

**Recommendations of the Task Force constituted under the Chairmanship of Dr. Proneb Sen to explore issues other than price control to make available life-saving drugs at reasonable prices.**

***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 often 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 encouraged 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 Drugs 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 all 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 the drugs contained in the NLEM ( other than the drugs procured by hospitals directly and which an individual does not have to purchase from the market ) on the basis of 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 weighted average of all the 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 (i.e. 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 L1 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 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.

5.13 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.

5.14 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 State Illness Funds (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 these

### **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.

Both 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 31<sup>st</sup> 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 DPCO, 1979 should be announced to settle these cases, most of which are under protracted litigation.