

# **Drugs Under Price Control: Why it needs to be revised in 2004 in the Light of the Public Health Crisis in India<sup>1</sup>**

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## **A. Situation Analysis**

### **1. Increase in Health Care Expenditure and Medicine Expenditures**

- 1.1 The expenditure on health care has increased significantly in the last two decades. On the other hand, India is a country where 37% of the population still live below the poverty line and where the proportion of out-of-pocket expenses out of the total expenditure on health is one of the highest in the world; with only 17% of the expenditure contributed by the government (figures from the National Health Policy 2002)
- 1.2 Nearly 50% of healthcare costs are contributed by expenditure on drugs. For example in a study done for the WHO on treatment costs incurred by patients with TB, it was found that 60% of the costs were contributed by drug costs. With the rise in health care costs the number of persons who do not seek treatment because of economic reasons has risen in both the urban and rural areas (NSS 52<sup>nd</sup> round), which is disturbing. According to a World Bank study, as a result of the costs of a single hospitalization, 35% of people fall below the poverty line. (*India - Raising the Sights: Better Health Systems for India's Poor*, World Bank May 2001).
- 1.3 The same study also suggests that out-of-pocket medical costs alone may push 2.2% of the population below the poverty line in one year.

### **2. Onset of New Diseases and Trends and Increasing Drug Resistance**

The crisis in public health in India has in fact deepened since the last revision of the DPCO with wide dissemination of the HIV epidemic in India, increasing prevalence of hypertension, diabetes mellitus, ischemic heart disease, cancer and increasing drug resistance being seen in infections such as tuberculosis, malaria, typhoid, and other bacterial infections.

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<sup>1</sup> Extracts from the Written submission on behalf of mfc, LOCOST, JSS and AIDAN to the Committee on Pricing set up by the Government of India under the Chairmanship of Shri G.S.Sandhu, Ministry of Chemicals and Fertilisers, New Delhi, Nov 2004. For complete text see mfc website.

This crisis in public health has been referred to in the National Health Policy 2002 and would require an appropriate response in policies on drugs and their pricing

### **3. Departures from the Objective of Provision of Drugs at Affordable Prices**

3.1 The drug policy since the 1970s as well as the drug price control orders being framed as a result of these policies have always had as the first objective, the provision of essential drugs and prophylactics of good quality to be made available at affordable prices To this effect the DPCO always included a list of drugs thought to be essential in light of the prevalent public health problems in the country.

3.2 The “Modifications in Drug Policy 1986 ” proposed in 1994 for the first time criteria which did not consider the nature of the drug and its use in healthcare and public health, but were based on turnover and market share of the manufacturer. Drugs with an annual turnover of more than 4 crores, in which there was either a monopoly situation (one formulator having a greater than 90% share in the market), or evidence of insufficient competition were subjected to price control.

3.3 These criteria although seemingly objective are not in tune with the realities of India’s vast pharmaceutical market where such monopoly situations are generally the exception rather the rule what with more than 8000 formulators present.

### **4. Criteria for Drugs Under Price Control not in Tune with Public Health Realities**

4.1 The result of a list based on turnover and market share criteria was and is not in line with the interests of public health in India. Many key drugs were left out in the preparation of the list according to these economic criteria. Oral rehydration salt which is a key drug for prevention and treatment of diarrheal dehydration which kills more than 1 lakh children per year was excluded from price control. Similarly drugs for the treatment of iron deficiency anemia which is India’s most prevalent disease also were excluded from this list based on the same criteria. Quinine which had been earlier under price control and which is now increasingly required in the light of development of chloroquine resistance in Falciparum malaria was also excluded. Newer drugs for malaria like artesimisinin derivatives which are increasingly used in India and worldwide and which are many times more expensive than chloroquine were also not put under price control. Only one drug for tuberculosis got included in the final list, whereas all drugs for tuberculosis should have been under price control given the fact that TB is the single biggest killer disease in India with nearly 500,000 deaths annually.

4.2 Also based on the same criteria which gave primacy to turnover and market share, a host of drugs whose utility was highly doubtful and some which were clearly outdated and non-essential found their way into the list, at the cost of drugs important for public health. Examples that can be quoted are of Analgin, Vitamin E, Phenylbutazone, Sulphaguanidine, Sulphadimidine, etc.

4.3 In a large market where a number of formulators exist, both turnover and market share can change and monopoly or oligopoly situations may not persist. Also the data on the above 2 counts may be contested given the limitations of the data like ORG-MARG. This can and does give rise to litigations by drug companies who may question the criteria for control,

when a drug is put under price control. . This has been the case with some drugs put under DPCO 1995 e.g. ciprofloxacin. Using criteria based on therapeutic use and public health importance can help prevent such litigious situations from developing. The market share data for ciprofloxacin may be contested but what cannot be contested is that it is an essential drug for the treatment of typhoid fever that is India's public health problem.

## **5. Imperfect and Inefficient Markets and Failure of Competition**

The government has promulgated the DPCOs from time to time and announced its intention to closely monitor the price situation of drugs put outside price control. The government had hoped that the market forces would regulate drug prices and keep them affordable. The experience of the behavior of prices of drugs, which were placed outside price control, has not been in keeping with this assumption. What is being witnessed very often can only be termed unregulated profiteering at the expense of the consumers. Unlike in the case of any other consumer good, with respect to the purchase of drugs, the consumer is uniquely powerless (since he cannot buy drugs without the prescription of the doctor), vulnerable and in distress (with even the threat of life hanging over him), and ignorant. It is the responsibility of the government to see that the market does not endanger the well being of people by artificially inflating drug prices.

## **6. Unregulated Market Forces: High Trade Margins**

Very high trade margins are being given without lowering the retail price of drugs. The recent experience of the Ministry of Chemicals with regard to just 3 drugs, viz. Omeprazole, Nimesulide, and Cetrizine, where nearly 1000% trade margins were documented, are only a tip of the iceberg and representative of the trade practices gaining prevalence. No benefit is passed on to the consumer who is forced to pay a very inflated cost, whereas easily they could have been lower, while ensuring reasonable profits both for the manufacturers and the pharmaceutical trade.

## **7. Large Variations in Prices of Branded Drugs**

The Indian pharmaceutical market is dominated by the presence of branded drugs. In many developed countries only the originator/innovator company is allowed to use a brand name. When a drug is under patent, other companies would have to pay royalty to the originator company for manufacturing the drug. In India all companies can use a brand name, (even if they are not even manufacturing the drug), and moreover because of the Indian Patents Act they did not have to pay any royalty to the originator company.

In the segment of generic drugs we have noted that there are huge trade margins. Similarly in India a survey of prices of established brands will show a several fold variation amounting to 200%-1000% that is inexplicable except in terms of unregulated profits for the companies. Why should 2 formulations by well-known companies, which have the same ingredients differ by 100% or 500% in price?

Market forces would dictate that the leading brand would be one of the most cost-effective of the drugs of a particular category. However the aggressive promotion of brands by means (ethical and unethical), results in the costlier brand being the market leader, at the cost of inflated treatment costs for patients, e.g., ciprofloxacin made by Ranbaxy is 3 times costlier

than that made by FDC, another well known company, but sells 5 times as much. Similarly Gliclazide made by Sun Pharma is twice the price of the same drug made by Modi-Mundi Pharma but has a moving annual turnover which is 10 times more than the lower priced product.

Does this kind of data provide any reassurance about the role of the market is being able to provide affordable drugs for people?

## **8. Lack of Rational Relationship between MRP and Cost of Manufacture**

Under the DPCO the retail price is computed using the cost of manufacture and a specified amount of maximum allowable post manufacturing expenses. For all other drugs there is no such restriction of MAPE.

If the tender prices of drugs procured by quality conscious pooled procurement processes like that of the Delhi State is compared to retail prices of the same drug it would be noted that the tender rates are a mere 3% to 20% of the retail price of the leading brand. For example in the Delhi state pooled procurement a tablet of diazepam 5 mg was procured at Rs. 0.05 while the retail price of Diazepam made by NPIL is Rs. 1.6 which is a mere 3%. Similarly with regard to Ciprofloxacin, the tender price was Rs. 0.94 which is 11% of the retail price of the leading brand made by Ranbaxy, which is Rs. 8.96.

The vast differences between the tender prices and the retail prices suggests that the costs of manufacture are not the major components of the drug price in the market. The companies are using this difference as profits for themselves, as trade margins for the pharmaceutical trade, and towards the costs of aggressive brand promotion with the doctors. This situation suggests that a more rational relationship between the cost of manufacture and the retail price would vastly help the people of India, without affecting the reasonable profits for both the pharmaceutical sector and the trade. What would be affected are the unreasonable profits that are being made at the cost of the patients.

## **9. Problems with Partial Regulation of Drugs: Altered Pattern of Production, Marketing of More Expensive, Less Rational Preparations.**

9.1 The Indian pharmaceutical market is huge with over 20,000 formulations. Most countries of the world have a system of regulation of drug prices, which covers all drugs. The Indian market is unique in being dichotomous with regard to price regulation. There are some drugs under price control with specified ceiling prices and trade margins. While the rest are outside price control which have no specified ceiling prices and trade margins.

**9.2 The price control on drugs of any category is partial at best,** with only one or two drugs of a category of drugs being represented in the price controlled list. For example in the case of NSAIDS only ibuprofen, aspirin, and phenylbutazone are represented in the previous DPCO list while in the market under the category of NSAIDS 21 drugs are available. . While Asprin and Ibuprofen have 6 brands in the top 300 brands according to the ORG-MARG data (oct. 2003), the other NSAIDs including diclofenac, nimesulide, paracetamol, rofecoxib have 16 brands in the top 300 brands. While quinolone group of drugs viz., ciprofloxacin, norfloxacin, and nalidixic acid are represented in the DPCO there are now 10 quinolones in

the market. There has been a similar proliferation of the number of drugs available in any therapeutic category in the market, be it antibiotics, antihypertensives, anti-cancer, and only a minority of these find representation in the price controlled list.

9.3 This partial representation of drug categories and therapeutic classes of drugs has inherent limitations which seriously dilute the efficacy of the DPCO in making essential drugs available to people.

The foremost limitation of the partial representation in the DPCO is that it leads to a shift in promotion away from a price-controlled drug to those drugs which are alternative drugs in the same category or therapeutic class which is not under price control.

If a particular drug from a drug category is included in the price controlled list, the drug companies start seeking higher profits by making alternative drugs that are outside price control, and which can give unregulated profit margins. E.g. the inclusion of ibuprofen in the list of price-controlled drugs without including the category of NSAIDS creates an incentive to market nimesulide (trade margins of over 100%) or rofecoxib (banned recently) which have higher profits.

9.4 Similarly incomplete representation of the drugs for a particular for a patient for malaria, chloroquine is under price control but if a patient develops severe malaria then the drugs required like quinine or artemisinin derivatives which are manifold more expensive are outside price control

9.5 A further illustration of this problem can be had from an analysis of the top selling 300 brands in India (data from ORG-MARG, Oct. 2003). The sales from these 300 brands themselves account for Rs. 18,000 crores.

Out of the 300 top selling brands only 36 (i.e. only 12%) were of drugs which are under price control. The rest of the drugs i.e. 88% of the brands were of drugs which are outside price control.

Out of the top 300 top selling brands only 115 brands were of drugs which are included in the National List of Essential Medicines 2003; i.e. 62% of brands were of drugs which were not considered relevant by experts to be included in the National List of Essential Medicines. These include more expensive alternatives of essential drugs, irrational combinations, and irrational drugs.

*9.6 This shows that the pattern of production and sales in India is skewed away from price controlled and essential drugs towards non-price controlled and less or non-essential drugs. This can be only be corrected if the pharmaceutical sector will be subjected to scrutiny in the way it prices drugs outside price control and if corrective action is applied to the way the DPCO is framed and unfair pricing and/or trade practices are curbed.*

## B. THE CRISIS IN PUBLIC HEALTH IN INDIA

The urgent need to respond with a appropriate national pharmaceutical policy.

### 1. Causes of Morbidity and Mortality

**The major causes of morbidity and mortality in India at all ages are a host of communicable and non-communicable diseases.**

Although significant improvements in life expectancy have occurred since independence, the health indicators overall and the situation with regard to specific diseases remains a cause for concern. These are one of the major reasons for India's poor performance on the Human Development Index. Access to low-cost essential medicines would be a crucial prerequisite for addressing these health problems, since it is known that the major expenditure on health care in India is made from out-of-pocket expenses.

### 2. Our Major Challenges

The major challenges in communicable and infectious diseases in India are:

**Acute respiratory infections** especially in children which result in an estimated 969,000 deaths per year.(WHO estimates\*)

**Acute diarrheal diseases**, with an estimated 19 crore illness episodes in children less than 5 years of age with 1.7 episodes per child per year, and an estimated mortality of 1 lakh children per year.(WHO estimates\*)

**Tuberculosis:** There are an estimated 2.2 million cases occurring annually, with an estimated mortality close to 0.5 million per year.

**HIV disease and Sexually transmitted diseases (STDs):** India is now second only to South Africa in having the largest number of HIV affected in the world with an estimated 4.58 million affected and an annual mortality of 600,000 cases. STDs are widely prevalent in India, and their occurrence is a major factor in fueling the HIV epidemic in India.

**Protozoal infections: Malaria** especially falciparum malaria is a public health problem with an estimated 2-3 million cases per year and a mortality of 20,000 per year.**Kala-azar** is a significant public health problem in certain states and causes...

Parasitic infections include **hookworm infections**, which contribute in a major way to iron deficiency anemia, and filariasis.

*To address the problem of these diseases the list of drugs under the DPCO would have to contain drugs for the above conditions.*

### 3. Increasing Drug Resistance

A problem, which has complicated the control and treatment of infectious and communicable diseases in India, is the increasing problem of drug resistance in common infections and diseases of public health importance.

*This problem of drug resistance in disease organisms has been highlighted in the National Health Policy 2002:*

In tuberculosis, the organisms have been showing levels of resistance to the primary anti-tuberculosis drugs, and strains resistant to both INH and Rifampicin (multi-drug resistant tuberculosis) are becoming more frequent (3.4 % in New cases) which poses a great danger to public health. The calculated cost for treating a patient with multi-drug resistant tuberculosis has been shown to be approx. Rs. 45,000 which can be brought down substantially if the drugs for this disease were under price control. No drug required for treatment of multi-drug resistant tuberculosis is under patent, and it should be possible to provide these drugs at much more affordable prices once the government decides to intervene in their pricing structure. It may also be mentioned that at present no drug for multi-drug resistant TB is provided in the National TB Control program, making it all the more important for these to have regulated prices.

Falciparum malaria, which is an acute disease of public health importance with lethal potential, is, in many parts of the country is showing resistance to the effect of chloroquine, which was otherwise the mainstay of therapy for nearly 5 decades. Newer antimalarial involves a more than 10 fold escalation of cost to the patient.

In typhoid fever, widely prevalent in India, first resistance to the effect of chloramphenicol was seen. Then quinolones were seen to be effective. Now increasingly resistance to even quinolones is being seen, which has again resulted in a dramatic escalation of cost, requiring the use of 3<sup>rd</sup> generation cephalosporins.

Earlier acute respiratory infections were responsive to the effect of co-trimoxazole, which is an inexpensive drug. Now increasingly resistance to co-trimoxazole is being reported necessitating the use of other drugs for acute bacterial infections in children.

Urinary tract infections are one of the common causes of fever in women. E.Coli, which causes the majority of these infections, has also shown disturbing levels of resistance, first to co-trimoxazole, and now to quinolones and even cephalosporins.

*The problem of drug resistance in common infectious diseases have to be factored into the framing of the DPCO. Therefore drugs for malaria should include both chloroquine as well as alternative drugs to be used in chloroquine resistant cases. Similarly in the case of Tuberculosis the list should contain drugs for treatment of resistant Tuberculosis. Otherwise the benefit of the DPCO will only be partial.*

#### **4. Need to bring sera and vaccines under price control**

Vaccines are important tools of public health, and sera are life-saving drugs for many conditions which are of public health importance in India, viz., Tetanus, Diptheria, Rabies, Snake Bite. They need to be available and affordable to people.

Vaccines for 6 diseases are covered under the expanded programme of immunisation, and are provided free by the Government of India. However in the recent years a number of other vaccines have appeared in the market, which are not yet available in the expanded programme of immunisation. Some of these vaccines are those for Hepatitis B, Hepatitis A, Typhoid fever, Hemophilus Influenzae B, Varicella, Pneumococcal vaccine. Some of these have a definite role to play in public health. At present most of these vaccines are very highly priced and are imported into India.

Sera are required in diseases like tetanus, diphtheria, snake bite, suspected rabid dog bite, which can otherwise all result in death of young people. These drugs too need to be brought under price control.

It may be mentioned here that the first objective of the Drug Policy 1986, which was reiterated in the Modifications in Drug Policy 1986 was as under:

ensuring abundant availability, at reasonable prices, of essential and life saving and *prophylactic* medicines of good quality.

***Therefore the exclusion of prophylactics in the DPCO is a little inexplicable.***

Prophylactics (e.g like rabies vaccine) are essential and life saving and therefore should be under price control.

Most of the vaccines and sera are made only by a handful of manufacturers, and this is a segment with insufficient competition.

The fact of high prices and imported nature of many sera and newer vaccines is also a fact that needs to be considered. The consumer needs protection against high prices.

*The vaccine against Hepatitis A for example would cost more than 6 times of the monthly expenditure that is used to define the poverty line in India.*

## **5. Crisis of Non-Communicable Diseases in India**

A major public health crisis, which has arisen in the last few decades with the demographic transition, increasing urbanisation, and lifestyle related factors, is the increasing prevalence of a host of non-communicable diseases. Some problems related to low nutrition, poor sanitation like iron deficiency anemia has remained.

Consider the following:

**Anemia:** Anemia is a major public health problem in women and children with a prevalence of 74.3 in children of 6-35 months and a prevalence of 49-56% in women.(NFHS 1998/99) Anemia contributes to 1/3 of maternal mortality.

**Diabetes:** India has the highest number of patients with diabetes in the world. (Source: The burden of non-communicable diseases in South Asia. *British Medical Journal*, April 2004), with estimates ranging from 19.4 million in 1995 to around 32.7 million affected. An increasing prevalence of diabetes in urban areas has been documented.

**Hypertension:** The number of patients with hypertension is also high with an estimated prevalence in adults of 20-40% in urban areas and 12-17% in rural areas.( Source: The burden of non-communicable diseases in South Asia. *British Medical Journal*, April 2004)

**Coronary artery disease:** The prevalence of coronary artery disease in urban areas is estimated to be 10% in people over 35 years of age.(ibid)

**Chronic respiratory diseases:** These include bronchial asthma, and chronic obstructive airways disease. Morbidity from respiratory diseases accounts for 65 million cases and 580,000 deaths.(ibid)

**Cancer:** Estimates of age standardised rates of cancer range from 99.0 to 129.6 per 100,000 in males and 104.4 to 154.3 per 100,000 in females (BMJ, op.cit). About **700,000** new cases with cancer occur each year.

## **6. Why should drugs for non-communicable diseases be placed under price control?**

### **A. The degree of morbidity and mortality associated with these non-communicable diseases**

The figures mentioned above mean that the numbers of patients with hypertension and diabetes mellitus would be more than the entire populations of many developed countries. *We are talking about problems affecting crores of people.*

### **B. These diseases often carry the burden of lifelong therapy**

Drugs for diabetes, hypertension, asthma, cannot be stopped but have to be taken life-long. Drugs for epilepsy have to be taken for a minimum duration of 3 years. They impose a tremendous economic burden on the patients. Many patients cannot afford the cost of treatment and suffer premature death or other complications like stroke, heart failure and kidney failure as a result.

### **C. Patients with non-communicable diseases most often have to take multiple medications, which further adds to cost.**

**E.g.** patients with diabetes may have to take 2 different anti-diabetic pills, in addition to drugs for hypertension, which often coexists, drugs for cholesterol reduction etc.

The average cost of care for a patient with diabetes has been calculated at Rs. 4500 per year.<sup>2</sup> It has been estimated also that a person from a lower socio-economic group may have to spend 59% of his income on care of diabetes.<sup>3</sup>

It has been calculated by us that the cost of the multiple medications required in the treatment of coronary artery disease according to the leader rates in the market would be Rs. 12,500 per year which is clearly unaffordable. This figure can be brought down to less than 20% if more rational pricing regimes were in place.

**Most of these drugs are at present outside price control, and there is evidence of wide inexplicable differences between brands made by reputed companies that vary by 400-900% in their retail prices, which indicates profiteering by the companies at the cost of the patient.**

## **7. Case for Bringing Some Other Categories of Drugs under Price Control**

There are some other categories of drugs, which are used for very common conditions in health care, or represent public health problems:

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<sup>2</sup> Shobana R etal. *Diab.Res.Clin.Prac* 2000. 48; 37-42.

<sup>3</sup> Shobana R etal. *Diab.Res.Clin.Prac* 2002. 55; 45-48.

## 7.1 Vitamins and Micronutrient Deficiency

**Vitamin A deficiency** is widely prevalent as a cause of preventable blindness in India. **Vitamin D deficiency** is also common and leads to rickets in children and osteomalacia in women. **Vitamin B<sub>1</sub> deficiency** can occur as a life threatening condition, **pyridoxine deficiency** can develop in patients on treatment for TB. Vitamin B-1, Thiamine, is necessary in treatment of alcoholics.

Micronutrient deficiencies of iron, and iodine are also highly prevalent.

In fact the National Health Policy 2002 has noted:

“Another area of grave concern in the public health domain is the persistent incidence of macro and micro nutrient deficiencies, especially among women and children. In the vulnerable sub-category of women and the girl child, this has the multiplier effect through the birth of low birth weight babies and serious ramifications of the consequential mental and physical retarded growth.”

## 7.2 Mental Disorders and Epilepsy

Surveys of mental morbidity carried out in various parts of the country suggest a morbidity rate of not less than 18-20 per 1000 population, which indicates the extent of the problem. (Ref: Park's Textbook of Preventive and Social Medicine, 17<sup>th</sup> edition)

Drugs for mental disorders have to be taken for prolonged periods of time, (even lifelong), and are expensive in many cases relative to their cost of manufacture.

Epilepsy is also a common problem in India, with an estimated prevalence of 5.5 million patients. In this disease it is a necessary to take drugs intake for prolonged periods. The direct and indirect costs of epilepsy treatment in a recent study have been calculated to be around Rs. 13,000 per year.<sup>4</sup> Non-compliance because of drug costs can have serious effects on the patient, including serious accidents and injuries.

## 7.3 Painful Conditions and Dyspepsia Including Peptic Ulcer

Dyspepsia is one of the commonest symptoms with which patients present in everyday practice. Certain drugs like antacids, H<sub>2</sub> blockers, proton pump inhibitors are routinely required in their treatment.

Pain syndromes are also common in healthcare settings. Rheumatoid arthritis is a common condition, which in the absence of proper and continued therapy can be crippling.

Osteoarthritis is a very common problem of old age.

## C. Drug Price Control: Suggested Principles

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<sup>4</sup> S. V. Thomas, et al. Economi Burden of Epilepsy in India *Epilepsia* Volume 42, Issue 8, August 2001

## 1. Based on Disease Conditions Prevailing and Emerging

The new drug price control order should base itself firmly on the need to address the priority disease and health care conditions of Indians and to regulate the market through rigorous monitoring closely followed by corrective action

The drug price related policy statements have always laid down the framework for a list of drugs to be under price control. They have also given reassurance to people in case the list has been modified that the prices of drugs outside price control shall be monitored for any abnormal behavior and price control re-imposed if the need be.

The previous DPCO list, formulated on the sole basis of market share and moving annual turnover was found to be at variance with the interests of public health in India as it resulted in a lot of diseases not being represented at all, and also inadequate representation also to drugs for key diseases, or health problems. Access to affordable drugs for anemia, diarrheal diseases, tuberculosis, malaria, all forms of cancer, hypertension, ischemic heart disease, and vaccines for preventable diseases suffered as a result. *This experience should reaffirm the need to base the list of drugs under price control in line with the priority diseases and healthcare problems of Indians.*

The other aspect of the previous DPCO, namely the scrutiny of drug prices, which were outside price control, has also revealed disturbing aspects. Very high trade margins (even above 1000%), inexplicable and marked variations in prices of competing brands, and high retail prices inspite of a low cost of manufacture as revealed in tender prices and prices to the pharmaceutical trade, also call for a strong corrective response. *The behavior of prices of drugs which are outside price control provide strong proof that poor, ignorant, powerless, choiceless patients, who are forced to make out of pocket expenditure, can not be left to the devices of the market.*

*Although the previous drug policy formulation made clear its intent to monitor drug prices, certain operational details about which drugs to monitor, tools for monitoring, definitions of abnormal behavior of prices needed to be more clearly defined.*

## 2. Two Options

We feel that there are **two options** with regard to the list of drugs to be under price control.

**The first and the preferred option** are to have a list of categories of drugs that address key disease and healthcare problems and which shall be under price control.

The **second option** if the first is not considered operationally suitable, is to have a core list of drugs for price control which are drawn from key categories and a supplementary list of drugs whose prices, trade margins and market shares shall be closely monitored and brought under the ambit of price control based on their quantum of sales, market share, price movements, trade margins.

The National List of Essential Medicines 2003 represent a selection of the efficacious, safe, and cost-effective medicines for the priority conditions affecting health in India.

Therefore the National List forms a sort of reference list from which the list of drugs to be placed under price control has been drawn.

The National List of Essential Medicines represents an expert consensus on the kind of drugs, which would address the majority of health care problems in the country. *Unfortunately it is at the moment only a guideline and a prescriptive tool, and does not accurately reflect the reality of pattern of drug production, prescription, and drug availability in the country. If the DPCO has the aim of ensuring availability of drugs at reasonable prices then it has to look beyond the NLEM*

For example, drugs from the National List of Essential Medicine however cover only a smaller part of the Indian drugs market. In the ORG-MARG retail audit of Oct. 2003, out of the top selling 300 brands in the country, only 115 (i.e. only 38%) were drawn out of the National List of Essential Medicines. Thus the reality of the pattern of prescriptions is that most of the drugs prescribed are outside the National List of Essential Medicines. The people therefore need regulation of prices of drugs outside this list, which means that the alternative drugs to the ones mentioned in the National list also require regulation, e.g., the sales of the oral anti-diabetic drug glibenclamide which is mentioned in the National List is exceeded by the combined sales of other non-glibenclamide drugs. The cost of some of these drugs. E.g. glimepride in the market is more than 10 times that of glibenclamide, although it confers no additional advantage. Obviously then it would be beneficial to the patient to have this more expensive alternative to an essential drug be brought under price control. Similarly low molecular weight heparins figure in the top 300 selling drugs while the conventional heparin does not.

Some of the drugs mentioned in the National List of Essential Medicines are not easily available in the market, e.g. a simple combination of ferrous sulphate and folic acid is difficult to procure. Many other kinds of iron salts are more easily available, where iron salts are combined with many other ingredients without any therapeutic rationale. None of which are under price control and

The drugs mentioned in the list for rigorous price monitoring will be largely from the same therapeutic categories mentioned in the price control list, so as to prevent a shift in promotion of more expensive alternatives of an essential drug. Sometimes such a shift has even resulted in decreased production of a price-controlled drug, and the mechanism and span of price control should ensure that such conditions are not created.

**3. The list should cover all the salts, isomers, (e.g. cetirizine as well as levocetirizine, amlodipine and s-amlodipine would both be under price control) dosage forms and formulations of the drugs and combinations of the drugs (e.g. enteric coated preparations, or eye drops or topical compounds made from the drug under price control would also be covered under price control). If a combination contains additional ingredients it shall remain under price control, and the manufacturer shall have to provide cost of manufacturing data.**

#### **4. Entire Therapeutic Category**

The list of drugs in the list of price control as well as the in the supplementary list should not be considered in isolation, but seen as representing key drug categories and therapeutic categories. What matters is not only that the particular drug be under price control but also

that the entire therapeutic category be available at affordable prices. This is necessary because the availability of a particular drug may change if the pattern of drug production, promotion and prescription by the doctors changes to favor alternative (and often more expensive drugs) from that category.

This principle should be followed also in the monitoring of drug prices. If the drug list has ferrous sulphate mentioned but if it is seen that alternative drugs like iron hydroxide polymaltose or carbonyl iron are outselling the above salt, the above drugs should be brought under price control.

## **5. MAPE Percentage**

The drugs under price control will have a MAPE of 100% over basic cost of manufacture. The government may contemplate incentives to favor the production of essential drugs, especially at the bulk stage.

## **6. Drugs to be Monitored**

The supplementary list of drugs whose prices would be monitored rigorously would be subjected to checks to ensure that the interests of patients and of public health is not compromised by unfair pricing, trading practices, or by changing patterns of production in favor of more expensive drugs.

### **7. A. Drug Price Movements**

- i. If a drug price increases by more than 10% in any year (without any evidence of increase in bulk prices), then clamping price control will be considered.
- ii. If the drug price does not decrease inspite of significant decrease (>15%) in bulk prices, then clamping of price control will be considered.

### **7.B. Drug Price Variation**

If the variation in prices between two brands in the market is greater than 33%, then price control will be considered, after a notice has been given to the manufacturers to lower their prices with immediate effect. A 10-20% mark up on retail prices shall be allowed to those companies that are now schedule M compliant.

### **7 C. Market share and sales**

- If the market share of the retail market of any one company is more than 10% or
- the drug figures in the top 300 selling brands in the market or
- the top 10 brands in its therapeutic group.

Then price control will be considered, since the above data will indicate that it is a drug of mass consumption. . The drugs under price control would again have a MAPE of 100% over the cost of manufacture.

## **8. Periodic Revision**

The list should be dynamic and revised periodically, at least once every 2 years. If there are new drugs, which are of relevance to public health, or there is evidence of abnormal increase in drug prices in any drug or class of drugs then the list may be revised accordingly. Newer drugs may be introduced which are either more efficacious, safer, more convenient, or even more expensive, and these may need to be brought under the monitoring and or price control list. New molecules developed by Indian companies would be free from price control for a particular duration as mentioned in previous policy documents.

## **9. Irrational Drugs**

One of the disturbing features of the drug market in India is the presence of formulations of uncertain therapeutic rationale, many of which are unique to India and not permitted in other countries. This has been admitted in various policy documents of the government. On the other hand they have irrational retail prices that are many times their cost of manufacture. These preparations were earlier called tonics and now bear the term of nutritional supplements.

The sale of various multivitamin and mineral preparations in syrup forms with the addition of a variety of ingredients amounts to several hundreds of crores of rupees every year (ref: ORG MARG retail audit). This does not add value to therapy but is a tremendous waste of resources. To curb this wastage, it is important to introduce ceiling prices for these preparations, pending their removal from the market.

To this end multivitamin preparations are being mentioned in the core list for price control.

## **10. FDCs of Drugs Under Price Control**

Also fixed dose combinations of drugs under price control should be under price control and should be allowed a lower MAPE of 75%. This is to act to discourage irrational combinations of rational, essential drugs.

The Kelkar Committee in the late eighties had suggested uniform markup for all FDCs of essential drugs. We go one step further and suggest the Government examine the feasibility of either of the following:

- a) no markup for the drug added to an essential drug or
- b) same ceiling price for the essential drug under price control as well as for the fixed dose combination of the controlled drug

## **11. Fiscal Incentives for Production of Essential Drugs**

In addition, we suggest fiscal incentives be given for essential drug production in the form of tax breaks, tax exemptions, etc. Specifically, we suggest that formulators making drugs

under price control may be allowed to retain the amount collected under sales tax, and excise duty and be income tax deductible. A prorata income tax exemption on profits made from essential drugs may also be allowed. The loss to the exchequer as a percentage of total revenues is negligible apart from the potential societal health benefits. In addition, direct and indirect taxes on socially debilitating and disease causing items like pan masala, tobacco products, alcohol, etc. may be increased (the MOCF and MOHFW may have to strongly suggest these measures to the MOF).

## **12. Methodology for Monitoring Prices of Formulations**

For monitoring prices of formulations, a combination of ORG reports and specifically instituted market survey, consumer organisations, NGOs, may be asked to give feedback. For confirming overpricing and extent of overpricing, tender prices of good, reputed procurement systems like that of TNMSC and Delhi may be relied upon.

## **13. Methodology for Monitoring Bulk Drug Prices**

For monitoring of bulk drug prices, a combination of ongoing surveys and feedback from ORG like organisations, consumer organisations, NGOS, prices quoted in trade journals, may be used. Also excise returns of bulk drug producers may be requisitioned from the MOF to be fed online to NPPA. (The price mentioned in the return plus trade margin of 10-15 percent normally would constitute the price to the formulator.) The multiple data feedback is for crosschecking accuracy of data on prices to the extent possible and may facilitate quicker decision on price-fixation.

## **14. Cross-Check on Formulation Prices**

Likewise excise returns of formulators may be used to check on the prices at which the formulations are made available to the trade and may give some idea of trade margins of decontrolled drugs or drugs to be monitored. However there is greater possibility of distortions here.

## **15. Price Control Post-2005**

Those in patent would have to be automatically put under price control as suggested by Section VI c of the Pharmaceutical Policy 2002. If the patent holders are not willing to submit themselves to price control, option of compulsory licensing may be exercised in line with the Doha Agreement and provisions of WTO. Efforts should be made here by comparing prices with International Procurement agencies to avoid excessive profiteering through transfer pricing.

## **16. Online Inputting of Data and Quick Decision Making**

All efforts may be made to make all data feedback online and such that price fixation becomes practically automatic and routine as well as quick (price revision within 15 days as the goal).

## **17. Involvement of Civil Society**

Civil society organisations (voluntary organisations, consumer groups) as well as health professionals and their groups could be of help in the monitoring the compliance with the DPCO as well as monitoring the behavior of price movements in the supplementary list.

The NPPA should respond about drug price matters raised by civil society groups (with established credentials) as well as health professionals, within a particular time frame. The creation of institutional mechanisms of response with regard to such inputs could go a long way to augment the reach of the NPPA.

## **D: OPTION A -DRUG PRICE CONTROL BASED ON THERAPEUTIC CATEGORIES AS DEFINED IN THE NATIONAL LIST OF ESSENTIAL MEDICINES**

The National List of Essential Medicines 2003 as well as the WHO List of Essential Medicines mentions 27 categories of drugs. Of these for the purpose of price control 17 categories have been selected. The categories chosen represent drugs required for the public health problems, for common conditions in health care, categories in which drugs are at present expensive or there is evidence of overpricing. All drugs included in these therapeutic categories are proposed to be covered by price control.

I. ANTIINFECTIVE MEDICINES: (including Antihelminthics, Antibacterials including betalactam and other antibacterials, antileprosy, antituberculosis, Antifungals, Antivirals, Antiprotozoals),

II. MEDICINES AFFECTING THE BLOOD: (Antianemia medications and medicines affecting coagulation)

III. CARDIOVASCULAR MEDICINES( Antianginal, antiarrhythmics, antihypertensives, medicines used in heart failure, antithrombotic medicines)

IV. MEDICINES ACTING ON RESP.TRACT.(antiasthmatic medications, antitussives)

V. HORMONE, OTHER ENDOCRINE MEDICINES, CONTRACEPTIVES.(including antidiabetics and thyroid and antithyroid medicines)

VI. IMMUNOLOGICALS (including sera and immunoglobulins, and vaccines)

VII. GASTROINTESTINAL MEDICINES (including antacids and anti-ulcer medications, antiemetics, antiinflammatory medicines, medicines used in diarrhea)

VIII. PSYCHOTHERAPEUTIC MEDICINES (including medicines used in psychotic disorders, mood disorders, generalised anxiety and sleep disorders)

VIII. ANTICONVULSANTS/ANTIEPILEPTICS:

IX. ANTINEOPLASTIC, IMMUNOSUPPRESIVES, AND MEDICINES IN PALLIATIVE CARE

X. ANALGESICS, ANTIPYRETICS, NSAIDS, DISEASE MODIFYING AGENTS USED IN RHEUMATOID DISORDERS

XI. ANTIALLERGICS AND MEDICINES USED IN ANAPHYLAXIS.

XII. BLOOD PRODUCTS AND PLASMA SUBSTITUTES

XIII. DERMATOLOGICAL MEDICINES

XIV. DISINFECTANTS AND ANTISEPTICS

XV. DIURETICS

XVI. OPHTHALMOLOGICAL PREPARATIONS

XVII. VITAMINS AND MINERALS

### **E: OPTION B**

**A core list of drugs from key therapeutic categories to be under price control and a supplementary list comprising alternatives from the same therapeutic categories whose prices will be rigorously monitored.**

### **LIST 1: CORE LIST**

**ANALGESICS, ANTIPYRETICS, NSAIDS, DISEASE MODIFYING AGENTS USED IN RHEUMATOID DISORDERS**

#### **Non-opioid analgesics, antipyretics, Non-steroidal anti-inflammatory medicines**

- 1) Acetyl salicylic acid
- 2) Ibuprofen
- 3) Diclofenac
- 4) Nimesulide
- 5) Paracetamol

#### **Opioid analgesics**

- 6) Morphine
- 7) Pentazocine
- 8) Pethidine hydrochloride

#### **Disease modifying agents used in rheumatoid disorder**

9. Methotrexate
10. Sulfasalazine

### **ANTIALLERGICS AND MEDICINES USED IN ANAPHYLAXIS.**

- 11) Pheniramine maleate
- 12) Cetirizine
- 13) Dexamethasone
- 14) Hydrocortisone
- 15) Prednisolone

### **ANTICONVULSANTS/ANTIEPILEPTICS:**

- 16) Carbamazepine

- 17) Diazepam
- 18) Phenytoin sodium
- 19) Sodium valproate

## **ANTIINFECTIVE MEDICINES**

### **Anthelmintics**

- 20 Albendazole
- 21 Pyrantel pamoate

### **Anti-bacterials**

#### **a. Betalactam antibacterials**

- 22 Amoxicillin
- 23 Ampicillin
- 24 Benzathine penicillin
- 25 Benzyl penicillin
- 26 Cefotaxime
- 27 Ceftriaxone
- 28 Ceftazidime
- 29 Cloxacillin

#### **Other antibacterials**

- 30 Amikacin
- 31 Gentamicin.
- 32 Azithromycin
- 33 Cephalexin
- 34 Clarithromycin
- 35 Chloramphenicol
- 36 Ciprofloxacin
- 37 Cotrimoxazole
- 38 Doxycycline
- 39 Erythromycin
- 40 Metronidazole
- 41 Norfloxacin
- 42 Vancomycin

### **Antileprosy medicines**

- 43 Clofazimine
- 44 Dapsone

### **Antituberculosis medicines**

- 45 Ethambutol
- 46 Isoniazid
- 47 Ofloxacin
- 48 Pyrazinamide
- 49 Rifampicin
- 50 Streptomycin

### **Drugs for drug resistant TB:**

- 51 Cycloserine
- 52 Ethionamide

- 53 Kanamycin
- 54 Capreomycin

### **Antifungal medicine**

- 55 Fluconazole
- 56 Griseofulvin
- 57 Amphotericin B

### **Antiviral medicines**

#### **Antiherpes**

- 58 Aciclovir

#### **Anti retrovirals**

- 59 Lamivudine
  
- 60 Stavudine
- 61 Zidovudine

#### **Non-nucleoside reverse transcriptase inhibitor**

- 62 Efavirenz
- 63 Nevirapine

#### **Protease inhibitor**

- 64 Indinavir
- 65 Nelfinavir
- 66 Ritonavir
- 67 Saquinavir

### **ANTIPROTOZOAL MEDICINES**

#### **Anti amebic and anti giardiasis medicine**

- 68 Diloxanide furoate
- 69 Metronidazole
- 70 Tinidazole

#### **Anti-Kala azar medicine**

- 71 Pentamidine isoethionate
- 72 Sodium stibogluconate

#### **Antimalarial medicines**

- 73 Artemisinin derivatives. (artesunate, artemether, etc)
- 74 Chloroquine phosphate
- 75 Primaquine
- 76 Quinine
- 77 Sulfadoxine+ Pyrimethamine

## **ANTINEOPLASTIC, IMMUNOSUPPRESSIVES, AND MEDICINES IN PALLIATIVE CARE**

- 78 Inj. Cisplatinum
- 79 Inj. Doxorubicin
- 80 Inj. 5-Fluorouracil
- 81 Tamoxifen

### **Palliative care**

- 82 Ondansetron

## **MEDICINES AFFECTING THE BLOOD:**

### **Antianemia medications**

- 83 All iron salts and iron containing compounds
- 84 Folic acid
- 85 Vitamin B<sub>1</sub>
- 86 Combinations of iron containing compounds with folic acid with/without other ingredients.

## **CARDIOVASCULAR MEDICINES**

### **Anti anginal medicines**

- 87 Isosorbide dinitrate
- 88 Isosorbide mononitrate
- 89 Metoprolol
- 90 Propranolol
- 91 Glyceryl trinitrate

### **Antiarrhythmic medicines**

- 92 Amiodarone
- 93 Adenosine
- 94 Lignocaine hydrochloride
- 95 Mexiletine
- 96 Diltiazem

### **Antihypertensives**

- 97 Amlodipine
- 98 Atenolol
- 99 Enalapril
- 100Thiazide diuretics.
- 101Losartan

### **Medicines for heart failure**

- 102Digoxin
- 103Frusemide
- 104Dobutamine
- 105Dopamine

### **Antithrombotic medicines**

- 106Streptokinase

- 107 Clopidogrel  
108 Heparins including low molecular weight heparins.

## **DERMATOLOGICAL MEDICINES**

### **Antifungal**

- 109 Miconazole  
110 Clotrimazole

### **Antiinfective**

- 111 Framycetin sulphate  
112 Silver sulphadiazine

### **Antiinflammatory**

- 113 Betamethasone dipropionate  
114 Clobetasone  
115 Clobetasol.

### **Scabicides**

- 116 Gamma Benzene hydrochloride  
117 Benzyl benzoate

## **DISINFECTANTS AND ANTISEPTICS**

### **Disinfectants**

- 118 Glutaraldehyde

## **DIURETICS**

- 119 Mannitol  
120 Spironolactone  
121 Amiloride  
122 Triamterene

## **GASTROINTESTINAL MEDICINES**

### **Antacids, Anti-ulcer**

- 123 Aluminium hydroxide, magnesium hydroxide  
124 Ranitidine  
125 Famotidine  
126 Omeprazole

### **Antiemetics**

- 127 Domperidone  
128 Metoclopramide

### **Laxatives**

- 129 Bisacodyl  
130 Isphagula husk

### **Medicines used in diarrhea**

131 Oral rehydration salt

## **HORMONE, OTHER ENDOCRINE MEDICINES, CONTRACEPTIVES.**

### **Contraceptives**

132 Ethinylestradiol+levonorgestrel

133 Ethinylestradiol + norethisterone

### **Anti-Diabetic**

134 Glibenclamide

135 Glipizide

136 Gliclazide

137 Glimepride

138 Pioglitazone

139 Insulin (Soluble) bovine/porcine/human

140 Intermediate acting Insulin (Lente/NPH) bovine/porcine/ human

### **Thyroid and Antithyroid medicin**

141 Carbimazole

142 Levothyroxine

## **IMMUNOLOGICALS**

143 Anti-D immunoglobulins

144 Anti-snake venom

145 Anti-tetanus horse/human

146 Diphtheria antitoxin

147 Rabies immunoglobulin

### **Vaccines**

148 Hepatitis B vaccine

149 Hemophilus influenzae vaccine

150 Rabies vaccine cell culture, purified chick embryo, vero cell

## **OPHTHALMOLOGICAL PREPARATIONS**

151 Sulphacetamide sodium

152 Tetracycline hydrochloride

### **Anti-glaucoma medications**

153 Betaxolol hydrochloride

154 Pilocarpine

155 Timolol

## **PSYCHOTHERAPEUTIC MEDICINES**

### **Medicines for psychotic disorders**

156 Chlorpromazine

157 Haloperidol

### **Medicines in depressive disorders**

158 Amitriptyline

159Fluoxetine

160Imipramine

**Medicines in bipolar disorders**

161Lithium carbonate

**Medicines in anxiety**

162Alprazolam

**MEDICINES ACTING ON RESP.TRACT.**

**Anti-asthma medicines**

163Beclomethasone dipropionate

164Salbutamol sulphate

165Salmeterol

166Theophylline compounds

**Anti-tussive**

167Codeine

168Dextromethorphan

**VITAMINS AND MINERALS**

169Calcium salts

170Multivitamin combinations.

171Nicotinamide

172Pyridoxine

173Riboflavine

174Thiamine

175Vitamin A

176VitaminD<sub>3</sub> (ergocalciferol)

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**OPTION B: LIST 2**

**SUPPLEMENTARY LIST OF DRUGS AND THEIR THERAPEUTIC CATEGORIES  
FOR RIGOROUS MONITORING OF PRICES**

- I. Anti-bacterials: ( Penicillins like Amoxicillin-clavulanic acid, piperacillin, Cephalosporins like cefoperazone, cefixime, cefepirome, cefnidir, quinolones like gatifloxacin, levofloxacin, monobactams like aztreonam, carbapenems like imipenem etc)
- II. Analgesics and Non-steroidal anti-inflammatory drugs: (e.g. COX-2 inhibitors and others)
- III. Drugs used in Rheumatoid arthritis: (Leflunomide, etc)
- IV. Antiallergics : (Fexofenadine, Loratadine, etc)
- V. Anticonvulsants (including gabapentin, lamotrigine, topiramate, clobazam, and others)

- VI. Immunosuppressives like Azathioprine, Ciclosporin, etc.
- VII. Cytotoxic medicines: (Bleomycin, Busulphan, Cytosine arabinoside, Danazol, Flutamide, Hydroxyurea, Paclitaxel etc)
- VIII. Antiparkinsonism medicines like Levodopa-carbidopa, Bromocriptine, Piribedil)
- IX. Medicines affecting coagulation  
Coumarin derivatives
- X. Antihypertensives: (Beta blockers like carvedilol etc, calcium channel blockers like nifedipine, sodium nitroprusside, ACE inhibitors like lisinopril, ramipril, other Angiotensin receptor antagonists, and others)
- XI. Diabetes mellitus: (Repaglinide, Rosiglitazone, Acarbose, etc)
- XII. Immunologicals Combinations of DPT with Hemophilus/Hepatitis  
Varicella vaccine
- XIII. Gastrointestinal medicines: (Proton pump inhibitors, drugs for H.pylori)
- XIV. Medicines affecting the respiratory tract: (antiasthma medications like Budesonide, Fluticasone, Ipratropium, Montelukast, etc)
- XIV. Psychotherapeutic medicines (newer sedatives, newer antidepressants, new antipsychotics)
- XV. Solutions affecting water, electrolytes.
- XVI. Vitamins (all combinations of vitamins, Methyl cobalamin, Calcitriol)



