CHAPTER VI

DRUG PRICE REGULATIONS

The price of any commodity is central to the concern of any consumer. Effective protection of human health demands that drugs be sold at reasonable prices. Pricing of drugs has always been a very sensitive subject. The policy objective in this area should be to ensure that prices are fair and reasonable to the producer and consumer. The best guarantee of consumer protection is considered to be a competitive production and market structure. As long as the market is characterised by more or less free competition, the consumer is guaranteed that the price paid for the product does not imply a monopolistic profit accruing to any specific firm producing the product. However, through their control over manufacturing technology and distribution channels, these firms often have the possibility of affecting the price of their product without regard to the general economic principle of demand and supply and thereby realise huge profits. Hence the problem is high prices bearing little relation to the cost of production. Therefore it may be pointed out that no country leaves price-fixing of drugs entirely to free market forces.¹

Price regulation is a very complex issue. Many factors influence the price of commodities. Cost of the raw materials used, cost of power utilised, salaries of the employees and other conversion costs, packaging materials used and packing costs and advertisement costs go into the total cost of production.

of a drug and add up to the ultimate price payable by the consumer. In addition to this various duties and taxes payable to government also form part of the ultimate price payable by the consumer. Irrational combinations in the formulation activity is considered another aspect which needlessly enhance the cost of a drug. A sound price control system may have to take all these factors into account and take all the possible steps to reduce the cost of all these items and ensure a fair price to the consumer. This require a very comprehensive price control mechanism which should not leave any of these elements to play havoc on the economic interest of the consumer.

It is in this background an analyse of the provisions of the Drug (Price Control) Orders framed for this purpose is undertaken. It is also examined whether these are adequate to provide drugs at fair price to the consumer. The study also intends to look for other alternatives, if any, available which can provide a satisfactory solution to this problem.

**Objectives of regulation on prices of drugs**

At present the prices of drugs are controlled under the provisions of the Essential Commodities Act 1955. One of the principal objectives of the Essential Commodities Act is to fetter and curb the profiteering in the scarce resources of the community which are needed for life sustaining food and life-saving drugs. The law considers profiteering in this area as an evil and diabolic. The object of the Act and Orders framed under it appears to have been designed to fulfil the mandate of Article 39(b) of the Constitution. It must be remembered that Art 39(b) enjoins a duty on the State towards securing "that
the ownership and control of the material resources of the community are so
distributed as best to subserve the common good 2. The Essential
Commodities Act enables the Central Government to regulate production,
supply and distribution of essential commodities for the purpose of maintaining
and increasing the supply of such commodities3. It enables the Central
Government to make an order—providing for controlling price at which any
essential commodity may be bought or sold. It is in pursuance of the powers
granted to the Central Government by the Essential Commodities Act, that first
the Drugs (Price Control) Order, 1970 and later the Drugs (Price Control)
Orders 1979, and 1987 were made. Now DPCO, 1995 is in force4. These
orders are issued from time to time to give effect to the drug policy formulated
from time to time. DPCO, 1995 is issued in pursuance of the new drug policy
guidelines framed in 19945.

Before we turn our attention to the terms of the Drugs (Price Control)
Order 1995, it may be appropriate to make certain general observations of the
legality of these price regulating provisions.

3 Essential Commodities Act 1955, section 3(1) reads: “3. Powers to control production, supply,
distribution, etc. Of essential commodities—
(I) If the Central Government is of the opinion that it is necessary or expedient so to do for
maintaining or increasing supplies of any essential commodities or for securing their equitable
distribution and availability at fair prices, or for securing any essential commodity for the defence of
India or the efficient conduct of military operations it may, by order, provide for regulating or
prohibiting the production, supply and distribution thereof and trade and commerce therein.”
4 For the text of the Order see Gazette of India, Extra ordinary, part II section 3(ii) dated 6-1-95.
See also 1995 C.I.S. 112 (Central notifications).
5 Modifications to Drug Policy 1986, see for text (1994) 4 Comp.L.J. (Statutes) 49.
Legality of price control orders

The notification issued under the Essential Commodities Act relating to Sugar Control Orders were challenged in *D.S.G. Mills v. Union of India*[^6]. In this case the legality of the order was challenged on the ground that it imposed an unreasonable restriction on the right to trade under Article 19(1) (g) of the Constitution because it compels the factories to sell sugar at a loss, it fixes the price arbitrarily and there is no reasonable safeguard against the abuse of power. Answering these issues the Supreme Court observed that since the order provides for factors that the Government will have to take into account before fixing the prices like minimum price fixed for sugarcane manufacturing cost, taxes and reasonable margin of profit for producers, it cannot be said that the Order gives uncontrolled, unguided and unfettered power to the executive to fix the prices arbitrarily[^7].

On the question whether it is beyond the authority conferred on the Central Government the Court, said:

"the object of the Act and rules is to provide for controls of production, supply and distribution of trade and commerce in essential commodities in the interest of the general public so that the supplies of such commodities may be maintained or increased, their equitable distribution secured and they may be available to the general public at fair price"[^8].

[^7]: *Id.*, p. 630.
Hence the Court held that the Order would subserve the purposes of the Act and so it is within authority of the law. The Court dismissed the petition by holding that so long as the Central Government exercises the power to fix prices in the manner provided by the Act and the Order and the prices fixed were not below the cost of production it cannot be said that any further safeguards are necessary and held that the exercise of power cannot be said to be arbitrary.\(^9\)

In *Shree Meenakshi Mills v. Union of India*\(^{10}\), the petitioners challenged the Cotton, Textile (Control) Order on similar grounds. They argued that these orders conferred arbitrary powers on the executive to fix prices of essential commodities unrelated to the cost of production and reasonable margins of profit. According to them the fluctuation in the price of cotton is not taken into consideration. Raw materials, wages and profits were not considered. Nothing had been done with regard to those who suffered electricity cut in some States. Hence according to the petitioner, these regulations become void by reason of infringement of Fundamental Rights.

The Court while answering these arguments underlined the need to maintain equilibrium between the interests of consumer and the trader. The Court cautioned that the control of prices may have effect on the supply of the commodity and stressed the need to maintain increasing supply of commodity. For this purpose the Court recognised the need to take into account the cost of

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\(^{10}\) *A.I.R. 1974 S.C.* 367.
production and a reasonable return to the producer of the commodity. It observed that the producer must have an incentive to produce. The fair price must be fair not only from the point of view of consumer but also from the point of view of producer. At the same time the Court said:

"In fixing the prices, the price line has to be held in order to give preference or predominant consideration to the interest of the consumer or the general public over that of the producer in respect of essential commodities. The aspect of ensuring availability of the essential commodities to the consumer equitably and at fair price is the most important consideration"11.

Simultaneously, the Court struck a note of caution that the producers should not be driven out of his producing business because of these controls. That would lead to short supply of essential goods. Therefore, the Court said:

"any restriction in excess of what would be necessary in the interest of general public or to remedy the evil has to be very carefully considered so that the producer does not perish and the consumer is not crippled."12

However the Court held that the mere suggestion that no provision was made for adjustment on account of changes in the cost of production did not amount to infringement of Fundamental Right to carry on business and hold and dispose of property. According to the Court the fixing of controlled price

11 ld., 383.
12 Ibid.
of yarn was much more than a fair price to the producer on the date when it was fixed\textsuperscript{13}.

Realising that they may not succeed in their traditional mode of attack, the petitioners in \textit{Union of India v. Cynamide India Ltd.}\textsuperscript{14}, adopted a different device to challenge the provisions of the Drugs (Price Control) Orders 1979.

In this case they contended that the exercise of power of price fixation under DPCO 1979 was a quasi-judicial activity and should comply with the rules of natural justice. According to the petitioner the provisions of DPCO unlike other price regulations, were designed to induce better production by providing for fair return to the manufacturer. In course of their argument references were also made to the Hathi Committee report and Statement on Drug Policy 1979 which had recommended a return of 12 to 14 percent post tax return on equity and that ceiling prices may be determined by taking into account production costs and reasonable return. In their argument emphasis was laid on second clause of paragraph 3 of 1979 Order.\textsuperscript{15} This provided that in fixing the price of a bulk drug, the government may take into account the average cost of production of such bulk drug manufactured by an efficient manufacturer and allow a reasonable return on net worth. It was also submitted that the provision for an enquiry preceding the determination of the price of the

\textsuperscript{13} \textit{Id.}, p. 384.

\textsuperscript{14} A.I.R. 1987 S.C. 1802.

\textsuperscript{15} Drug (Price Control) Order 1979 Para 3 reads: "3(2) while fixing the price of a bulk drug under sub-paragraph (1), the Government may take into account the average cost of production of such bulk drug manufactured by an efficient manufacturer and allow a reasonable return of net worth."
bulk drug, and provision for a review of the order determining the price would become futile if they were not heard before the determination of the price and were not disclosed the grounds on which the decision was based and therefore violated the principles of natural justice.

To counter the argument that price fixing activity is a quasi judicial activity, the Court elaborated the distinction between legislative activity and administrative or quasi-judicial activity. The Court made the observation that price fixation is more in the nature of legislative activity and hence the question of hearing the prospectively affected persons will not arise before venturing in such legislative activity. The Court observed that though it is difficult to draw a distinctive line between legislative and administrative function because of the proliferation of delegated legislation, the line must sometimes be drawn as different legal rights and consequences may ensure out of such distinction. According to the Court the distinction between the two is one as between the general and the particular. A legislative act is the creation and promulgation of general rule of conduct without reference to particular cases and an administrative act is the making and issue of a specific direction or the application of general rule to a particular case in accordance with the requirements of the policy. The Court, accordingly, held:

“A price fixation measure does not concern itself with interests of an individual manufacturer or producer. It is generally in relation to a particular commodity or class of commodities or

\[16\text{ Id.}, \text{p.1806.}\]
transactions. It is a direction of a general character, not directed against a particular situation. It is intended to operate in the future. It is conceived in the interest of the general public."\(^{17}\)

The right of the citizen to obtain essential articles at fair prices and the duty of the State to provide them are transformed, as observed by the Court, into the power of the State to fix prices and the obligation of the producer to charge not more than the price fixed. The Court refused to agree with the premise that the price fixation primarily affects manufacturers and producers. It held that those who are most vitally affected are consumer public. It is for their protection that price fixation is resorted to and any increase in price affects them as seriously as any decrease does a manufacturer\(^{18}\). The Supreme Court categorically said:

"Nothing in the scheme of the Drugs (Price Control) Order induces us to hold that price fixation under the Drugs (Price Control) Order is not a legislative activity, but a quasi-judicial activity which would attract the observance of the principles of natural justice. Nor is there anything in the scheme or provisions of the Drugs (Price Control) Order which otherwise contemplates the observance of any principle of natural justice...."\(^{19}\)

According to the Court the enquiry contemplated by paragraph 3 of the Drugs (Price Control) Order was intended for the purposes of fixing the maximum price at which a bulk drug may be sold with a view to regulating its

\(^{17}\) Ibid.

\(^{18}\) Id., p. 1807.

\(^{19}\) Id., p. 1816.
equitable distribution and making it available at fair price. This enquiry need not be confined to obtaining information from manufacturers in general or 'an efficient manufacturer' but it may go beyond that if it thinks fit. Hence the Court held that no implications of natural justice can be read into it unless it is a statutory condition\textsuperscript{20}.

With respect to the true nature of the review power provided by paragraph 27 of the Order in relation to fixation of the price of the bulk drug, the Court observed that the reviewing authority has the fullest freedom and discretion to prescribe its own procedure and consider the matter brought before it so long as it does not travel beyond the parameters prescribed by paragraph 3\textsuperscript{21}.

On the issue of factors that are to be taken into account and the items that are to be excluded before the determination of the price of a bulk drug, the Court observed that ‘price fixation is neither the function nor the forte of the Court’. It said.

“'The assembling of the raw materials and the mechanics of price fixation are the concern of the executive and we leave it to them. And we will not re-evaluate the considerations even if the prices are demonstrably injurious to some manufacturers or producers.'\textsuperscript{22}"

\textsuperscript{20} Id., p. 1817.

\textsuperscript{21} Id., p. 1817.

\textsuperscript{22} Id., p. 1805.
Therefore, it is beyond any doubt that the authority to fix the price of any essential commodity including drugs is perfectly legal and constitutional.

**Drug price control orders: An evaluation**

Nature of control of a drug under the 1987 Orders varied depending on the Schedule in which the drug was included and category of formulation. Some aberrations have also been noticed in the listing of drugs and their categories for the purpose of price control, under DPCO 1987\(^\text{23}\) which resulted in acute market shortage of some vital drugs of which India is a largest consumer in the world.\(^\text{24}\) The new Drug Policy has changed the Price Control system substantially. Keeping in view of the changes in the national and international level, price control provisions have been liberalised to a great extent. Now the system of price control operate through a single list of price controlled drugs based thereon with a Maximum Allowable Post Manufacturing Expenses (MAPE) of 100 per cent on all the drugs.\(^\text{25}\) The categorisation of drugs into two list with different MAPE were allowed in 1987 Order. A lower MAPE of 75 per cent for the drug required for National Health Programmer (NHP)\(^\text{26}\) and a grant 100 per cent for others. Because of this there were reports of inadequate supply of drugs required for N H.P\(^\text{27}\). Perhaps it is to encourage

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\(^{24}\) Ibid. and also see *Times of India*, January 28, 1990.

\(^{25}\) Supra n.5 para 27.7.1.

\(^{26}\) DPCO 1987, Category I drugs.

\(^{27}\) Id., Category II drugs.
production and availability of these drugs, it was thought necessary to allow a uniform MAPE in all cases of drugs under price control. The criteria of including drugs under price control will be the minimum annual turnover stipulated in the Orders\textsuperscript{28}. High turnover of a drug is considered as an index of its extent of usage and considered to meet requirements of objectivity justifiable on economic consideration.

We may have a look at some of the important phrases used and their meanings before going to summarise some of the essential features of the DPCO 1995. The expressions, ‘bulk drug’, ‘formulation’, ‘Scheduled formulation’, ‘non-scheduled formulation’, ‘free reserve’, ‘networth’, ‘pretax return’ and ‘sale turn over’ have been defined under the Order. ‘Bulk drug’ is defined to mean any pharmaceutical, chemical, biological or plant product. It includes the components and derivatives which conform to pharmacopeial or other standards specified in the Drugs and Cosmetics Act\textsuperscript{29}. ‘Formulation’\textsuperscript{30} to mean a medicine processed out of one or more bulk drugs with or without the use of pharmaceutical aids and which is used for internal or external use for diagnosis, treatment or prevention of disease in human beings or animals. It expressly excludes any medicine included in the ayurvedic, sidha, unani and homeopathic system of medicine. ‘Scheduled formulation’ means\textsuperscript{31} a formulation containing any bulk drug specified in the First Schedule either

\textsuperscript{28} Supra n.5 para 27.7.2(l)
\textsuperscript{29} Supra n.4 para 2(a).
\textsuperscript{30} Id., para 2(h).
\textsuperscript{31} Id., para 2(v).
individually or in combination with other drugs which may include one or more drugs not specified in the first schedule. It does not include a single ingredient formulation based on bulk drugs, specified in the First Schedule and sold under generic name. ‘Non-scheduled formulation’ means\textsuperscript{32} a formulation not containing any bulk drug specified in the First Schedule.

‘Free reserve’ means\textsuperscript{33} a reserve created by appreciation of profits, but does not include reserves provided for contingent liability, disputed claims, goodwill, revaluation and other similar reserves. ‘Net worth’ means the paid up share capital of a company plus free reserve and surpluses. It excludes outside investments which are not readily available for operational activity\textsuperscript{34}. ‘Pretax return’ means profits before payment of income tax and surtax and includes such other expenses which do not form part of the cost of formulation\textsuperscript{35}. ‘Sale turnover’ means the product of unit of formulations sold by a manufacturer or an importer, as the case may be, in an accounting year multiplied by retail price which includes sales tax paid directly by the manufacturer or importer but does not include excise duty and local taxes\textsuperscript{36}.

In DPCO 1995, there are three schedules. The First Schedule lists bulk drugs which are used in formulations. Most of the Schedule I drugs are considered to be relatively important drugs. Second Schedule consists of forms

\begin{itemize}
\item \textsuperscript{32} Id., para 2(p).
\item \textsuperscript{33} Id., para 2(i).
\item \textsuperscript{34} Id., para 2(n).
\item \textsuperscript{35} Id., para 2(q).
\item \textsuperscript{36} Id., para 2(w).
\end{itemize}
which are to be submitted by the manufacturers or importers. It provides for three kinds of forms and an annexure. Form I is meant for application by the manufacturer or importer for fixation or revision of prices of Scheduled bulk drugs. Form II is intended to be used as an application by the manufacturer or importer to furnish information for enabling the Government to fix the price in respect of non-Scheduled bulk drugs. Form III is an application for approval or revision of the price of Scheduled formulations. Annexure intends to obtain information of cost of production of Scheduled bulk drugs. The Third Schedule gives details about the maximum pre-tax returns on sales of manufacturers or importers of formulations depending upon the category to which the manufacturer belong under this Schedule. Categorisation was based on the maximum sale turnover in a financial year.

With a view to regulate equitable distribution and increase in supply of bulk drugs specified in first Schedule and making them available at fair prices from different manufacturers the Government was empowered under the rules to fix from time to time, after making an enquiry, a maximum sale price at which a bulk drug is to be sold. It is mandatory on every manufacturer producing a Scheduled bulk drug to furnish the details of cost of each bulk drug in a separate form within 30 days of the commencement of the order and before end of September every year. For the purpose fixing the price under this paragraph the Government is empowered to inspect the manufacturing

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37 *Id., para 34*)
38 *Id., para. 4.*
process, facilities and records to enable itself to obtain information in addition to what has already been furnished by the manufacturer. While fixing the price of a bulk drug the consideration must be given to the post-tax returns of fourteen percent on net worth or return of twenty two percent on capital employed or in respect of new plant an interest rate of twelve percent based on long term marginal cost depending upon the option of the manufacturer. The Government will take into consideration a post-tax return of eighteen percent on net worth or return of twenty six percent on capital employed if the production of such bulk drug is from basic stage. But the option with regard to rate of return once exercised by the manufacturer will be final and change of rates can be made only with the prior approval of the Government. Once the maximum sale price of Scheduled bulk drug is fixed by the Government, any sale in excess of the price fixed is prohibited. But until the price of a bulk drug is fixed, the price of such drug would be the price which prevailed immediately before the commencement of this order and it should not be sold in excess of such price. If any manufacturer commences production of any scheduled bulk drug after the commencement of the Order he has to furnish the details of costs and other information to the Government within a stipulated period. Basing on the information furnished by the manufacturers or after obtaining

39 Ibid.
40 Id., para. 3(2).
41 See id., para. 3(3).
any additional information the Government may fix the maximum price for such bulk drug\textsuperscript{42}.

Any manufacturer who is aggrieved by the decision of the government in fixing the maximum price may make an application to the government. The government after making necessary enquiry may either revise or reject such application. But any such decision must be taken within a period of six months and the order must be a speaking order\textsuperscript{43}.

There is a different procedure for fixing the price of bulk drugs not listed in the First Schedule\textsuperscript{44}. Manufacturer who is producing a non-Scheduled bulk drug has to furnish a list of such drugs. He has to furnish the details of the cost of each such drug to the government within a stipulated period. Basing on the details of cost submitted by such manufacturer or importer the government may in the interest of public fix or revise the price of such drug within fifteen days of the receipt of such information\textsuperscript{45}.

The provisions of DPCO also empowers government to fix the retail price of any formulation in accordance with the formula laid down in the Order\textsuperscript{46}. The formula for calculating the retail price of such formulations is provided under paragraph 7 of the DPCO\textsuperscript{47}. If any manufacturers utilises a

\textsuperscript{42} See id., para. 4(4).
\textsuperscript{43} See id., para. 4(5).
\textsuperscript{44} See id., para 5.
\textsuperscript{45} Ibid.
\textsuperscript{46} See id., para. 8
\textsuperscript{47} Id., para 7 states, R.P. = (M.C. + C.C. + P.M. + P.C.) x (1 + MAPE / 100 ) +ED).

"R.P." means retail price.
bulk drug, for which the price has been fixed by the government under these provisions, in his formulations he has to make an application to the government within thirty days of such fixation for price revision of all such formulations. The retail price of formulation once fixed by the government cannot be increased by the manufacturers without prior approval of the government. If an application is filed by any manufacturer for revision of retail price the government has to take a decision either to revise or reject the application within two months from the date of receipt of application. The government has to record reasons for its decision.

Under paragraph 7 the maximum allowable post manufacturing expenses (MAPE) for indigenously manufactured formulation should not exceed hundred percent. However in the case of imported formulations landed cost is to be the

"M.C." means Material cost and includes cost of drugs and other pharmaceutical aids used including averages, if any, plus process loss thereon specified as a norm from time to time by notification in the official Gazette in this behalf.

"C.C." means conversion cost worked out in accordance with established procedures of costing and may be fixed as a norm every year by notification in the official Gazette in this behalf.

"P.M." means cost of the packing material used in the packing of concerned formulation and includes process loss, and shall be fixed as a norm every year by notification in the Official Gazette in this behalf.

"P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the official Gazette in this behalf.

"M.A.P.E." (Maximum Allowable Post-Manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retaining and includes trade margin and margin for the manufacturer and it shall not exceed one hundred percent for indigenously manufactured formulations.

"E.D." Means excise duty...
basis for fixing its price with a margin to cover selling and distribution expenses including interest and importer's profits which together should not exceed fifty percent of the landed cost. For this purpose landed cost means cost of import of the formulation including customs duty and clearing charges.\textsuperscript{48}

No manufacturer or importer may market a new formulation or a new dosage form of his existing Scheduled formulation without obtaining the prior approval of its price from the government.\textsuperscript{49} The government has also taken the power to fix a ceiling price of Scheduled formulation in accordance with formula provided in para.\textsuperscript{7}  \textsuperscript{50}. Ceiling price is to be fixed by keeping in view of the cost of major manufacturers of such formulation. Such ceiling prices operate for all packs including those sold under generic name. And such price is applicable even to small scale manufacturers. If a manufacturer desires to sell those formulation in pack size different to the pack size for which ceiling price has been notified, he has to work out the price for such pack size and intimate the same to the government. He is not permitted to release such formulation packs for sale until the expiry of sixty days from such intimation.\textsuperscript{51}

\textbf{Power to Revise the price}

\textsuperscript{48} See id., explanation to para. 7.

\textsuperscript{49} Id., para. 8(7).

\textsuperscript{50} Id., para. 9.

\textsuperscript{51} Id., para. 9(3).
The Government may revise the price of any bulk drug or formulation including non-scheduled formulation if it considers necessary in the interest of public. This power is to be exercised in the manner provided under the Order. It has to take into account the pre-tax return on the sale turnover of the manufacturer. It has to ensure that the pre-tax return on the sale turnover of any manufacturer does not exceed the maximum pre-tax return specified in the Third Schedule.52

If the government considers necessary in the public interest, it may include any bulk drug in the First Schedule and fix the price of such bulk drug and formulation containing such bulk drug.53

Power to exempt

Any manufacturer may be exempted from the operation of the provisions of all or any of the provisions of the Order. Before exempting any such manufacturer, regard must be had to factors like number of workers employed, the amount of capital invested, range or type of products manufactured and sales turnover. Another factor to be taken into account is the production of bulk drugs from basic stage by a process developed through indigenous research and development and production of new drug which has not been produced elsewhere.54

52 See id., para. 10.
53 Id., para. 10(c).
54 Id., para. 25.
A special power is conferred on the government to fix price in respect of any bulk drug or formulation for which manufacturer or importer fails to furnish the information required by it under these provisions. Every manufacturer or importer has to implement the price fixed by the government within the stipulated time. Likewise, every manufacturer, importer or distributor of a formulation is required to display on the label of the container the retail price with the words “retail price not to exceed” preceding and “Local Taxes Extra” succeeding it. But a manufacturer or importer or distributor of a non-Scheduled formulation has to display in indelible mark on the label of container of the formulation and on the minimum pack offered for sale, the retail price of that formulation with words “maximum retail price” preceding it and words “inclusive of all taxes” succeeding it. The manufacturer or importer has to issue a price list to the retailer or dealer and every such retailer or dealer is duty bound to display the price list on a conspicuous part of the premises where he carries on his business. This display is to be easily accessible to any person who wish to consult it. This rule applies to prices of non-Scheduled formulations also.

A reference should also be made to some of the items included and excluded in the forms provided under the schedules and the annexure to be attached to Form I. As already pointed out Form I is meant for an application
for fixation or revision of the scheduled bulk drug. The contents of the form are intended to enable the government to obtain information relating to, among other things, capital employed, manufacturing process, rate of production, cost of raw materials used and number of persons employed, their grades and emoluments and cost of production. For furnishing the details of cost of production, an annexure is to be attached to this Form. Annexure includes, among other things, contents like details of cost, cost of raw materials, power, conversion cost, packing materials and expenses, transport charges and selling expenses. It also specifically provides items of expenses which are not to be included in the cost. The items of expenses excluded from cost are bonus in excess of statutory minimum, bad debts, donations and charities, loss on sale of assets, brokerage and commission and other expenses not recognised by income tax authorities.

Some of these provisions including the phrases defined under the Orders have been contentious issues between the government and the drug manufacturers. For example it was argued that in calculating “net worth” the exclusion of the cost of new works in progress and the amount invested outside the business could not be justified on any known principle of accountancy. Attacks were also made in respect of items of expenses to be excluded in ascertaining the cost. They argue that ‘bonus in excess of statutory minimum’ should not have been excluded. So also other item of expenditure excluded.

59 See id., item 17 of Annexure.
60 The arguments of manufacturers are reproduced from the Cynamide case, supra n.14 at p.1819.
Their contention is that where bonus in excess of statutory minimum was payable under the provisions of the Bonus Act, there was no option left to the manufacturer not to pay the bonus in excess.61

Another contention of the manufacturers was relating to the norms for conversion costs, packing charges, process loss of materials and packing material required to be notified for the purpose of calculating retail price of formulation. The argument was that the formula in regard to conversion cost as provided under the Order is not scientific. According to them, the same can be done in a more scientific manner.62 But these arguments were rejected by the Supreme Court on the ground that it was sufficient to adopt a rough and ready but otherwise not unreasonable formula rather than going for a needlessly intricate one.63

**Measures needed for a better price control system**

The rules relating to display of price on the label appears to conflict with some provisions of the Standards of Weights and Measures Act 1976. This controversy assumes importance because of strict enforcement of the Packaged Commodities Rules 1977 framed under the above Act in some states. It has created problems for producers and sellers of drugs. Such problem may not arise after DPCO 1995 in case of non-Scheduled formulations. But the problem may persist with regard to scheduled formulations. For example,

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61 *Id.* at 1820.
maximum retail prices of drugs are fixed under the DPCO. The prices of scheduled formulations are exclusive of local taxes and the local taxes vary from place to place and time to time. Under the Packaged Commodities Rules, however the maximum retail price of a drug package must be inclusive of all local taxes. The government ought to suitably amend the relevant rules to avoid disputes and litigation caused by these conflicting provisions.

It was suggested that the drug industry may be exempted from the relevant provisions of the Standards of Weights and Measures Act and the rules framed thereunder.64 Significantly the Act itself provides that "the Central Government may, by rules, specify the classes of commodities or packages in relation to which all or any of the provisions shall not apply or shall apply with such exceptions or modifications as may be specified therein"65. It is nobody's case that the Standards Act should not be made applicable to the drug industry. It must, however, be ensured that there is no conflict between the two sets of rules required to be observed by the industry and avoid confusion in the minds of consumers. If the maximum retail price fixed under DPCO is exclusive of local taxes, retailer gets an opportunity to defraud consumers by inflating local taxes. There is every need to levy local taxes at uniform rates throughout the country for protecting consumers.

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65 Standards of Weights and Measures Act 1976, section 39(9).
There are allegations that industry has been adopting devices to minimise even these limited controls. Many big companies get certain products manufactured by small scale units through loan licensing system and market them under their brand names. The large companies decide from where and at what price the small scale units should import intermediates and penultimates for formulations to be marketed by them. Drugs of popular use, in which there is a monopoly situation are to be kept under price control. As an experimental measure, drugs having adequate competition are kept away from price control. The idea is that if this proves successful, it may pave the way for further liberalisation. However, strict watch on the movement of prices of these products is required.

The government may determine the ceiling levels beyond which increase in prices would not be permissible. The ceiling price will be determined by taking into account the production costs and reasonable returns for the units which are market leaders. It intends to keep close watch on the prices of medicines which are taken out of price control. In case, the prices of these medicines rise unreasonably, appropriate measures, including reclamping of price control would be initiated. The genetically engineered drugs produced by recombinant DNA technology and specific cell or tissue targeted drug

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67 A Bombay based non FERA Company has as many as 23 drugs manufactured under the loan licensing system.
formulations are to kept away from price control for five years from the date of manufacture in India\textsuperscript{68}.

As an answer to the allegations that there is an unreasonable delay in fixing the prices of the drugs,\textsuperscript{69} a time frame for granting price approvals has been fixed as 2 months for formulation and 4 months for bulk drugs from the date of receipt of the complete information. To encourage the production from basic stage the rate of return has been enhanced to 18 per cent on net worth or 22 per cent on capital employed.

All these measures of direct controls on the pharmaceutical industry failed to yield the intended results for various reasons. The machinery created under the provision is inadequate to monitor these controls apart from its reluctance to antagonise the industry. It is compounded by the difficulty of obtaining an accurate information of the cost of materials used and the actual turnover of the respective industries because of the ability of multinationals who engage in many devices like over invoicing of imported materials and transfer pricing methods\textsuperscript{70}. However there are serious complains that

\textsuperscript{68} Though the new drug policy 1994 makes such proposal, the same has not been provided under DPCO 1995. It only allows exemption of new drugs produced through indigenous research and which has not been produced elsewhere. Perhaps drugs produced by DNA technology may be covered impliedly, see DPCO 1995 para 25.2(f).

\textsuperscript{69} See \textit{Indian Express}, January 20, 1990.

\textsuperscript{70} Even in England where the laws are more rigorous this practice is followed. For details see Hoffmann La Roche affairs. Here the company held a patent for two very widely used tranquillisers, Librium and Valium. Following a reference from the Government, the monopolise Commission reported that profits on drugs were too high - profits on sales upto 60 per cent and 70 per cent on capital in a year. A salient piece of evidence was that although the price of drugs falls from the time they are patented, the price of Librium and Valium had remained stable. Moreover, the active
manufacturer and importers have been over invoicing imports. The power to revise the prices of drugs has been constantly invoked by the drug companies on the pretext of hike in the cost of imports and on account of devaluation of the rupee. The Department of Chemicals did not bother to find out either the prevailing international price of the concerned items or the imported stocks with the manufacturers.

It is doubtful whether any other price fixing agency could have been assigned a more thankless job than the Bureau of Industrial Cost and Prices (BICP) which had to examine the cost data from the stage of basic production, work out the 'mark-up' consisting of several components at the final stage of formulations and sale prices of several hundreds of items.

The constitution of an independent body to implement the provisions of DPCO is also envisaged under new drug policy. As per these provisions, an independent body of experts, to be called National Pharmaceutical Pricing Authority, will be entrusted with the task of price-fixation or revision and other related matters. It will also update the list of drugs under price control regime by inclusion and exclusion on the basis of established criteria or guidelines. It would be empowered to take all final decisions. But the government would

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1. "ingredients for Librium and value cost £9 and £20 per kilo in Italy, but the cost of manufacture was said by the company to be £437 and £279 for the same amounts. Acting on the Monopolies Commissioner's report, the Government fixed maximum prices for drugs under the Fair Trading Act, 1973. See Harvey Teff, "Regulation under the Medicine Act 1968: A continuing prescription" 47 Mod.L.Rev. 303 at p.319.
2. Supra n.5 para 27.7.4.
3. Ibid.
have power of review. It would also monitor the prices of decontrolled drugs and formulations and oversee the implementation of the provisions of DPCO.

Need for use of brand names

With the introduction of new drug policy most of the basic drugs and formulations were excluded from price control regime on the ground that the operation of market forces would reduce the prices. These excluded drugs constitute large chunk of the total consumption. But the order of the day between drug companies is product competition, rather than price competition. Thus, different brand name drugs are promoted which are therapeutically similar. With product competition there is little incentive for companies to reduce their prices. It may even increase the cost of drugs by encouraging the search for unnecessary variations of existing products.

The use of brand names as opposed to generic names enables the drug industry to sell essentially similar drug formulations at widely varying prices. Quite often it is difficult for the doctor and almost impossible for the patient to have at their disposal information which would enable them to compare prices of drugs which are virtually identical. Advertisements rarely mention prices and in general the medical representatives canvass the superiority of their particular brands of medicine with the doctor not on grounds of prices but on other grounds such as therapeutic effectiveness or advantages of the new and improved drug.

The concern about drug prices really arises from the fact that many of them are essential to health of the community and that there is no justification
for the drug industry changing prices and having a production pattern which is based not upon the needs of the community but on aggressive marketing tactics and created demand.

At the same time the proposals to introduce essential drugs list or generic drugs available for prescription seems unlikely to prevail over the objections that it would constitute an unacceptable interference with the clinical freedom of the doctors, though several countries do have such list.\(^{73}\) Moreover, many doctors would see such a move as depriving patients of higher quality and more suitable drugs. But for these objections introduction of generic substitution is a potential source of price control.\(^{74}\) These generic products marketed under the name of their chemical components are offered at much lower prices than the same products marketed under their brand names. The generic and brand name controversy has acquired the notoriety of international status. Therefore, it has been suggested that the brand name of the product be followed by the international non-proprietary name recommended by the World Health Organisation, where such names exist.\(^{75}\)

By fiscal or legal measures the production of irrational and hazardous drugs are to be made unattractive. Indirect constraints on the doctor may also be imposed to reduce the burden of cost of the prescription drugs on the

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\(^{73}\) For example Bangladesh and some other countries have such list.

\(^{74}\) Brand name prescription constitute 80 per cent of the total consumption. In 1983 British Government acknowledged that, if introduced for nine commonly taken drugs alone, it would save some £30 million a year. See Teff (1984) of cit. at p.320.

\(^{75}\) See L. Krames, *EEC Consumer Law*, of cit. at p.86.
consumer. One such move, which has already been in vogue elsewhere, is to make physician responsible to meet the additional cost if he prescribes beyond a fixed per capita limit. It will certainly enable physicians to prescribe the less expensive products among the available brand name products having equal pharmaceutical properties. A magnificent effort was also made by some voluntary organisations to overcome widespread irrational prescription practices. They manufacture solely generic drugs and opened a chemist's shop only to sell generic drugs. The consumers are free to choose between costlier brand name drugs and the cheaper generic drugs. That the prices are cheap can be seen from a comparison of some of the more common and often used medications people normally need. Such organisations are to be encouraged with proper tax incentives.

**Use of Patent System**

Apart from direct price control, another avenue for lowering drug prices is through preventing the abuse of the patent system. Section 97 and 99 of the Patents Act 1970 enables the government to grant a licence to persons other than the patent holder “if it is necessary or expedient in the public interest.” The Patents Act also provides that a patent could be compulsorily

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76 Germany has introduced such laws, though it has no direct Price Control on drugs. See Ross Canston, *Consumer and the Law* of cit. at p. 408.

77 SEWA a drug manufacturing voluntary agency was set-up at Baroda. See Andrew J. Rebello, “Effort to make popular generic drugs,” Indian Express, July 28, 1989.

78 Similar provisions were invoked in Britain in early 1970s to permit the importation of tetracycline for hospitals from countries such as Italy which did not grant drug patents. The House of Lords
licensed to another drug company, "if the demand for a patented article in
India is not being met to an adequate extent and on reasonable terms." But
survival of these provisions is doubtful in the light of the impending Patents
Bill 1995 which, if enacted, would take away the spirit of the compulsory
licensing philosophy under patent system.79

Rational packing of drugs

Another important element in the prices of drugs which needs particular
attention is the cost of packing. It has been noticed that the cost of packing
materials constitute fairly high proportion of the costs of pharmaceutical
products.80 In some preparations the costs of the packing materials could be
much higher than the cost of ingredients used.81 The Hathi Committee felt that
greater attention should be paid to the standardisation and economy in the use
of packing materials consistent with the protection of consumer interest.82 It
should be assured that competitive packing is not resorted to as a sales
promotion measure.

Rationalisation of taxes on drugs

The issue of bringing down drug prices is also directly related to the
problem of taxes and duties on medicines, at the manufacturing and distribution
stages. The excise duties, customs duties, sales tax and other impost on raw
materials and intermediates are imposed on drugs. It is disconcerting that the Union and state governments treat medicines as a source of revenue. It has been noted that these taxes together account for nearly 35 per cent of the price paid by the consumers.\textsuperscript{83}

It is bad enough that the government is tardy in lowering the incidence of taxes on medicines. What is worse is that state governments are still to aim for uniformity in the rates of sales tax and Octroi. There are indications that some states are imposing turnover tax or ‘basic tax’ on medicines.\textsuperscript{84} On the whole, by all these means consumer is exploited. If the government is genuinely interested in protecting consumers it will do well by significantly lowering down the burden of taxes and duties on medicines. There are reports that some of the customs duty concessions announced to the industry to help the consumer did not percolate down to the consumer because of the failure to monitor its impact on production of drugs.\textsuperscript{85} But the concession was not withdrawn. Therefore, the loss to the exchequer has gone to the pockets of the drug manufacturers and not to the consumers.

A satisfactory solution regarding the pricing of the drugs has not yet been devised. Though the existing regulations have helped to control price escalation to some extent, there are deficiencies in its approach. The operation


\textsuperscript{84} Enadu, November 9, 1993.

of price control so far certainly helped in preventing very large profits by pharmaceutical industry. But it does not appear to have contributed materially to the emergence of a product or price pattern which is more consistent with the social needs and national objectives.\textsuperscript{86}