Report of The Committee on Category II Drugs : Chairman, Vijay L. Kelkar, Chairman BICP (New Delhi, Aug. 1987)

(Excerpts)

Introduction

In pursuance of the new measures announced by Government in December, 1986 for rationalisation, quality control and growth of the drugs and pharmaceutical industry, a Committee was constituted in January, 1987 under the Chairmanship of Dr. Y.K. Alagh, the then Chairman, Bureau of Industrial Costs and Prices to identify drugs to be included in Category II. The Category II drugs would consist of drugs other than those in Category I comprising drugs required for the National Health Programme with MAPE (Maximum Allowable Post Manufacturing Expenses) of 75%—but which are also considered essential for health needs and a MAPE of 100% for formulations. The composition of the Committee was under—

1.	Dr. Y.K. Alagh, Chairman, BICP	Chairman
2	Two representatives of the Ministry of Health	Member
3.	Dr. M.A. Patel, Commissioner, Food & Drugs Control Administration Gujarat	Member
4.	Prof. V. Ramalingaswamy, Ex-Director General, Indian Council of Medical Research	Member
5.	Shri M.S. Murthy, Adviser (Chemicals)	Member
6.	Director (Drugs), Deptt. of Chemicals & Petrochemicals Convenor	Member

2. The following overall objectives were set forth with regard to the pricing in the new measures :

(*i*) To make the price control system less cumbersome but more effective by reducing the span of control.

(*ii*) To stimulate production of drugs and pharmaceuticals which are essential to the needs of large majority of the people of the country.

(*iii*) To ensure reasonable return to producers of essential drugs while at the same time restricting undue increase in their prices.

(*iv*) To ensure adequate availability at reasonable prices of essential drugs to all sections of the community, especially weaker ones even in remote areas.

3. Keeping in view the above objectives, the Committee was to be guided by the following criteria :

(*a*) Identification of therapeutic groups which are essential for curing the common diseases.

(*b*) Identification of formulations in each of the above therapeutic groups having strong market share.

EXECUTIVE SUMMARY

The Committee was reconstituted in March, 1987 with Dr. Vijay L. Kelkar, Chairman, Bureau of Industrial Costs and Prices, as Chairman.

At its first meeting, the Committee decided to invite views and suggestions of various interests in the drug industry such as IDMA, OPPI, IPA, Small Scale Producers and also various Consumer Groups. Accordingly, the Committee visited important centres of the drug industry, namely, Baroda, Bombay, Hyderabad, Madras, Calcutta and Ahmedabad on different dates.

Drug prices have been controlled in India since 1962, which were revised during 1970 and also in 1979. The present pricing regime follows from the Drug (Price Control) Order,

1979 which was framed mainly on the Hathi Committee's Report. Under this pricing regime, the number of bulk drugs for which the prices are controlled was 347 and the number of formulations for which the prices are fixed was around 4,000. If different pack sizes are taken into account, the number would be around 15,000.

It has been noted that price determination and fixation of pharmaceutical products is more complex unlike homogenous industries like fertiliser, cement, etc. In the pharmaceutical industry, each bulk drug is a separate production activity in terms of technology, material requirement, market etc. In other words, in determining and fixing the prices of 347 bulk drugs, the pricing organisation like BICP will have to treat each industrial drug as a separate industry.

There are essentially 4 major technical routes that are followed in the bulk drugs industry—

(*i*) Synthesis route;
(*ii*) Fermentation route;
(*iii*) Phyto-chemicals route;
(*iv*) Biologicals.

It has also been observed that for the production of one drug, more than one route are also adopted. In the process, the determination of cost structure necessarily becomes a complex procedure.

Due to the enormous task involved in determining costs and prices for such a large number of bulk drugs and formulations and also the non-cooperation of efficient producers, many times this results in undue delay in fixing prices for the drug. This delay can have only adverse implications to the development of domestic capabilities and consumer welfare.

The drugs and pharmaceutical industry is not capital-intensive when compared against fertilizer, petrochemical and synthetic fibres and other such industries. Consequently, the

barriers against entry are low. Bulk drug industry is very raw-material intensive. Share of raw-material and utility cost in the retail prices can be as high has 85%.

The raw-material costs have increased substantially but bulk drug prices were not increased accordingly, due to the difficulties involved in the price determination. This led to gradual erosion of profitability in the bulk drug production. This has led to the shortages of essential and life saving drugs and these shortages have been more actual in the rural areas.

Similar phenomenon was observed in the case of formulations also. Consequent result is proliferation of sub-standard drugs. It has been estimated that about 20-25% of the drugs in India could be sub-standard at the time of their administration to the patients.

In many of the bulk drugs, the price regime encourages imports rather than domestic production. With present pricing regime, the reputed pharmaceutical firms are encouraged to divert their energies to produce products which are price controlled, even when the supply of such pharmaceutical products need not necessarily enhance the health care of our people. The present pricing regime also encourages large companies to set up small captive firms as it helps them to escape the price control.

The *raison d'etre* for pricing regime is to reduce the price at consumer level so that even the weaker sections of the society have access to health care. The Committee recommends that, to reduce the price at the consumer level, it would be also necessary to take fiscal measures at the Central and the States level. The Committee felt that there is an excellent case for waivng various levies at least on essential drugs under price control. This will help in reducing prices to the consumers of essential drugs substantially.

The revenue forgone by the above proposals can be recouped at least in substantial measure by increasing taxes and other duties on the drugs which are not in Category-I and II ilst as

well as on all drugs which are used in combination. The Committee further recommends that Government should conntinue to levy import duty of at least 25% to 40% on the imported raw-materials and intermediates for the production of bulk drugs.

There are some diseases which require prolonged medication *e.g.*, Tuberculosis requires at least a treatment period of twenty four weeks duration and consequently large majority cannot complete the treatment. Similar is the case of Leprosy. Incidence of such phenomenon in poorer sections of our society is relatively much more severe. The essential drugs required for such long term treatment of diseases *e.g.*, leprosy, T.B., Cancer, Heart Ailments etc., may be given subsidy by the Government.

The cost of drugs is not the only expenditure incurred for the treatment of diseases. The cost of treatment includes physician's fees, nursing facilities, pathological tests, hospital/ nursing home services, etc. The cost on account of such services has gone up very disproportionately in the recent years. Government should attempt to rationalise the cost structure in these areas.

The Committee recommends that the manufacturers of decontrolled drugs should declare the prices for such drugs as they have adopted for pricing their own formulations and also for outside sales. The same should be intimated to the Government within a period of 4 weeks of such adoption of prices.

The implementation of the New Drug (Prices Control) order may take some time. Meanwhile, there is possibility of slackening in production in anticipation of higher mark-up in future, as has already been announced by the Government. It is, therefore, proposed by the Committee that an immediate revision in formulation prices based on the minimum mark-up, *i.e.*, 7% (which is meant only for Category I) be given to formulations presently under price control.

While selecting Category II drugs for price control purposes, the list of Category I drugs was not available. Consequently, while determining various principles for the selection of Category II drugs, those drugs were also considered. The Committee agreed to accept the recent WHO list of essential drugs to form the basis for selecting drugs to be included in Category II list as per the new policy. It was, however, observed by the Committee that the WHO list was not exhaustive, considering the requirement of Indian people. The Committee, therefore, identified another 166 drugs to be considered for possible inclusion in the proposed list.

Given the inherent complexities and difficulties, it was, recognised that the List II will have to be selective as otherwise it can lead to ironical situations of shortages, higher imports and larger proliferation of sub-standard drugs. The key question is, how much should be done administratively and how much can be achieved through the skillful use of the market forces. Because of the trade off involved, the Committee recognized that the list shall be manageable and implementable. Consequently, the criteria of excluding drugs from the proposed category II list was adopted as follow :

(*i*) Exclude those drugs which are not produced in India, provided that the consumption is not significant either now or in the near future.

(*ii*) To exclude those drugs the turnover of which has been less than rupees fifty lakhs in 1986.

(*iii*) To exclude all new drugs for which process of manufacture were developed indigenously from the price control list at least for the first five years.

(*iv*) To exclude those life-saving drugs and pharmaceutical products whose availability is far more important than the price. The nature of their demand is such that these are required less frequently but the non-availability is fatal. The notable examples of such categories are sera and vaccines.

(v) Exclude those pharmaceutical products of drugs where the domestic production structure is so competitive that there is little possibility that the consumers will be over-charged compared to the cost of production.

The Committee felt that in some individual cases, there could be specific circumstances which will make it prudent to include a particular drug in the Category II list although it could have been eliminated according to one or more of the above exclusion principles.

The therapeutic group as per WHO list is the basis of grouping the identified drugs for category II list. The therapeutic group-wise discussions for inclusion/exclusion of various drugs from Annexures II and III are detailed in Chapter III. The total number of drugs proposed to be enlisted as Category II drugs which also includes a larger number of Category I drugs is 154. After removal of Category I drugs, the total number of Category II drugs *pari passu* would reduce.

The Committee recommends that Vitamin formulations containing a single vitamin will not come under price control even when the bulk drugs is under price control.

The Committee recommends that all single drug formulations sold under generic name should be kept out of the price control. This benefit, however, may not be extended to combinations other than those with strict therapeutic usage. The Ministry of Health can be requested to identify those combinations which are of therapeutic benefit and thus qualify for exemption from price control.

In order to successfully implement the new price regime, it is necessary that it has built-in flexibility to revise the prices upward or downward, if necessitated by the changes in the prices of inputs in as automatic a manner as possible. In order to facilitate this, Committee would like to recommend that :

(*i*) Bureau of Industrial Costs and Prices may be asked to give price escalation formula whenever it recommends the fair price for the controlled drugs; and

(*ii*) Government may implement the escalation formula through the Price Revision Committee, chaired by Secretary, Chemicals and Petrochemicals, DGS & D and Chairman, Bureau of Industrial Costs and Prices as members. It is suggested that the Drugs Commissioner may be Secretary of this Committee.

In addition to the flexibility, it is necessary that prices are fixed and announced in the shortest time possible. As Government would move to the new price regime, it is suggested that BICP may be requested to set up a special Task Force with experts from various agencies *e.g.*, IDPL, HAL, etc., so that the new prices are announced within minimum possible time.

According to Drugs (Prices Control) Order, 1979, the Central Government had specified in paragraph 10 of the said order, the schedules for the formulation pricing norms for conversion cost and packaging charges, process loss, etc. These norms are more than a decade old. Consequently, they need immediate revision. The Committee recommends that the Government should appoint a group under the aegis of Drugs Prices Review Committee to quickly revise the above-mentioned norms.

To the consumers of drugs and pharmaceuticals, low prices, is only one of the concerns, albeit a major one. There are several other important consumer concerns which the drug policy will have to meet successfully. These are:

(*i*) Assurance of quality products.

(*ii*) Assured availability of those drugs which are not required frequently, *e.g.*, anti-rabies vaccine, anti-snake venom serum, etc.

(*iii*) Access to the latest drugs which have proven efficacies.

(*iv*) Safety from hazardous and spurious drugs.

Unlike any other commodity, when it comes to drugs and pharmaceuticals, quality is of paramount importance as the health and well-being are intimately involved in the use of pharmaceutical products. Hence, the Committee is of the view that in this sector the Government may have to compromise with some other industrial policy objectives, if it interferes with the supply of assured quality drugs to the consumers.

Majority of the States are not having correct and qualified regulating authorities for supervising production, sale and distribution of the drugs. As a result, the Quality Control is not regulated in these States right from production to consumption.

To ensure the quality of the drugs it is recommended that the testing facilities have to be created by each State at the earliest and till such facilities are created, the beginning may be done by starting the regional testing laboratories. This will also ensure the purchase and procurement of quality drugs by the Government institutions as there is always a bulk purchase and system of sampling can be created for testing of the randomized samples drawn from the stock received by the institutions.

The services of a registered pharmacist are very essential in dealing with the drugs. It is advisable that the services of registered pharmacists are used for dispensing of drugs and the implementation of Section 42 under the Pharmacy Act should immediately be enforced by each State. The selling needs the professional services at the back. The pharmacists should be allowed to charge prescription fees to the extent of Rs. 0.50 per prescription.

Prescribing medicines plays an important role in using drugs properly. Some of the studies of existing prescription practices show that there may be inadequate care in this regard. Hence, the Committee would suggest that the Government/ Indian Medical Association should undertake periodical prescription audit at hospitals, clinics and general practitioners.

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Drug Price Control Order 1979 and its Effects on Pharmaceutical Industry

1. Like many other countries, the drug prices have been controlled in India, since 1962. Over the two decades or so there have been major revisions of the Drug Price Policy in 1970 and 1979. The present pricing regime follows from the Drug (Prices Control) Order 1979 which was framed mainly on the Hathi Committee's Report. According to this Drugs (Price Control) Order, the Government was empowered to fix the maximum selling prices of selected bulk drugs manufactured in the country. Bulk drugs coming under the purview of price control have been grouped into 3 categories. In determining the sale prices of bulk drugs belonging to these categories, Government was to take into consideration the average manufacturing cost of the drug of an efficient producer. Return to be allowed to the manufacturer was 14% on net worth on bulk drugs used in the manufacture of categories I and II formulation and 12% on net worth of other bulk drugs (Category III).

2. As regards formulations, the DPCO, 1979 prescribed the formula for fixing the retail prices. Retail prices of formulations has two components:

(*i*) Ex-factory cost : It is the sum of raw-material cost, conversion charges, packing material cost and packing charges. Conversion cost and packing charges were allowed as per certain prescribed norms, and

(*ii*) Mark-up: This component of the retail price is the mark-up on the ex-factory costs which shall not exceed 40% in the case of Cat. I formulations, 55% in the case of Cat. II formulations and upto 100% in the case of Cat. III formulations. IVth category of formulations was kept outside the price control.

3. The Government has power to fix "Leader Prices" for formulations in Categories I, II and III which are based on production cost of an efficient manufacturer. These leader prices are the ceiling prices for manufacturers of such formulations, including those in the small scale industry. The small-scale

manufacturers who have a turnover of Rs. 50 lakhs or less per annum were kept outside the price control.

Profitabitity celling: The DPCO 1979 has prescribed an overall ceiling pre-tax return on the sales turnover of formulations. The ceiling level applicable to different categories of manufacturers ranged from 8—13%.

4. Under this pricing regime, 'the number of bulk drugs for which prices were controlled was 347 and number of formulations for which the prices were fixed was around 4,000. However, if one takes into account the different sizes of packages, this number of products for which prices are fixed will go well beyond 15,000.

5. Before we discuss the impact of this pricing regime, it is important to understand the complexity involved in the task of price determination and fixation of pharmaceutical products. Unlike an industry producing homogenous product like fertiliser, paper, cement etc. in the pharmaceutical industry, each bulk drug is a separate production activity in terms of technology, material requirements, market etc. In other words, in determining and fixing the prices of 347 bulk drugs, the pricing organisation like BICP will have to treat each individual drug as a separate industry.

6. There are essentially 4 major technical routes that are followed in the bulk drug industry :

(*i*) Synthesis route.

(*ii*) Fermentation route *e.g.*, antibiotics, steroids etc.

(*iii*) Phyto-chemicals route and

(*iv*) Biologicals *e.g.* anti-serum, vaccine, etc.

In the production of drugs, some time, all technologies can be involved with varying combinations. The combinations that are adopted can be different by the different producers even for the same drug. In fact, this is one of the implications of our practice of granting process patent rather than product patent.

This encourages the different producers to adopt different processes for the same product and this complicates the matter for price fixation or price determination.

7. In a typical important drug the number of producers could be more than 4 or 5. To fix the fair price, price determining organisation, *i.e.*, BICP has to obtain data from all organisations. After obtaining data, it has to verify this data especially relating to the costs and prices by making on the spot studies and detailed discussion. Under these conditions, the delay caused even by one participant firm in supplying data, delays the entire process of price determination. In addition, there are examples of deliberate attempts to supply data to BICP in such a manner that only high cost producers give the data. Naturally, further time is taken to persuade the lower cost producers to supply data to ensure that the consumers get the full benefit of low cost production in the economy. However, this process can further cause delay. After the BICP prepares the report it goes to the Government for their decision. Government's own decision making process naturally taken further time. It is for these reasons that the Government has not been able to fix even by 1987 the fair prices of all the 347 drugs and their 4000 or so formulations where prices are to be fixed under 1979 DPCO. Clearly this delay can have only adverse implications to the development of domestic capabilities and consumer welfare.

8. One of the most important features of the pharmaceutical industry is that compared to other industries, this is much less capital-intensive. The weighted average capital invested for drugs and pharmaceutical industry based on a sample of companies consisting of Public Sector and Private Sector works out only Rs. 94, 000/ per labour employed. In comparison, in the industries such as Fertilizers, Petrochemicals and Synthetic fibres etc., capital intensity in terms of the capital invested per labour employed at the above units works out to Rs. 61 lakhs, Rs. 38.9 lakhs and Rs. 24.1 lakhs, respectively. This clearly shows that the threat of entry in the pharmaceutical sector by potential

entrants will be always very high. This aspect will have important bearing on keeping a long term rate of profit in this industry at reasonable level. Although the capital costs are lower, it is interesting to note that in the retail prices the share of meterials cost is relatively much higher as these account for as much as 60% of the retail prices, as seen in the Table given below (See pages 178 & 179).

9. As mentioned earlier, each bulk drug requires different raw materials. Further not only the pharmaceutical industry is highly materials intensive but also the materials are of heterogeneous nature. Even if there are 4 or 5 different major materials used in each bulk drug, fixing the price of 347 bulk drugs implied that at least 10,000 to 20,000 materials or product prices are involved depending on the number of units. These raw materials are either imported or indigenously produced. The prices of these materials are usually not controlled. Further, each producer uses these in different combinations. This shows the complexity of the price determination and near impossibility of keeping any bulk drug price stable for a reasonably long pariod without hurting the producers.

In other words, this particular feature of this industry means we must have a periodic revision of the prices as the material prices do tend to vary. If this is not done, the consequences are that the bulk drugs prices will not increase although the cost of production have increased which will in turn erode the profit margins of the bulk drug production. This can have only adverse effect on the production of bulk drugs.

10. The development in bulk drugs prices over the last 5-6 years or so suggests that something similar might have happended. The Table given below (see page 180) shows that although. All India Consumer Price Index increased from 100 in 1960 to 582 in 1984-85, Wholesale Price Index increased from 100 in 1970-71 to 338 in 1984-85, the drug prices increased only from 100 in 1970-71 to 191.6 in 1984-85.

S.No	Name of the Drug	Unit Base	Retail price Rs.	Cost of raw materials & utilities (Rs.)	Percentage of impact of raw material and utility cost over the retail prices
1.	Streptomycin Sulphate	Kg.	1147.00	814.00	70.97
2.	Perachlorol Meta Xylen	Kg.	140.00	105.00	75.00
3.	Cyanocobalamine	Kg.	156.00	86.33	55.34
4.	Sulphacetanide	Kg.	314.00	159.75	50.88
5.	Riboflovin	Kg.	1820.00	1233.71	67.79
6.	Ascorbic Acid (Vit. C)	Kg.	234.50	161.95	69.05
7.	Prednisolone	Kg.	17475.00	12735.93	72.88
8.	Chloramphenicol	Kg.	849.00	566.93	66.78
9.	Chloroquine Phosphate	Kg.	544.00	316.51	58.28
10.	Procainc Hcl	Kg.	260.00	137.53	52.90
11.	Pethidine Hcl	Kg.	3009.00	994.39	33.04
12.	Methyl Dopa	Kg.	2145.00	1257.50	58.60
13.	Vitamin A	1000MU/g	991.00	536.01	54.09
14.	Ibuprofen	—	846.00	502.99	59.46
15.	Metronidazole	—	450.00	244.71	54.38

16.	Sulphadiazine	—	392.00	287.51	73.74
17.	Pot Penicillin G	BU	808.00	618.04	76 49
18.	Promethazine Hcl	Kg.	1275.00	861 00	67.32
19.	Tetracycline Hcl	Kg.	1079.00	762.57	70.67
20.	Chlortetracycline Hcl	Kg.	963.00	578.37	60.06
21.	Sod. Penicillin G	BU	1221.00	962.78	78.85
22.	Procaine Penicillin G	BU	1136.00	890.62	78.40
23.	Pot. Penicillin V	BU	1255.00	1062 00	84.62
24.	Paracetamol	Kg.	100.00	85.00	85.00
25.	Glycenclamide	Kg.	1820.00	844.20	46.38

	All Commodities (Base 1970-71 =100)	*Drugs & Medicines (Base 1970-71=100)*	*All India Consumer Price Index (Base 1960 =100)*
1980-81	257.1	137.2	401
1981-82	281.3	154.4	451
1982-83	288.5	171.4	486
1983-84	315.8	183.3	547
1984-85 (Provisional)	338.0	191.6	582

This is quite suggestive of gradual erosion of profitability in the bulk drugs production. As commented by many students of Indian pharmaceutical industry, this has been one of the major reasons for the relative stagnation in the growth of pharmaceutical industry. For instance, the investment during sixties and seventies in the pharmaceutical industry increased at the rate of 23% while since 1980, this has declined by half. Similarly, the bulk drugs production had consistently fallen short of the plan target. One of the striking examples of the phenomenon is the growing differece between the prices and cost of producing sera and vaccines e.g., Anti Snake Venom Serum, Anti Tetanus Serum, etc. This has led to the shortages of these essential drugs. These shortages have been more acute in the rural areas.

11. As far as formulations prices are concerned, the picture is not very different. The price determination procedures are equally complex and time-consuming. These difficulties were further compounded because of inadequate mark-ups that are available for the formulations. In DPCO 1979 the mark ups were 40% for category-I formulations and 55% for Category-II formulations. Because of inadequacy of these margins and the fact that underlying norms were not up-dated as frequently as it should have, the supply of many essential drugs fell down

sharply. The problem of scarcity was more acute in the mofussil areas because of lower distribution margins. The Committee is of the view that these developments are to be expected in an economy where production and distribution decisions are taken by the firms which are profit oriented. In such circumstances, if the prices or margins that are fixed are too low or do not take into account the cost escalation, it will lead only to the withdrawal of supply by the producers. In other words, there is an unavoidable trade off between the prices and the availability.

12. Yet another impact of the price control which the Committee observed, relates to quality of pharmaceutical products produced in the country. The Committee was told of a number of instances of substandard drugs. The Committee is of the view that one of the economic factors that encourages such a phenomena is our cumbersome price control mechanism. We have already noted that if the prices are too low, the producers will withdraw the supplies. However, in such scarcity conditions, there could be unethical or unscrupulous producers who would be willing to compromise quality in order to meet the price ceilings. Over the years, this phenomena has become significant. According to our estimates as much as 20% to 25% of the drugs in India could be sub-standard at the time of their administration to the patients. This percentage may by much higher for the drugs distributed in the remote areas. Needless to say, the Government should and must take administrative action against the unethical producers. It is the State's responsibility to safeguard the health of its citizens. However, it must be recognised that our pricing regime should not be such that it encourages the producers to indulge in such activities.

13. The Committee also wishes to point out two other important issues. Firstly, in many of the bulk drugs, our price regime encourages imports rather than domestic production, as there can be no price control on the imported bulk drugs; and secondly, the reputed pharmaceutical firms are encouraged to divert their energies to produce products which are not price controlled, even when the supply of such pharmaceutical product need not necessarily enhance the health care of our people.

In other words there has been diversion of scarce managerial, technological and capital resource of the country from essential drugs production to the production of inessential bulk products. The explosion in the production of cough mixtures, balm, vitamins combinations, expectorants are notable examples of this phenomena. Similarly, the price regime encourages the proliferation of unnecessary combinations of drugs as that helps the companies to avoid the rigid price control. Consequently, India has become the home of one of the largest number of combination formulations in the world. In most of the experts' view this is a dubious distinction. According to them, these combinations are not only just unnecessary but also can be harmful to the health of the people. Once again, the Government will have to take a number of steps on various fronts to reduce this menace. The Committee is of the view that properly framed pricing regime would facilitate the Government to weed out such undesirable practices.

14. Finally, the Committee would also like to mention that the present pricing regime also encourages large companies to set up captive small firms as it helps them to escape the price control as the present policy stipulates that small firms producing drugs worth less than Rs. 50 lakhs would be outside the price control. The Committee feels that this is not a healthy trend in terms of developing an internationally competitive pharmaceutical industry.

Principles for the Selection of Category II Drugs and the Proposed List

In drawing up the list of Category II drugs, the Committee was mindful of the impact of the pricing regime that was observed in India since 1980. The important aspects of this have already been highlighted in the earlier Chapter. The recent measures for rationalisation, quality control and growth of drugs and pharmaceutical industry in India announced by the Government outline the new price regime for this industry. Under this, there shall be two categories, Category I and Category II. For all the bulk drugs falling under the control-

led Category I and II, the manufacturers will be given the following three options:-

(*i*) 14% post-tax return on net worth; or
(*ii*) 22% return on capital employed; or
(*iii*) long-term marginal costing with 12% internal rate of return in the case of new plants.

2. The maximum retail price of domestically produced items excluding excise duty and local taxes, if any, would not be higher than the ex-factory cost by more than 75% in the case of Category I formulations and by more than 100% in the case of Category II formulations. This is to say, MAPE would be 75% and 100% respectively for Category I and II formulations, of the ex-factory cost. In respect of imported formulations, selling and distribution expenses, including interest and importer's margin shall not exceed 50% of landed cost.

3. Clearly, in spelling out the Category-II drugs, it presupposes identification of Category-I drugs. In the absence of this information, the Committee was handicapped. However, after great deal of deliberations and the detailed analysis made by the Committee of the national morbidity statistics and other health data, the Committee agreed to accept the recent WHO list of essential drugs to form the basis in selecting the drugs to be included in Category-II as per the new policy. It may be mentioned that the WHO list was prepared by a group of experts and it has been accepted internationally as the list of essential drugs to be used by the countries for working out their national policies for drugs and pharmaceuticals. Analysis of our health data showed that this WHO List was not exhaustive and the Committee identified another 166 drugs to be considered for possible inclusion in the proposed list. This list also took into account the consumption pattern as revealed by the ORG Group.

4. The Committee recommends that in selecting the Category-II list, we should take into account our experience of price control regime which was implemented according to the

DPCO 1979 as well as the underlying economic factors that govern the pharmaceutical industry. Committee noted that even in the developed countries, it has been recognised that there is a trade off between low drug prices and the introduction of new drugs. In India of course, given our stage of development, the trade off is more between the availability of quality products and the low prices. Committee was of the view that in designing the price regime, we should also be cognizant of the institutional features of our economy including the decision making process that usually govern the price fixation. Given the inherent complexities and difficulties, it was recognised that the List II will have to be selective as otherwise it can lead to ironical situations of shortages, higher imports and larger proliferation of sub-standard drugs. One could argue that all essential drugs should be price controlled. The key questions are how much should be done administratively and how much can be achieved through the skillful use of the market forces. Because of the trade off involved, the committee recognised that the list shall be manageable and implementable. Towards this, the Committee adopted the following criteria of excluding the drugs of WHO list as well as our own list from the proposed Category II List—

(*i*) Exclude those drugs which are not produeed in India, provided that the consumption is not significant either now or in near future,

(*ii*) To exclude those drugs whose turnover has been less than rupees fifty lakhs in 1986.

(*iii*) To exclude all new drugs for which process of manufacture were develeped indigenously from the price control list at least for the first 5 years.

(*iv*) To exclude those life saving drugs and pharmaceutical products whose availability is far more important than the price. As the nature of demand is such that it is required less frequently but its non-availability is fatal. The notable examples of such categories are sera and vaccines.

(v) Exclude those pharmaceutical products or drugs where the domestic production structure is so competitive that there is little possibility that the consumers will be over-charged compared to the cost of production.

5. The Committee accepted this set of criteria for excluding drugs from Category-II List. Of course, the Committee felt that in some individual cases, there could be specific circumstances which will make it prudent to include a particular drug in the Category II although it could have been eliminated according to the above exclusion principles.

6. In the paragraphs that follow, we have identified the drugs, each under separate heading, to be included in Category II. The Committee is of the view that the list should be periodically reviewed by the Government taking into account the exclusion principle so as to delete or add to the List of Category II drugs.

7. As far as the exclusion criteria (V) is concerned, it has to be recognised that there is an element of judgment involved in deciding whether the production structure in any particular drug is competitive or not and also whether there is any likelihood of producers exploiting their market power. We have already commented upon one of the key positive features of the drug industry in India, namely, the barriers against entry are likely to be low. Hence, the Committee adopted a criteria for identifying the products where domestic production is competitive, recognising that in competitive markets, the domestic prices will be very close to the fair cost of production and thus obviating the need of administered price control. Accordingly, the Committee adopted another exclusion criteria for deleting a group of drugs given in Annexure IV. These drugs are produced by at least 5 producers of bulk drugs and 10 producers of formulations and no monopoly in these cases could be established by the Committee.

8. As the Committee has exercised its judgment where it believes that there are possibilities of monopoly profits as only

one or two producers have disproportionately large shares, such drugs have been retained in the controlled list. Of course, if there is any further evidence of market power which has not been spotted by this Committee, the Government should include those particular drugs in the controlled category as has been done in the present selection of Category II drugs.

9. The WHO list, as updated in 1985 containing the names of essential drugs numbering 253, was considered. This list of essential drugs was basically very broad in nature and more in the nature of a model or guide list of essential drugs. It was noted that this list needs constant country-wise upgradation by deleting and including other drug depending upon, among other things, the disease pattern of the country and the morbidity rates, etc.

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65. The Committee, after careful consideration, decided that all the veterinary drugs may be kept out of the price control. The main reason for this recommendation is that marketing these products in the interior rural areas is very expensive. Further apart from the vaccines and seras which are sold by the Government departments, most of the other veterinary drugs are in the nature of food supplements, food mixtures and these are mostly used to improve the commercial value of the poultry and animals. These are not essential in nature and need not be price controlled.

66. Thus, the Committee recommended list for price controlled drugs under Cat. II would be as furnished in Annexure V. It may be noted that all the derivatives Salts/esters of the bulk drugs listed in Category-II also will be under price control.

67. The Committee, after deliberation, decided that all single drug formulations sold under generic names should be kept out of price control. This benefit may not be extended to

formulations other than those with strict therapeutic usage. The Ministry of Health can be asked to identify those combinations which are of therapeutic benefit and thus qualify for exemption from price control.

68. The number of drugs that have been proposed by the Committee will be much less compared against the drugs under prices control according to Drugs (Prices Control) Order, 1979. The Committee, however, strongly recommends that, while there will be a large number of drugs beyond price control list, there may be proliferation of drugs combination in this area. It is, therefore, proposed by the Committee that even if a drug combination is composed of only non-price controlled drugs, the formulation may be under price control. For this purpose, the list of such combinations should be prepared by the Government and companies could be asked to furnish cost data for such combination formulations in order to notify the maximum retail price.

69. In order to successfully implement the new price regime, it is necessary that it has in-built flexibility to revise the prices upward or downward, if necessitated by the changes in the prices of inputs in as automatic a manner as possible. In order to facilitate this, Committee would like to recommend that:

(*i*) BICP may be asked to give price escalation formula whenever it recommends the fair price for the controlled drugs; and

(*ii*) Government may implement the escalation formula through the Price Revision Committe, chaired by Secretary, Chemicals and Petrochemicals and DGS&D and Chairman, Bureau of Industrial Costs and Prices as members. It is suggested that the Drugs Commissioner may be the Secretary of this Committee. The Committee also recommends that as long as the price increase is less than 10 per cent, it could be approved

by the Price Revision Committee and is promptly announced. However, in case the price increase is more than 10 per cent within a period, it should be submitted to the Minister for his consideration. The corollary of this is that if the implied cost increase is less than 5 per cent of the fair price, it should be absorbed by the industry. In our view, such a procedure would make the drug prices flexible and responsive to the increase in costs.

70. In addition to the flexibility, it is necessary that prices are fixed and announced in the shortest time possible. As Government would move to the new price regime, it is suggested that BICP may be requested to set up a special Task Force with experts from various agencies *e.g.*, IDPL, HAL, etc. so that the new prices of 154 bulk drugs and formulations thereof exceeding 2000 are announced within minimum possible time. We understand that a similar Task Force was set up regarding the 1979 DPCO. Such a procedure may be followed so that the new prices are available to the drug industry as soon as possible after the Government accepts the new list of Category I and Category II drugs.

71. According to Drugs (Prices Control) Order, 1979, the Central Government had specified in paragraph 10 of the said order, the schedules for the formulation pricing norms for conversion cost and packaging charges, process loss, etc. These norms are more than a decade old. Consequently, they need immediate revision. The Committee recommends that the Government should appoint a group under the aegis of Drugs Prices Review Committee to quickly revise the above-mentioned norms.

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Measures for Enhancing Consumer Protection

In this Chapter, the Committee is making recommendations on the important issues which are complementary to the pricing regime. Although these are not strictly within the terms of reference of this Committee, the committee is convinced that these are relevant issues which the Government may wish to consider. These issues are:—

(*i*) Reduction of cost and prices of essential drugs; and

(*ii*) Shifting the production in drugs and pharmaceutical industry from non-essential to essential drugs by providing suitable incentives.

2. The *ratson d'etre* for pricing regime is to reduce the prices at the consumer level so that even the weaker sections of the society have access to health care. This will have to be done by taking several measures. Firstly, the price policy measures have stipulated maximum rates of profit the producer is expected to enjoy on the production of essential drugs. This is meant to ensure that no drug producer enjoys monopoly profits through higher prices. In other words, the drugs of which prices will be controlled would ensure that the consumer does not pay more than the fair price. Over time the price control measure will need to be supplemented by a liberal Import Policy especially vis-a-vis the bulk drugs. The threat of possible imports can be a powerful instrument against cartelisation for reaping of monopoly profits.

3. To reduce the prices at the consumer level, it is necessary to take fiscal measures at the Central and the States level. The Committee was surprised to find that in many of the essential drugs even in the case of antibiotics 20 to 40 per cent of the price that a consumer pays, is accounted by States and Central levies. Annexure-I gives the details of incidence of taxes and duties on the consumer price. The Committee feels that there is an excellent case for waiving of these levies, at least on the essential drugs. This will help in reducing prices to the

consumers of essential drugs substantially. This step can be of significance in the medium term of the next 2-3 years when the full impact of new pricing regime is going to be felt. The new pricing regime will lead to higher producer cost and retail prices due to allowing higher rate or return and mark-up for bulk drugs and formulations. In order to ensure that consumers do not suffer in the transitional period it is necessary the Government simultaneously waives the fiscal levies at least on the Category-I and Category-II drugs. This will also enhance the Government's moral authority to ask the producers to show self-restraint in their prices by adopting voluntary price structure mechanism. The Committee is aware that taxes and duties emanate both from Centre and the States. Hence, a suitable agreement between the Central Government and the State Governments is required to ensure that the benefits from the downward revision of Central levies are not appropriated at the States.

4. The revenue foregone by our proposals can be recouped, at least in substantial measure, by increasing taxes and other duties on the drugs which are not in the Category-I and Category-II lists, as well as on all drugs which are used in combinations. In other words, reduction of duty is to be confined to those drugs which are in single ingredient formulation. The Committee is aware that there are a few combinations where synergistic benefits have been demonstrated. These can also be exempted. The Health Ministry may be requested to prepare such a list of exemptions. There is one caveat regarding the reduction in taxes and duties. In order to reflect the cost of scarce foreign exchange, the Committee of course, recommends that Government should continue to levy import duty of at least 25 to 40 per cent on the imported inputs in the production of drugs.

5. There are some diseases which require prolonged medication *e.g.*, Tuberculosis requires at least a treatment period of twenty four weeks duration and consequently large majority of people cannot complete the treatment. Similar is the case of

Leprosy. Incidence of such phenomenon in poorer sections of our society is relatively much more severe. Hence, in different parts of the country, a number of physicians and consumer associations brought to our notice that most of the patients of the poorer sections of the society cannot complete the treatment because of high drug prices required to cure the diseases. The essential drugs required for such long term treatment of diseases, *e.g.*, leprosy, T.B., cancer, heart ailments, etc. may be given subsidy by the Government. The Committee would recommend that Government may request the Ministry of Health to prepare a list of such medicines and to recommend suitable level of subsidy. As all these drugs are specific, there is little possibility that they may be misused.

6. The cost of drugs is not the only expenditure incurred for the treatment of diseases. The cost of treatment includes physician's fees, nursing facilities, pathological tests, hospital/nursing home services, etc. The National Council of Applied Economic Research submitted their findings of household expenditure on medicines and medical care in January, 1985. According to the findings, the expenditure on medicines and medical care is set out below.

(*Rs. Crores*)

Region	*Medicals*	*Medical Care*
Rural	240.70	443.42+
Urban	705.22	1100.72+
Total	945.92	1544.14+

+The medical care expenses as reported by households do not include free or subsidized medical care facilities provided by Governments and employers. As specialists' services for treating serious diseases are available from these sources, the medical care expenses as reported by households are likely to be underestimated.

7. It will be seen from the above that a good percentage of the total expenditure on medicare is other than the cost of drugs. Government should attempt to rationalise the cost structure in these areas as it has been represented to the Committee by various groups that the charges on account of medical advice and nursing facilities have increased manifold during the recent years and these are disproportionate to the increase in drug prices.

8. The Committee considered the whole issue at length. It was noted that the provision for minimum trade margin was included in the DPCO, 1979 to help the wholesalers and retailers. This provision has gone a long way in improving their economic conditions and also increasing their bargaining power vis-a-vis the producer. It is now felt that in the new pricing policy, there is perhaps no need to spell out either the minimum or the maximum commission to the wholesalers or retailers. This may be left to the producers and distributors; they could mutually discuss this and come to an agreed conclusion. It was noted that the trade margin also could vary, it is possible that the producer wants higher sales of a particular product and is prepared to pay higher trade margin for these. On the other hand, there would be other products where there is no felt need to increase the same. Thus fixing the trade margin could mean closing the door of competition. It was felt that normal commercial relations between these two sectors would lead to a pattern trade margin acceptable to the parties and the Government need not normally interfere in such trade practices.

Further, in order to promote a professional trade, qualified pharmacists should be allowed to charge a professional fee of 50 paise per prescription. This will be his fees for scrutinising the prescription and dispensing drugs in the proper form. This will also help the consumers.

9. The Committee recommends that the manufacturers of decontrolled drugs should declare the prices for such drugs as they have adopted for pricing their own formulations and also

for outside sales. The same should be intimated to the Government within a period of 4 weeks of such adoption of prices.

10. The implementation of the New Drug (Prices Control) Order may take some time. Meanwhile, there is a possibility of slackening in production in anticipation of higher mark-up in future, as has already been announced by the Government. It is, therefore, proposed by the Committee that an immediate revision in formulation prices based on the minimum mark-up, *i.e.*, 75% (which is meant only for Category I) be given to all the formulations presently under price control. This will prevent unnecessary slackening in production and the availabliity of life saving medicines.

11. Government should continue to monitor the availability of all essential drugs as recommended by the Ministry of Health. In this connection, the Committee took into consideration the list of essential drugs circulated by the Director General, Health Services.

12. In our report, we have made a number of suggestions which would encourage our producers to increasingly shift the production base to the production of essential drugs and away from non-essential drugs and non-essential combinations. Similarly, our present proposals will also encourage induction of new technologies and introduction of new drugs, as these would be outside the price control for the first 5 years. Similarly, our suggestions, in keeping out generic drugs of single formulations from price control, will also go a long way in reducing costs and prices to the consumers.

13. One important area in consumer protection is purchase of drugs by the Central Medical Stores Purchase Organisation and Employees State Insurance Corporation. It has been brought to the notice of the Committee that in many parts of the country the system of drug sampling from suppliers to these organisations is not very satisfactory. The Committee, however, noted that in Gujarat a very good system of sample checking is

functioning. Gujarat State Laboratories is utilising 50% of its capacity for testing drug samples from suppliers to CMSPO and ESI. This goes a great deal towards improving and assuring high quality of drugs purchased by Central Government hospitals. The Committee recommends that this system be profitably employed in other States and Union Territories.

14. Finally it has to be recognised that effective and vigilant Drug Control Administration at the State level is bulwark for consumer protection. Such an administration has to be very vigilant against the sale of spurious, sub-standard and adulterated drugs; the administration should also ensure that good quality drug is sold at the approved price all over the State.

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