommendations has been prepared. The issue of criteria would be taken up in the final report. Following recommendations have been made in the Interim Report:-

- (i) On the Question of life saving drugs and the need to bring them under price control the Committee held extensive deliberations with various stakeholders. **The Committee was informed by the HeaHh Ministry that the term 'Life Savings MedlcInes'is not used. However, from a strict medical point of view. 'medicines' used in life threatening situations' or 'medicines used for emergency care' could be considered as life saving medicines. There Is a National List of Essential Medicines based on around 354 bulk drugs, which also Includes Medicines for Emergency Care and the fist of drugs used In NaHonal HeaHh Programmes. The Committee feels that these lists are quite comprehensive and could form the BASKET which could be subjected to some kind of price management.** This could be done in two ways namely through Price Control and an Intensive Price Monitoring. While the number of drugs for price control may be kept limited for ease of administration, improved availability and to avoid any adverse effect on the growth of industry, the remaining drugs in the BASKET could be subjected to Intensive Monitoring.
- (ii) Presently, monitoring of prices is being done by NPPA on the basis of certain guidelines framed by them. There are no clear cut provisions in OPCO for price monitoring. Also the present system of monitoring is not very effective_ The Committee felt that there should be two types of monitoring, **Intensive Monitoring** and **Normal Monitoring**. Under the

Intensive Monitoring, all those drugs out of the selected BASKET which are not covered under price control should be included and remaining drugs should continue to be subjected to normal monitoring as is presently being done by NPPA. Intensive Monitoring would be more rigorous in nature in the sense that a lower cap on price increase which could 10 to 15 per annum would be fixed. In case any company increases prices of its drugs beyond this limit it would be considered as overcharging and the extra amount would be recovered from it. However, in case it can justify price increase higher than this limit it can seek prior approval from NPPA. In such a situation it would not attract provisions regarding overcharging.

- (iii) As regards, trade margins the Committee felt that the present norms for Scheduled Drugs should continue i.e. 8 for wholesalers and 16 for retailers. In case of non-Scheduled Drugs the recommended trade margins are 10 for wholesalers and 20 for retailers for the branded category of drugs and higher margins of 15 and 35 for wholesalers and retailers respectively for the generic drugs. These margins would be inclusive of various trade discounts offered by industry to dealers. However, modalities of implementation need to be worked out in consultation with NPPA and industry.
- (iv) Among the other measures for making prices reasonable are price negotiations at the time of launching of a new patented drug by any company, greater coverage of health insurance schemes, special schemes for people below poverty line, reduction of taxes and levies in case of drugs falling in the National list of Essential Medicines.
- (v) The Committee also studied the Rajasthan Model of Medicare Societies, through which Life-line fluid Stores have been opened in all the Government Hospitals at State, Divisional and District levels. Through these Stores some of the essential drugs, antibiotics, injections, IV fluids etc., are procured through open tenders directly from the manufacturing companies. Some of these drugs are made available to patients at less than 50% of the prevailing market prices. A bottle of IV fluids is sold between RS.10 to 11 as against the ceiling price of RS.17.
- (vi) The Committee has also recommended that changes should be made in the legal framework pertaining to Essential Commodities Act and OPCD to enable compounding of certain offences. This would make it possible to implement the Act and DPeO more effectively.

- (vii) It has also been recommended that OPCO Cells should be set up in the Offices of State Drug Controllers on the model of Karnataka. Government of India should pay the establishment cost of these Cells for the first five years. A system of Special Cells for town planning and development of National Capital Region (NCR) already exists in States falling in NCR area where GOI reimburses the establishment cost of these Cells. A similar approach could be adopted for the proposed OPCO Cells. A plan scheme could be formulated in this regard.
- (viii) The Committee has recommended that NPPA should have efficient mechanism for interaction with State Drug Controllers and with the Consumer Organizations, NGOs and industry organizations. It has also been recommended that strengthening of NPPA and simplification of its procedures should be undertaken.
- (ix) Wide publicity to drug policy of Government and prices fixed by NPPA and decisions taken by Government from time to time should be undertaken. Public awareness will strengthen consumer movement which may keep a check on unreasonability of prices of drugs. A plan scheme for this purpose may be formulated.
- 00 For better monitoring of drug prices there is need to develop a price index for pharmaceuticals. This would give a better picture of behaviour/movement of drug prices and help in taking corrective action. Some expert body like ORG could be engaged for this purpose in consultation with NPPA and industry organizations.

REPORT OF DR RA. MASHELKAR COMMITTEE -2003

Executive Summary

1. There has been a wide-ranging national concern about spurious/counterfeit/substandard drugs. The Supreme Court of India, the National Human Rights Commission and the Members of Parliament have time and again expressed a concern about improving the drug regulatory system in the country. The Drugs and Cosmetics Act has not been reviewed in a comprehensive manner since its inception although the Rules have been amended from time to time. The Government of India, in the past, had constituted several Committees, which had examined the issues and had made many

2. The Government of India decided to constitute an Expert Committee under the chairmanship of Dr. R.A. Mashelkar to examine all the aspects regarding the 'regulatory infrastructure and the extent and problem of

spurious/substandard drugs in the country. The Committee was asked to make recommendations and suggest a roadmap for implementation of the recommended measures so that this problem could be solved in its entirety. The Committee had an eminent scientist, an eminent lawyer, and former police commissioners as its members. Officials representing key Ministries/Departments/States! drug manufacturers, trade, consumer and professional associations were also inducted as members. Drugs Controller General (India) acted as the Member Secretary.

3. The Committee examined the broader issues by looking at the recommendations of earlier committees, the extent of progress made and the bottlenecks in implementation of the recommendations. The Committee noted that while some measures had been initiated by the Central Government, much more needed to be done to improve the regulatory system. Further, the response to these issues at the State Government level was a matter of special concern.

4. The Committee noted that although the Drugs and Cosmetics Act has been in force for the past 56 years, the level of enforcement in many States has been far from satisfactory. The non-uniformity in the interpretation of the provisions of laws and their implementation and the varying levels of competence of the regulatory officials were the main reasons for this less than satisfactory performance.

5. The Committee noted that in the light of the assessment and the recommendations of several committees, the Ministry of Health & Family Welfare had made proposals for expansion and up gradation of CDSCD. Several posts to strengthen port offices, zonal offices and testing laboratories

were also created. These posts could not be filled due to some administrative complexities. The posts have since lapsed. The committee understands that efforts were made to revive these posts but actual filling of the posts has not been done yet.

6. In 1999, the Pharmaceutical Research & Development Committee (PRDC) had recommended comprehensive strengthening of *CDSCD* to enable it to carry out the multifarious activities that the Department was expected to perform. The Committee noted, however, that in spite of the fact that three year had lapsed from the acceptance of the PRDC report by the Government, no infrastructural improvement in respect of manpower had occurred in *CDSCO*.

7. The idea of setting up of National Drug Authority (NDA) starting with the Hathi Committee Report (1975) was reiterated by Drug Policy (1986), and Drug Policy (1994). However, it was not implemented.

8. The Committee concluded that the problems in the regulatory system in the country were primarily due to inadequate or weak drug control infrastructure at the State and Central level, inadequate testing facilities, shortage of drug inspectors, non-uniformity of enforcement, lack of specially trained cadres for specific regulatory areas, non-existence of data bank and non availability of accurate information.

9. The Committee concluded that the existing infrastructure at the Centre and States was not adequate to perform the assigned functions efficiently and speedily. The Committee felt that creating another authority will not solve the problem at hand, It was essential to strengthen the existing" organisations to enable them to undertake all the functions envisaged for NDA. A strong, well equipped and professionally managed *CDSCO*, which could be given the status of Central Drug Administration (COA) was the most appropriate solution. A detailed proposal to create such a structure and strengthen the State level regulatory apparatus with complementary roles of the Centre and the States, while at the same time ensuring uniform and effective implementation, has been considered and recommended by the Committee.

10. The Committee noted that the onus of monitoring drug manufacturing standards, drawing and testing of samples, taking legal action against ; infringers rested primarily with State Drug Regulatory agencies. Hence for any effective intervention, it was essential that the State Governments strengthen and support their Drug Control Organizations. This will include provision of additional personnel, with top class technical and investigative skills, appropriate infrastructure and adequate resources. Despite several directions from the Central Government, many State Governments were yet to upgrade the drug testing facilities and the competence of their regulatory infrastructure was not at the desired level.

11. The information collected from the States in response to a questionnaire sent by the Committee revealed serious inadequacies of the regulatory apparatus. Out of the information received from 31 States/UTs, only 17 drug-testing laboratories were found to be functioning. Out of 17 States having their testing laboratories, only 7 were reasonably equipped/staffed, while the others very poorly staffed and did not even have the bare minimum equipment.

12. The Committee further observed that right from the time of Hathi Committee Report (1975), the States had been repeatedly requested to set up an intelligence cum .legal cell but so far only 10 States had reported to have set up such cells. It was not clear as to how many of these are really functioning actively and effectively.

13. The Committee was able to obtain detailed *information* regarding different categories of manufacturing units licenced by the State authorities. It was found that as against the frequently quoted figure of about 20,000 manufacturing units. The actual number of drug manufacturing licenses issued was - bulk drugs (1333), formulations (4534), large volume parenterals (134) and vaccines (56). Thus, the total number of manufacturing units engaged in the production of bulk drugs and formulations is not more than 5877. Besides there are 199 medical devices units, 638 surgical dressings and 272 disinfectant units, 4645 loan licences and 318 repacking units, 1806 blood banks, 2228 cosmetics units and 2870 other units not covered in the above categories.

14. The Committee examined the various reports and statistics presented at various fora and the media by diverse individuals, associations and agencies concerning the extent of menace of spurious drugs. The reported extent ranged widely between 0.5 (based on the cases analysed by State regulatory authorities reported in this Report) to 35 (ascribed to WHO Studies). However, WHO itself has written in response to a query from the Indian Government that 'There is no actual study by WHO, which concludes that 35 of World's spurious drugs are produced in India'. Some estimation of the quantum of spurious drugs in the market quoted is available based on the cases detected in selected pockets and regions in the country. Validation of the claims made by several agencies was not available as concrete and authenticated evidence even at the time of the submission of this final report.

15. The Committee has concluded that it is absolutely essential to evaluate systematically and scientifically the extent of the problem. For this purpose several approaches including the model proposed by the Delhi

Pharmaceutical Trust were considered by the Committee. It is recommended that a scientifically and statistically valid methodology should be used to evaluate and quantify the extent of the problem of spurious drugs at various levels in the supply chain at the Regional and National levels. The Committee, in its interim report had recommended that the Government should provide funds for this study. The Government has since agreed to provide adequate funds for undertaking the study.

16. The Committee has come to the conclusion that while the present Drugs and Cosmetics Act contains various provisions for effective punitive action against manufacturers and distributors of spurious drugs, more deterrent measures were needed. Although in the overall context of legal system, the offences having penalty of more than 3 years are construed to be cognisable, there is a need to make a distinct provision in the Drugs and Cosmetics Act itself declaring all offences related to spurious drugs as cognisable and non-bailable. Apart from penalties of stiff fines and imprisonment for life, specifically in those cases, which had resulted in grievous body harm or loss of life, death penalty was required to be provided.

17. The Committee noted with dismay that most of the prosecution cases pertaining to offences related to spurious drugs remain undecided for years. There is no greater deterrent than a 'severe', 'sure' and 'swift' punishment. This problem needs to be solved squarely by making a separate provision for speedy trials of such offences.

18. For effective and successful implementation of the penal steps, it is necessary to involve the Police authorities in addition to the Drugs inspectorates, at an early stage, by authorising them to file prosecutions for spurious drug offences under the Drugs & Cosmetics Acts. It may be necessary to invoke changes in the related statutory provisions including related legislations for effective implementation of the steps needed to be taken for both punitive and deterrent punishments to those involved in criminal acts of manufacture and distribution of drugs, which may lead to mortality or serious threat to life of innocent consumers.

19. The Committee recommends that Drugs and Cosmetics Act should be suitably amended and the maximum penalty for sale and manufacture of spurious drugs causing grievous hurt or death should be enhanced from life imprisonment to death. Likewise, the Government should make the penalties more deterrent for other related offences.

20. While the prevailing penalties are decided by the courts following normal legal procedures, it is imperative that there should be an effective deterrence against such Offenders at the investigation level itself. The Committee, therefore, recommends a specific provision in the Drugs' and Cosmetics Act

that will allow persons indulging in spurious drug offences to be detained for a minimum period.

21 Specific recommendations for amending the provisions of existing Drugs & Cosmetics Act 1940 to give effect to the recommendations in 14-19 above have been made by the Committee. The details can be seen in Annexure 13 of the Report.

22. The Committee is of the view that the responsibility for effective management of the issue of spurious drugs, their manufacture and distribution lies not only with the Drug Regulatory Agencies at the Centre and in the States and the Police, but also with all the other stake holders, namely, the medical and para-medical professionals, pharmaceutical companies, distributors and retail trade, patients, the media, the NGOs and the public at large. This is largely because these components of the health care system are the most affected and in many cases are the first contacts in the supply chain.

23. The Committee feels that, while many of the stake holders, such as the regulatory agencies and the pharmaceutical companies have sufficient expertise to detect and analyse spurious drugs, others need to be made aware of the problems involved, the potential grievous harm which can be caused and the initiatives they could and should take in tackling this menace. The Committee suggests that the industry and trade associations should play a more active and collaborative role as has recently been done by Indian Pharmaceutical Alliance (IPA) to arrest the menace of spurious drugs in the country. Specific recommendations concerning the way ahead have been made in the Interim Report.

24 The report of the Committee has been divided in part A and part B according to the terms of reference of the Committee. Part A deals comprehensively with the issue of implementation of all the rules and regulations, which guide, monitor and control the activities of the providers of the healthcare system in the country and the way to bring them up to international standards. It provides the design of Central Drug

Administration (CDA), its size, functions and the sharing of the responsibilities vis-a-vis the States including directions for licensing of manufacturing unit; by a central authority. It also deals with the regulatory health food/dietary supplements/therapeutic foods, Indian system of medicines and herbal products, Over the counter drugs, medicines & diagnostics. It addresses the issue of drug development and clinical research in India with special reference to the drug regulatory agency including modern biotechnology. Part B covers the problem concerning spurious and substandard drugs in the country and the measures to deal with it