

Chapter 3

Drug Pricing Mechanisms

3.1 Drug Pricing Mechanism In India

The drug prices in India are regulated ever since the Drug Price Control Order (DPCO) came into force. The order has been revised several times since then. The prices of bulk drugs and the formulations included in the Schedules categories were being fixed by the Government of India as per the Drugs (Prices Control) Order, issued from time to time.

3.1.1 National Pharmaceutical Pricing Authority (NPPA)

NPPA is an organization of the Government of India which was established, inter alia, to fix/ revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995. The organization is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

NPPA is consisting of a Chairperson equal in status as a Secretary to the Government of India, Members having expertise in the field of pharmaceuticals, economics and cost accountancy and Member Secretary in the status of Joint Secretary / Additional Secretary to the Government of India. The NPPA was empowered to take final decisions, as and when considered necessary.

The NPPA is conferred the power to regulate its own procedure for performing the functions entrusted to it. The authority is empowered to maintain close touch with the Ministries of the Central Government, State Governments, Industry, consumers and other related organizations. Some of the other functions of the National Pharmaceutical Pricing Authority are as follows:

- To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- To deal with all legal matters arising out of the decisions of the Authority.
- To undertake and/or sponsor relevant studies in respect of pricing of drugs/pharmaceuticals;
- To recruit/appoint the offices and other staff members of the Authority, as per rules and procedures laid down by the Government;

- To render advice to the Central Government on changes/revisions in the drug policy;
- To render assistance to the Central Government in the parliamentary matters relating to the drug pricing.

In India, at present 74 drugs and approximately 10,000 formulations are under price control.

3.2 Control and Decontrol of Drug Prices in India

The drug prices in India are controlled under the Drugs Prices Control Order (DPCO). The DPCO is an order issued by the government under Section 3 of the Essential Commodities Act, 1955¹ empowering it to fix and regulate the prices of essential bulk drugs and their formulations. The order incorporates a list of bulk drugs whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and supposedly aims to ensure equitable distribution, increased supply and cheap availability of bulk drugs.

The DPCO was first passed in 1970 and then revised in 1979, 1987 and 1995. Individual as well as comparative analysis of all the DPCOs illustrates that there has been a measured but steady decontrol of drug prices in India.

3.2.1 1947-1970

At the time of independence, the bulk drug industry in India was in the infancy stage with a meager investment of Rs. ten crore and a production worth just Rs. 26 crore. Most of the bulk drugs and formulations were imported. Till 1962, the drug industry was bereft of any price control. In 1962, there was Chinese aggression on India and Emergency was declared. The government feared that, as a result, drug prices might rise. Accordingly, for the first time, under the Defense of India Act, 1915, statutory control was imposed on the prices of drugs and pharmaceuticals. The Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963 were promulgated. Under the Drugs Prices (Display and Control) Order of 1966, it was

¹ The Act defines “Essential Commodities” to include drugs since they are considered essential for the health of society. Section 3 of the Act authorises the Central Government to regulate or prohibit the production, supply, distribution, trade and commerce in any of the “essential commodities” if the same is necessary for maintaining or increasing supplies of these commodities for securing their equitable distribution and availability at fair prices. (Source: The Essential Commodities Act of 1955)

made obligatory for the manufacturers to obtain prior approval from the government before increasing the prices of any formulation. The Essential Commodities Act, 1955 was enacted for the control of production, supply, distribution, trade and commerce in certain commodities that were declared essential by the Central Government.

3.2.2 DPCO, 1970

On 16 May 1970, a comprehensive order was promulgated under Section 3 of the Essential Commodities Act and in super session of all the earlier orders on the subject. This order was called the Drugs Prices Control Order, 1970. In its introductory form, DPCO was a direct control on the profitability of a pharmaceutical business, and an indirect control on the prices of pharmaceuticals. The government stipulated that a company's pre-tax profit from its pharma business should not exceed 15% of its pharma sales (net of excise duty and sales tax). In case profits exceeded this sum, the surplus was deposited with the government. So, a pharma company had the freedom to decide the prices of its products. Product-wise margins were also flexible, so long as the overall margin did not exceed the stipulated norm. Since individual product prices did not require approval from the government, bureaucratic hurdles were low. At that time, the Indian pharmaceutical industry was largely dominated by MNC affiliates and subsidiaries. These MNCs were hardly affected by the relatively mild form of DPCO and continued operating in the domestic market. However, FERA (Foreign Exchange Regulations Act) which came in mid 70s did curb the operations of MNCs. Overall, the Indian pharma industry prospered from 1970 to the next DPCO in 1979.

3.2.3 The Hathi Committee, 1974

In 1974, the GOI appointed a committee under the chairmanship of Rajya Sabha MP Jaisukhlal Hathi to enquire into the conditions prevailing in the sphere of pharmaceuticals in the country. The committee submitted its report in 1975, which is widely known as the Hathi Committee report. The report strongly emphasized greater role for the public sector in the manufacturing of drugs. The DPCO, 1979 was loosely based on the recommendations of the Hathi committee but many provisions were not implemented.

3.2.4 DPCO, 1979

The Drugs Prices Control Order of 1979 was issued on March 31, 1979. In its revised version, the DPCO stipulated ceiling prices for controlled categories of bulk drugs and their formulations. In fixing the price, the government continued to advocate the profitability ceiling and an upper limit was put on the return on net worth or capital employed for pharma companies. The retail prices of controlled formulations were decided by applying the concept of MAPE (Maximum Allowable Post manufacturing Expenses). It was a mark-up on ex-factory costs, provided to cover selling and distribution costs including retail and wholesale trade margins.

The pricing formula was

$$\text{Retail price} = (\text{MC} + \text{CC} + \text{PM} + \text{PC}) \times (1 + \text{MAPE}/100) + \text{excise duty}$$

where MC was the material cost including cost of bulk drugs/excipients, CC was the conversion cost as per the dosage form is, PM was the cost of packing material suitable to dosage form and PC was the packaging charge worked out in accordance with established costing procedures. The DPCO, 1979 put 347 drugs under price control. These drugs were segregated into three categories, having different MAPE. See the table 3.1. The most important drugs, including life saving drugs were put in Category I which had the least MAPE.

Table 3.1 : Categories of drugs and MAPE, DPCO 1979

Category	MAPE
I Life Saving drugs	40%
II Essential	55%
III Less Essential	100%
IV Non-essential/simple remedies	60%

Through this DPCO, the first three categories being price-controlled and around 80-90% of the Indian pharma industry (in value terms) was brought under strict price control. The MNCs were the worst hit. With profitability falling steeply, they discontinued many products, especially the life saving products in Category I. In addition, the industrial licensing requirements made it impossible for MNCs to introduce new products. The local players were, nonetheless, in a better position. They could obtain licenses much easily than MNCs could. They were also able to speedily introduce new drugs. The local players, as a result, were able to keep the

coverage of DPCO low and fight the might of established MNCs. However, profitability wise, the Indian pharma sector went through its worst phase from 1979 to 1987.

3.2.5 The Kelkar Committee, 1984

In 1984, the Kelkar Committee came out with its report in which it recommended the exclusion of a number of drugs from the purview of price control. Various suggestions were made for determining the criteria for inclusion and exclusion. The committee stressed the need to liberalise the strict profitability curbs that were acting as a hurdle to the growth of the pharma sector.

Since 1975, the Indian Pharmaceutical Industry had grown to be the most diversified and vertically integrated pharmaceutical industry in the entire third world. The country had achieved self-sufficiency in formulations and also in a large number of bulk drugs. In 1984-85, imports of formulations were only Rs.10.17 crores or about 0.5% of the total formulation production in the country and imports of 49 bulk drugs were negligible. During the same period, the exports of drugs and formulations were Rs.217.49 crores while imports were Rs.215.62 crores. A wide range of bulk drugs and formulations are being exported to several countries, including the U.S. and the West European countries.

3.2.6 Drug Policy 1986

The Drug Policy of 1986, which was titled "Measures for Rationalisation, Quality Control and Growth of Drugs & Pharmaceuticals industry in India" was evolved under the dynamic guidance and leadership of late Shri Rajiv Gandhi. This was done after a detailed examination of the various issues. The main objectives of the Drug Policy, 1986 are as under:

- ensuring abundant availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality;
- strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;
- creating an environment conducive to channelising new investment into the pharmaceutical industry to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs; and,
- Strengthening the indigenous capability for production of drugs.

For meeting the requirements of medicines for health needs at reasonable prices and strengthening the indigenous base, the Government has, over the years been guided by the above Policy. Implementation of the main policy provisions has been through the I(D&R) Act on Industrial Licensing aspects and through Drugs(Prices Control) Orders under the Essential Commodities Act in regard to the pricing mechanism. The Drug Policy has also given the policy frame work in regard to Quality Control and Rational Use of Drugs. Enforcement of quality and standards in medicines is done through the provisions contained in the Drugs & Cosmetics Act, which is administered by the Ministry of Health and Family Welfare, Government of India.

Abundant availability on a continuous basis, at reasonable prices, of essential, life saving and prophylactic medicines of good quality, is the corner stone of the new measures. Changes were made in the system of price control of drugs as well as in the licensing and approval procedures in 1986. Experience gained in the implementation of the Drugs (Prices Control) Order, 1979 had demonstrated that the pricing system needed to be simpler and rational, if the benefits of the price control are to be effectively realised by the consumer, particularly the weaker sections of the society for safeguarding whose interests the government is committed.

In order to provide drugs to the masses, the government has short listed the list of Bulk Drugs reserved for public sector. The following fifteen drugs were, therefore, reserved for the public sector.

1	Streptomycin	9	Vitamin B1
2	Tetracycline	10	Vitamin B2
3	Oxytetracycline	11	Folic Acid
4	Gentamycin	12	Quinine
5	Sulphaguanidine	13	Analgin
6	Sulphadimidine	14	Phenobarbitone
7	Sulphamethoxy-pyridazine	15	Morphine
8	Sulphadimethoxine		

3.2.7 DPCO, 1987

The DPCO, 1987 was promulgated on August 26, 1987 on the basis of the Drug Policy of 1986 and the Kelkar Committee Report. In the DPCO, 1987, the number of bulk drugs under price control was significantly reduced from 347 to 142. 20 drugs

were taken off from Category I and 122 from Category II. In addition, the categories of control were reduced to two and higher MAPE was provided for each category of controlled drugs. See the table 3.2. The MAPE for Category I and Category II was increased from 40% and 55% respectively to 75%. The MAPE for Category IV was increased from 60% to 100%. Even the new drugs that were brought under price control got a liberal 75% MAPE.

Table 3.2 : Categories of drugs and MAPE, DPCO 1987

Category		MAPE
I	Drugs required for National Health Programmes	75%
II	Others	100%

3.2.8 The Drug Policy of 1994

In 1994, the drug policy of 1986 was modified. It is the Drug Policy of the government that decides the criteria for selecting bulk drugs or formulations for price control. The Modified Drug Policy liberalised these criteria. In addition, industrial licensing was abolished for all bulk drugs. All hindrances to capacity expansions were removed and it was expected that, as a result, supply would rise resulting in higher competitive pressures. Foreign investment up to 51% was also permitted in case of all bulk drugs, their intermediates and formulations. FDI above 51% was to be considered on a case to case basis. Nevertheless, five bulk drugs; Vitamin B1, Vitamin B2, Folic Acid, Tetracycline and Oxytetracycline were reserved for the public sector till 1998.

The modified criteria in the new drug policy (September 1994) were:

- The system of price control may be operated through a Single list of price controlled drugs and formulations based thereon with a MAPE of 100 per cent.
- The criterion of including drugs under price control will be the minimum annual turnover of Rs.400 lakhs.
- Drugs of popular use, in which there is a monopoly situation will be kept under price control. For this purpose if for any bulk drug, having an annual turnover of Rs. 100 lakhs or more there is a single formulator having 90% or more market share in the Retail Trade (as per ORG) a monopoly situation would be considered as existing.

- Drugs in which there is sufficient market competition viz. at least 5 bulk drug producers and at least 10 formulators and none having more than the 40% market share in the Retail Trade (as per ORG) may be kept outside the price control. However, a strict watch would be kept on the movement of prices as it is expected that their prices would be determined by forces of market competition. The Government may determine the ceiling levels beyond which changes would not be permissible.
- Government will keep a close watch on the prices of medicines which are taken out of price control. In case, the prices of these medicines rise unreasonably, the Government would take appropriate measures, including re-clamping of price control.
- For applying the above criteria, to start with, the basis would be the data upto 31st March, 1990 collected for the exercise of the Review of the Drug Policy. The updating of the data will be done by the National Pharmaceutical Pricing Authority.
- Genetically engineered drugs produced by recombinant DNA technology and specific cell/tissue targeted drug formulations will not be under price control for 5 years from the date of manufacture in India.

3.2.9 Current Regime - DPCO, 1995

The latest Drug Price Control Order was passed on 6 January, 1995. The basic structure of this DPCO is the same as that of the earlier two orders. Nevertheless, the span of price control under DPCO 1995 has been liberalised considerably from 142 drugs to just 74.

The Pricing of Bulk Drugs

The 76 bulk drugs (Now 74 drugs as Amikacin Sulphate and Mefenamic Acid were omitted by S.O. 626(E) dated 2/9/1997), the prices of which are controlled under DPCO 1995, have been enlisted in the First Schedule annexed to the order. As per para 3 of DPCO, 1995 prices of scheduled bulk drugs are fixed by the NPPA to make them available at a fair price from different manufacturers. These prices are fixed from time to time by notification in official gazette. Each company submits to the government, a detailed working of the prices of various bulk drugs that it requires. The prices submitted by the companies are such that the allowed profitability parameters are achieved. The government subsequently studies the

applications made by the major players for every bulk drug and cost audits reports of manufacturers, before arriving at the final price.

Following steps are involved in fixation/revision of bulk drug prices:-

Step 1 : Identification of bulk drugs :

Bulk Drugs are taken up for study on following basis :-

- Whose validity period is due to expire.
- Request from the concerned manufacturer/company.
- Drug produced in the country for which no price has been notified under DPCO, 1995.

Step 2 : Collection of data :

Data is collected by issuing questionnaire/Form I of DPCO, 1995/cost-audit report etc. and verification by plant visits, if required.

Step 3 : Preparation of actual cost statement :

Actual cost for the year for which data is submitted is prepared based on data submitted / collected & verified during plant visit.

Step 4 : Preparation of Technical Parameters :

Technical parameters are prepared based on data submitted, collected and verified during plant visits. Plant capacity is assessed considering 330 working days for normal operation of plant leaving 35 days for scheduled maintenance of plant. The achievable production level is considered at 90% utilization of assessed capacity allowing 10% production loss on account of unforeseen break down and non-scheduled maintenance.

Step 5 : Preparation of Estimated Cost :

The estimated cost for the pricing period are then prepared based on actual cost & the technical parameters. While projecting the future cost, an increment is recognized at 5% per annum in respect of salaries & wages. Wage agreement, if any, which has been finalized and signed is also recognized while preparing the estimates. In respect of other overheads of fixed/semi variable nature, increase at 2.5% per annum is made to cover the normal incremental effects. The customs duty and other taxes as per the current budget are considered.

Step 6 : Calculation of Fair price of bulk drug :

Fair price is calculated by providing returns as specified in sub para (2), para 3 of DPCO, 1995.

While fixing the maximum sale price of the bulk drug, a post tax return of 14% on net worth or a return of 22% of capital employed or in respect of a new plant an internal rate of return of 12% based on long term marginal costing is considered depending upon the option exercised by the manufacturer of the bulk drug. In case, the production is from basic stage, additional 4% return is considered on net worth/capital employed.

Step 7 : Fixation of maximum sale price of the drug :

When the number of manufacturers of the said drug is more than one, the maximum sale price is fixed at 2/3rd cut off level or weighted average price, depending upon the situation.

Step 8 : Notification of bulk drug price in official Gazette.

The Pricing of Formulations

The Drug Price Control Order covers all the formulations that utilise the bulk drugs listed in the First Schedule. The methodology through which prices of formulations are fixed is as follows. Under DPCO 1995, a uniform MAPE of 100% is given on all formulations under price control. This is in contrast to the earlier practice of giving a MAPE of 75% on some formulations. In order for the government to decide the price of a controlled formulation, each manufacturer is supposed to submit to the government details of material cost, manufacturing process etc. The ceiling prices, once decided, are notified in the Official Gazette. For imported drugs and formulations, the landed cost including customs duty and clearing charges is the benchmark to fix prices. The margin allowed to the importer is such that selling and distribution expenses including interest and profit are covered. However, the margin allowed cannot exceed 50% of the landed cost.

Prices of formulations based on scheduled bulk drugs are fixed in two ways viz.

- based on applications of the manufacturers and
- on suo-motu basis.

As per para 8 (2) of Drug (Prices Control) Order (DPCO), 1995, a manufacturer using scheduled bulk drug in his formulation is required to apply for fixation of price of formulation within 30 days of fixation of price of such bulk drug (s).

Applications received in NPPA from manufacturers in Form III and importers in Form IV of DPCO are considered for price fixation. As per para 8(4), the time frame for granting price approval on formulation is 2 months from the date of receipt of the complete information from the company. The procedure is:

A. Based on applications of the manufacturers

(a) Examination of Technical Parameters :

Checking the Quantity of Bulk Drug as per label claim. The overage claim is allowed as per batch production record or norms fixed by Govt.

(b) Examination of Prices of Bulk Drug :

When notified price of bulk drug exists, the notified price or actual price is considered. In the case of imported bulk drug used in the formulation, weighted average import price is considered vis-à-vis the price submitted by the applicant. For non-scheduled bulk drug used, the available information on prices are applied.

(c) Examination of Excipient claims :

Excipient claims given in the application are examined and allowed after referring to information available in NPPA.

(d) Examination of PL, CC, PC and PM cost :

The process loss (PL), conversion cost (CC) and packing charges (PC) are considered as per the norms notified in the Gazette vide S.O. 578(E) dated 13.07.99. The packaging material cost (PM) cost is allowed as per the actual claim supported by invoices and after referring to information available with NPPA.

(e) Application of MAPE :

Maximum allowable post manufacturing expenses (MAPE) is given at 100% on the ex-factory cost for indigenous formulation, while MAPE upto 50% of the landed cost is allowed for imported formulation.

(f) Working out the retail price :

The retail price of formulations are worked out as per the formula given in para 7 of DPCO, 1995 viz.

"R.P. = [M.C. +C.C.+P.M.+P.C.] x [1+MAPE/100] +E.D.",

where

R.P., M.C., E.D. respectively denote retail price, material cost, excise duty and the

other symbols as denoted earlier. It is this price that is printed on the pack of a DPCO-controlled formulation. This price is not the Maximum Retail Price (MRP). Local taxes are additional.

(g) Treatment of Taxes :

For bulk drugs used in formulation, all the statutory taxes are considered at the actuals and net of MODVAT. Allowance upto 8% on the notified price of scheduled bulk drugs is considered on this account. The excise duty element is worked out in NPPA based on companies claim. Allowance is made for 16% margin on price to retailer (as per DPCO, 1995) and 8% margin to wholesaler as per practice, both on the ex-factory price, which is the assessable value.

The prevailing excise duty rate is applied to the said assessable value. For ceiling packs, notified prices are exclusive of excise duty. Manufacturers are required to work out the excise duty.

B. Suo - Motu Cases :

If the manufacturers or companies do not apply for revision of formulation prices as required under Para 8(2) of DPCO, 1995 within a period of 30 days of price reduction of bulk drug or fall in other statutory levies, steps are taken for suo-motu revision. Broadly the procedure given above is followed.

C. Notification of ceiling prices in the Gazette of India :

Ceiling prices are fixed or revised under Para 9 of DPCO, 1995 for commonly marketed standard pack sizes of price control formulations. It is obligatory for all, including small scale units, to follow the ceiling prices which are notified in the Gazette of India (Extraordinary). The ceiling prices are usually notified as exclusive of excise duty, local tax etc. but maximum retail price (MRP) printed includes excise duty.

D. Pro-rata price :

NPPA has issued notification no. S.O.83 (E) on 27.01.98.on pro-rata pricing. As per this notification, the manufactures of all the scheduled formulation pack sizes different from the notified pack sizes under sub-paragraph (1) and (2) of the paragraph 9 of the DPCO, 1995, shall have to work out the price for such pack sizes, in respect of tablets and capsules of the same strength or composition packed in

different strips or blisters, on pro-rata basis of the latest ceiling price fixed for such formulations.

E. Non-ceiling Price Order :

Non-ceiling Prices are fixed under Para 8 (1), (2) and (4) and Para 11 of the DPCO, 1995. They are specific to particular pack size and dosage form of scheduled formulation of a particular company. Hence they are pack specific and company specific. The prices fixed for non-ceiling packs are communicated to the respective firms by issuing office orders. In such order, usually excise duty element is shown separately. However, local taxes are not included in Non-ceiling price.

Key Issues in DPCO '95

Based on outdated data: The criteria of selection for drugs to be put under price control were decided so as to prevent a cartel of manufacturers from exploiting the customers (patients). But, the basis of selection was the 1990 turnover values. As a result some drugs where there was high level of competition as players had mushroomed after 1990, were unnecessarily included under DPCO.

High span of control: As per the 1990 turnover records, only 50% of the pharma industry is under DPCO '95. But, as sales of some of the controlled drugs, earlier outside price control, have grown at a higher rate than the overall industry, the actual span of control encompasses 60-65% of the domestic pharma industry.

Lack of stability: The number of drugs under DPCO can be modified, either increased or decreased any time. There is no stability about the inclusion or exclusion of any drug or formulation under DPCO. So, prices of drugs and formulations in the domestic market can undergo drastic changes, irrespective of the competitive market forces.

Prices of input materials are not controlled: Even key intermediates used in the pharma sector are outside DPCO purview. These intermediates often find application in various other chemical industries. As a result their price trends, both in India as well as internationally follow a very different cycle compared to the bulk drugs wherein they are used. Prices of some intermediates get indirectly regulated, if they are largely used in a bulk drugs under DPCO.

For eg Penicillin G and Amoxicillin are both bulk drugs under DPCO. Amoxicillin can be developed from basic Pen G stage from 6-APA, a derivative of Pen G. As 6-APA is classified as an intermediate (it has no medicinal properties), it remains free from

any direct price controls. But naturally, its price varies due to presence of alternate process of manufacturing Amoxicillin from Pen-G stage.

Artificial disallowances: Prices of DPCO drugs and formulations have to be fixed after taking into the cognizance the cost of inputs used in their manufacturer. But, in many cases the actual input costs are not recognized by the Government. For eg in case of sugar, a common ingredient in most formulations, the Government considers price of levy sugar as a benchmark while actually the pharma companies procure their requirement from the open market at a price that's 20-25% higher. In case of wages, power etc the norms are as prevalent 3-5 years earlier and inflationary impact is not considered.

Delays in announcing prices: Price fixation exercise of DPCO drugs (and their formulations) is undertaken only once every 4 years by the Government. Interim price changes are made only on specific price revision applications made by any manufacturer. In such a case, the Government has to collate data of other manufacturers and then come to a conclusive judgment whether the price revision is justified. The Government is expected to give the revised price with 4 months of submitting the application in case of bulk drugs and within 2 months in case of formulations or reject the application with reasons thereof recorded in writing. But, in reality the revisions are much delayed, even taking upto a year after an application for price revision has been filed.

Market forces: For the drugs and formulations under DPCO, only the maximum price is specified. As a result of competition from various players and price undercutting in some products where supply exceeds demand, the actual price may fall below that specified under DPCO. In such cases, artificial price regulation becomes unnecessary.

New product launch delayed: A product made by an indigenous process for the first time in India gets a 5 year exemption under DPCO. If any other company launches the same product through another new process, it too has to apply for separate DPCO exemption pre-launch. Else, if the application has not been filed, the product may be included under DPCO for the second manufacturer. However, once the drug/ formulations developer has filed his application for his new process, he can launch the product without waiting for DPCO clearance. So product launches are not unduly delayed.

Trade margin: For formulations derived from DPCO drugs, Government decides the trade margins as well. For DPCO formulations, the minimum retail margin is 16% (otherwise 20% as per industry norms) and minimum wholesale margin is 8% (otherwise 10%) as fixed by the Government. Formulators are free to give margins. Some also try to push their products by giving free packs to retailers for eg against 6 injection vials, 1 vial comes free. This is as good as giving the retailer a higher margin.

3.2.10 Pharmaceutical Policy 2002

The main objectives of this policy are:-

- Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.
- Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
- Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.
- Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to channelising a higher level of investment into R&D in pharmaceuticals in India.
- Creating an incentive framework for the pharmaceutical industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.

Pharmaceutical Policy 2002 has not been implemented. Drug pricing mechanism in India is still based on DPCO 1995. Table 3.3 shows number of drugs and percentage of market under price control.

Table 3.3 : Number of Drugs under Price Control

DPCO Year	No. of drugs	Percentage of controlled market
1970	All	100
1979	347	90
1987	142	70
1995	74	50

3.2.11 Draft Recommendations of the Pronab Sen Taskforce

The draft recommendations of the task force for pharma pricing, which was headed by Dr. Pronab Sen, has recommended options other than price control for achieving the objective of making available the life saving drugs at reasonable prices.

The draft recommendations of the task force are as follows:

A. The Strategic Approach

- A.1 In the opinion of the Task Force, no price regulatory mechanism can be effective unless there is a credible threat of price controls being imposed and enforced. However, it is also felt that the present price control system is dysfunctional and its legislative authority inappropriate.
- A.2 Price controls should be imposed not on the basis of turnover, but on the 'essentiality' of the drug and on strategic considerations regarding the impact of price control on the therapeutic class. This must be a dynamic process.
- A.3 Price controls should be applied only to formulations, i.e. the medicine actually used by the consumer, and not to upstream products such as bulk drugs. In other words, intra-industry transactions should not be controlled unless there are compelling reasons for doing so.
- A.4 There should be no attempt to impose uniformity in prices of controlled drugs on a lowest common denominator basis, and only a ceiling should be prescribed.

Companies should be free to decide their price-quantity configuration within the prescribed price limit.
- A.5 The ceiling prices of controlled drugs should normally not be based on cost of production, but on readily monitorable benchmarks.
- A.6 All other drugs should be brought under a comprehensive price monitoring system with appropriate market-based reference prices and with mandatory price negotiation, if necessary.
- A.7 Licensing and marketing approval of drugs should be centralized and tightened. In particular, no combination drug should be approved unless there is a demonstrated therapeutic advantage.

- A.8 The regulatory mechanism should be significantly strengthened both at the Centre and in the States. Since quality, quantity and price are to be addressed in an integrated manner, there should be a unified regulatory structure covering all aspects.
- A.9 A process of active promotion of generic drugs should be put in place, including mandatory debranding for selected drugs.
- A.10 All public health facilities should be required to prescribe and dispense only generic drugs, except in cases where no generic alternative exists.
- A.11 In the case of proprietary drugs, particularly anti HIV/AIDS and Cancer, drugs the government should actively pursue access programmes in collaboration with drug companies with differential pricing and alternative packaging, if necessary.
- A.12 Public Sector Enterprises (PSEs) involved in the manufacture of drugs should be revived where possible and used as key strategic interventions for addressing both price and availability issues. Arrangements may need to be made to ensure their continuing viability.
- A.13 Fiscal incentives should be provided on a long-term assured basis to research and development activities in drugs.
- A.14 The government should institute a voluntary programme for quality certification and marking of formulations, in addition to Schedule M compliance, and should promote and publicize such quality marking strongly.
- A.15 The government should consider providing financial support to small scale units for achieving Schedule M compliance and for obtaining quality certification. For this, the Department of Chemicals & Petrochemicals should formulate a separate Plan scheme to be funded through the Budget.
- A.16 The government should create and maintain a public website with complete data on prices of all formulations by APIs and therapeutic categories which can be used by medical practitioners, and perhaps even consumers, for price comparison purposes.

- A.17 The drug regulator must maintain a data base on brands and their compositions, and all brand registration of drugs must compulsorily approved by the drug regulator. In particular, no change should be permitted in the composition of a given brand.
- A.18 Availability of essential medicines through public health facilities should be ensured both through bulk purchase by government agencies cooperatives or consumer bodies, through public-private partnerships if necessary. Seed money may be given to states to kick start this process through a Centrally Sponsored Scheme to be formulated by the Department of Health.
- A.19 Insurance companies should be encouraged to extend health insurance to cover medicines. Public-private partnerships for providing health care services, including insurance and group health plans, should be actively encouraged. The Department of Health should take up this matter in conjunction with the IRDA.

B. Drugs and Therapeutics (Regulation) Act

- B.1 The Drug Price Control Order (DPCO), which is presently an order under the Essential Commodities Act (ECA), 1955 should be converted into a legislative enactment – The Drugs and Therapeutics (Regulation) Act (DATA). The main features of this Act are outlined in the following paragraphs.
- B.2 Empowering government or its designated authority to impose a price or limit the increase in the price or control the price in any other manner of any time it deems appropriate in public interest.
- B.3 Requiring the government or its designated authority to clearly lay down the principles governing or the reasons leading to imposition of any such price control or any deviations permitted there from.
- B.4 Authorizing the government or its designated authority to seek compel disclosure of any information or data relevant to its functioning from all manufacturers, marketers, distributors or retailers of drugs and therapeutic products.
- B.5 Requiring all companies involved in the manufacture or marketing of drugs and therapeutic products to submit authenticated price lists of all their products

along with other relevant details to government or its designated authority on a regular basis with frequency to specified by the latter.

- B.6 Granting the government or its designated authority the power to approve a brand name for specific product, to prevent changes in the composition of products marketed under an approved brand name and to determine the nomenclature under which product can be marketed, if necessary, for all drugs and therapeutic products.
- B.7 Providing penalties, for violation or non-compliance with the provisions of the Act or the Rules framed and orders issues under the Act. These penalties could be graded – fines, temporary withdrawal of marketing approval, withholding of marketing approval, sealing of production facilities, compounding of offences, etc:
- B.8 Other powers with regard to production and prices ad mentioned in the EC Act, 1955 should be incorporated in the Act to the extent possible.
- B.9 The powers and provisions of the DATA would be in addition to those contained in the Drugs and Cosmetics Act and the Essential Commodities Act.
- B.10 Greater role and accountability of State Drug Controller should be specifically provided for under the Act.

C. National Authority on Drugs and Therapeutics

- C.1 The Task Force endorses the proposal made by the Planning Commission in the Mid-term Appraisal of the Tenth Five Year Plan to establish a National Authority on Drugs and Therapeutics (NADT), which would integrate the offices of the Drug Controller General of India, the Central Drugs Standard Control Organisation (CDSCO) and the National Pharmaceutical Pricing Authority (NPPA), along with all the powers and functions of these bodies. The Drugs and Cosmetics Act would have to be amended for this purpose. The NADT would also be the designated authority of the government for implementation of DATA.
- C.2 Ideally the NADT should be an independent regulatory agency under the Ministry of Health & Family Welfare with appropriate statutory backing from

DATA, but for the immediate future it may be set up as an attached office through the issue of the necessary government orders.

- C.3 The NADT should constitute two Expert Committee which would be responsible for: (a) Regular updating and revision of the National List of Essential Medicines (NLEM), which may be approved by Government in consultation with the States through a joint Committee of Concerned Departments; and (b) Price negotiations as prescribed under the Rules framed under DATA. These Committees should be chaired by the Chairman, NADT, and comprise primarily of outside experts drawn other government Ministries/Departments, ICMR, health professionals, pharmacologists, civil society organizations, etc.
- C.4 The NADT should not only carry out all the regulatory functions implied by para 3.1 above, but also be responsible for the promotional activities which are mentioned in this Report, such as quality certification and marking, promotion of generic drugs, maintenance of the public web-site/data base on drug prices, etc.
- C.5 The functions proposed to be assigned to the NADT will require a significant enhancement in both the manpower and the skill sets available in the existing organizations which are proposed to be merged. The Mashelkar Committee Report (2003) has detailed the requirements for the Drug Controller's office, which should be adopted as the initial blue-print. In addition, a suitable manpower and training requirement plan should be drawn up for it to effectively carry out the other functions that have been indicated.
- C.6 A suitable mechanism for financing the NADT will need to be evolved, especially if it is to be made into an independent regulator. The Planning Commission has suggested a Cess for this purpose, which could be considered.
- C.7 Since the constitution of NADT may take some time since it will involve resolving several interdepartmental issues and legislative enactments, there is an immediate need to bring about some fundamental changes in NPPA pending its formation. These are:
- a) review the present structure of NPPA to make it more effective

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

D. Other Regulatory Issues

- D.1 Since the NADT will be wielding considerably greater powers and authority than any extant organization, there is need to consider the establishment of an appellate body, and provisions will have to be made in the Rules framed under the concerned Acts.
- D.2 Consistent with the strengthening of the Central drug regulatory system, the state supervisory and regulatory capacity should also be strengthened. The Centre should financially support state governments to bring their state drug control formations to a minimum level. The recommendations of the Mashelkar Committee 2003 report should be adopted as a blue-print for this purpose.

E. Principles of Prices Regulation

- E.1 The National List of Essential Medicines (NLEM) should form the basis of drug to be considered for intensive price monitoring, ceiling prices and for imposition of price controls, if necessary.
- E.2 To start the process, the government should announce the ceiling price of all drugs contained in the NLEM on the basis of the weighted average prices of the top three brands by volume of single ingredient formulations prevailing in the market as on 01.04.2005 in cases where there are less than three brands, the average of all existing brands would be taken. The Org-IMS data set can be used for this purpose initially with a 20 percent retail margin provided. There is, however, a need to improve the available data coverage, which should be taken up with ORG-IMS or any other data provider.
- E.3 For drugs which are not reflected in ORG-IMS data, the NPPA should prepare the necessary information based on market data collection.

- E.4 The Government should specify the reference product in terms of strength and pack size for each product which would form the basis for price determination. The price ceiling would be specified on a per dosage basis, such as per tablet/per capsule or standard volume of injection.
- E.5 The prices of all other strengths and dosages would be determined on the basis of a standard formula, which would be related to the ceiling price of the reference formulation.
- E.6 Price relaxations may be permitted for non-standard delivery systems, packaging and pack sizes through applications to the negotiations committee, which should become applicable for all similar cases.
- E.7 In the case of formulations which involve a combination of more than one drug in the NLEM, the ceiling price would be the weighted average of the applicable ceiling prices of its constituents.
- E.8 For formulations containing a combination of a drug in the NLEM and any other drug, the ceiling price applicable to the essential drug would be made applicable. However, the company would be free to approach the price negotiations committee for a relaxation of the price on the basis of evidence proving superior therapeutic effectiveness for particular disease conditions.
- E.9 In order to determine the reasonableness of the ceiling prices fixed as above, the L1 prices quoted in bulk procurement by Government and other designated agencies would be used after the system of bulk procurement is streamlined. Recognizing that retail distribution has costs not reflected in bulk procurement, a mark up of 100 per cent over this reference price is recommended.
- E.10 Since it would take time to streamline the bulk procurement procedures and to generate reliable data on such bulk procurement prices the ceiling prices should be allowed to rise on the basis of the price index manufactured goods (this would be a subset of Wholesale Price Index readily available from the Ministry of industry).
- E.11 The regulatory should set up a computer based system which would scan the prices data provided by companies against the ceiling prices determined as above and identify formulations which breach the relevant price ceiling. The

company manufacturing or marketing such a product would be required to reduce its price or to face penal action.

- E.12 Companies should be permitted to represent for any price increase on valid grounds, which should then become applicable to the entire class of products.
- E.13 In the case of drugs not contained in the NLEM, intensive monitoring should be carried out of all drugs falling into a pre-specified list of therapeutic categories. The reference prices for this purpose would be the ceiling prices of drugs contained in the NLEM, and any significant variation in the relative prices (say above 10 per cent) would be identified for negotiation.
- E.14 Any new formulation based on existing APIs would be required to submit its intended price along with application for marketing approval regulator, which would be granted only if the indicated price is consistent with the relevant ceiling price. Till such time as the NADT is formed, this function will be carried out by the DCGI and NPPA in a coordinated manner.
- E.15 The NLEM should be revised periodically, say every 2 years, in order to reflect new drugs and significant changes in pattern of drug sales within the therapeutic categories. Till NADT is formed, the Department of Health may set up a Standing Committee for this purpose.

F. Patented Products

- F.1 All patented drugs and their formulations should compulsorily be brought under price negotiation prior to the grant of marketing approval. Failure of such negotiations should then invite either price control or compulsory licensing. Till NADT is formed, the committee may be located in the Department of Chemicals & Petrochemicals and the DCGI must be a permanent member.
- F.2 The reference prices to be used for such negotiations should be based on:
- a) The prevailing price of the closest therapeutic equivalent in the domestic market.
 - b) The lowest price at which the drug is marketed internationally.

It is suggested that a convenient starting point for such negotiations could be the premium enjoyed by the drug in the lowest priced market abroad compared to its

therapeutic equivalent, applied to the corresponding price prevailing in the domestic market.

G. Bulk Procurement

G.1 Since the long-term operation of the proposed price regulatory mechanism is depending upon the prices prevailing in bulk procurement activities, it is imperative that the bulk purchase mechanism be streamlined to ensure that the current malpractices are curbed so that the prices reflect the true value of quality drugs.

G.2 It is suggested that the following conditions should be considered as minimum criteria for evaluating bulk purchase operations for inclusion in the reference price computations:

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

G.3 Care should be taken to ensure that the bulk purchase orders are not so large as to exclude smaller manufacturers if they qualify otherwise.

G.4 In order to ensure that bulk purchase data is available from a variety of sources, the government should consider financial support to State and other designated agencies for procurement of drugs (only in generic form) for distribution through the public health care system and also for retailing it within the hospitals. Some states like Rajasthan are doing it on a small scale, and such experiments should be increased.

H. Promotion of Generics

H.1 Public procurement and distribution of drugs through the public health system should only be for generic drugs.

- H.2 The government should consider reduction in the excise rate applicable to generics to half of the standard of the excise rate (8 per cent as against the standard rate of 16 per cent at present). This would help in reducing the prices of these drugs to some extent. This benefit should be passed on to the consumer.
- H.3 Quality certification may be provided free to generic drug manufacturers through an appropriate scheme to be formulated by the Department of Chemicals & Petrochemicals.
- H.4 No control on price or distribution margins may be specified for generic drugs.

I. Access Arrangements

- I.1 In the case of low volume high priced drugs which are nevertheless life saving, the government should consider entering into access arrangements with the concerned manufacturers whereby a lower priced generic equivalent would be produced and marketed through the government health system or other agencies to be designated by Government.

J. PSUs-purchase policy

- J.1 It is well recognized that PSUs can play a significant role in ensuring availability and keeping a check on the prices of drugs produced by them. There is need to revive them to a limited extent (keeping in view their viability) and to provide them an assured market in the public health system. It must be made mandatory on all departments of Central Government to first procure their drugs from these PSUs at prices approved by NPPA for the covered under price control category. For other drugs produced by these enterprises procurement can be done at prices certified by NPPA. Another system can be to have a common Pricing and Supply Committee for all the Central pharma PSUs which can determine the prices of drugs produced by them and also the list of drugs which must be necessarily produced for the public health system.

K. Scheme for BPL families

- K.1 A major issue in India has been the accessibility of drugs by the poor families, particularly the BPL families. Some States have taken initiatives in this regard and are providing free health care, including medicines, to BPL families. There

is the National Illness Assistance Scheme of Government of India which was started in 1996-97 with a budget of Rs. 25 crores to be provided to the states for assisting the BPL families. However, States have not fully utilized the scheme and only some states have taken advantage of this – Rajasthan and MP are the noteworthy examples. There is an imperative need to assist the States for making available medicines free of cost to the BPL families, and they should be encouraged to come forward with proposals.

L. Excise duty relief

L.1 In order to mitigate the rigors faced by and to provide a level playing field for small units it is essential that the following measures are taken:

- a) Reduce the excise duty on small scale units from 16 to 8 percent.
- b) Enhance the exemption limit of small scale units from the present Rs 1 crore to Rs 5 crore.

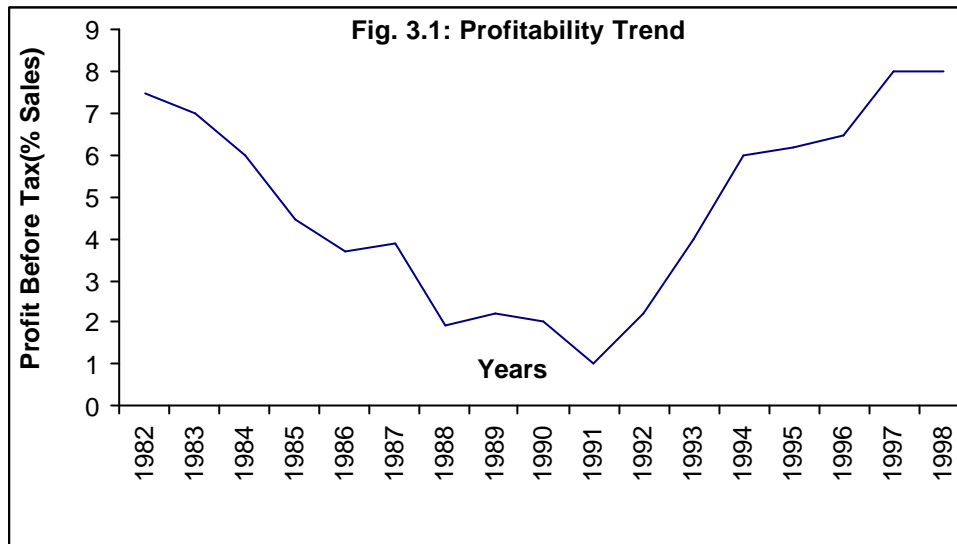
Both these steps are likely to provide the much needed relief to the small scale units leading to their survival, improved quality and better tax compliance which would have a positive effect on the revenues of Government.

3.3 Implications of Drug Price Control and Decontrol for the Pharma Industry

The impact of drug price control and decontrol on the Indian pharmaceutical industry is summarized as follows:

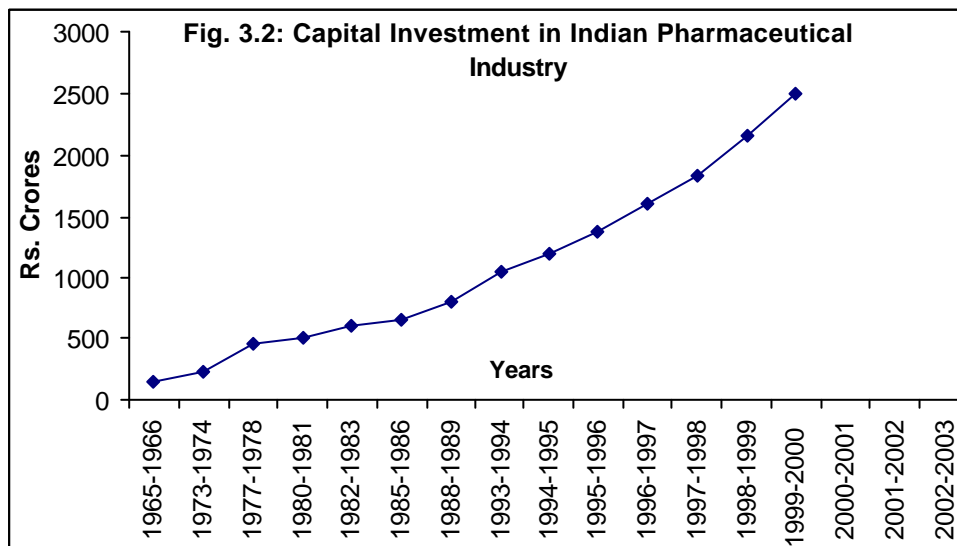
The parameter of profitability is the most important parameters that can be used to judge the impact of drug price control and decontrol on the pharma industry,.

The fig 3.1 depicts the profit before tax (as % of sales) for the Indian pharma industry for the period 1982-1998. The illustration is unique in that we get an unambiguous “V-shaped” graph. It is obvious from the graph that the profits of the pharma industry plummeted over the period 1982-1991 and thereafter registered a stupendous increase. The control and decontrol of drug prices played an important role in this trend. Till 1987, 90% of all drugs produced in India were controlled as regards their prices. This put severe strain on the profit margin of the industry. There might have been other factors as well but drug price control was certainly a major factor responsible for the decline in industry profits in the pre-1990 period.

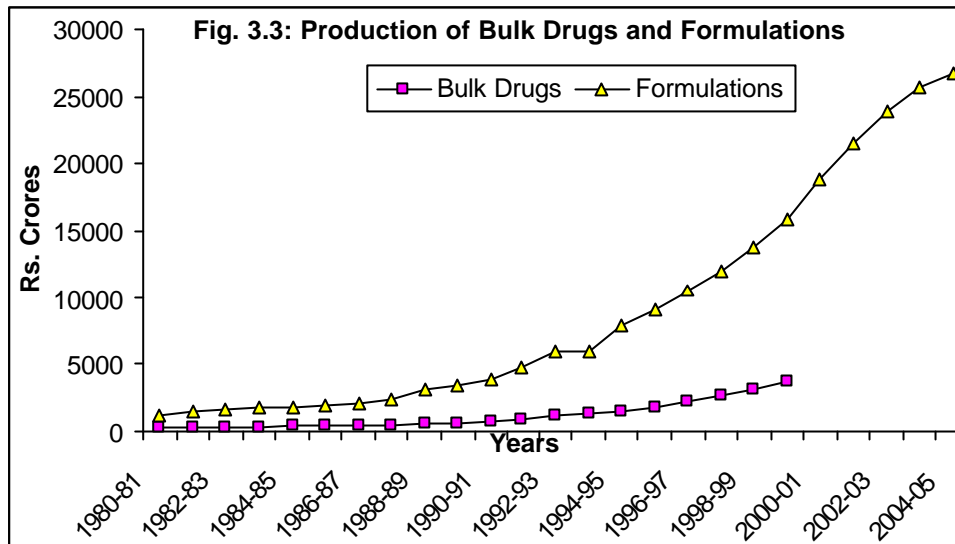


The post-1987 period saw the DPCO being revised twice—first in 1987 and then in 1995. In the first revision, price control on drugs was eased and made applicable to 65% of all drugs as opposed to 90% earlier. In the second revision, this came down to 40%. With the strain on profit margin being eased, the industry’s profits skyrocketed.

As the industry became more profitable and viable, capital investment into the Indian pharma Industry increased as shown in fig. 3.2.



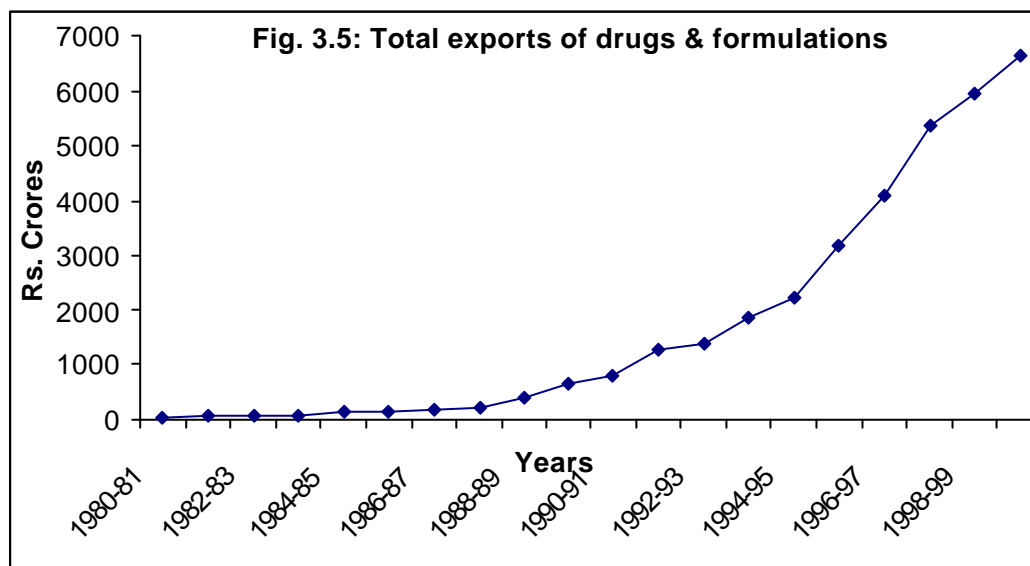
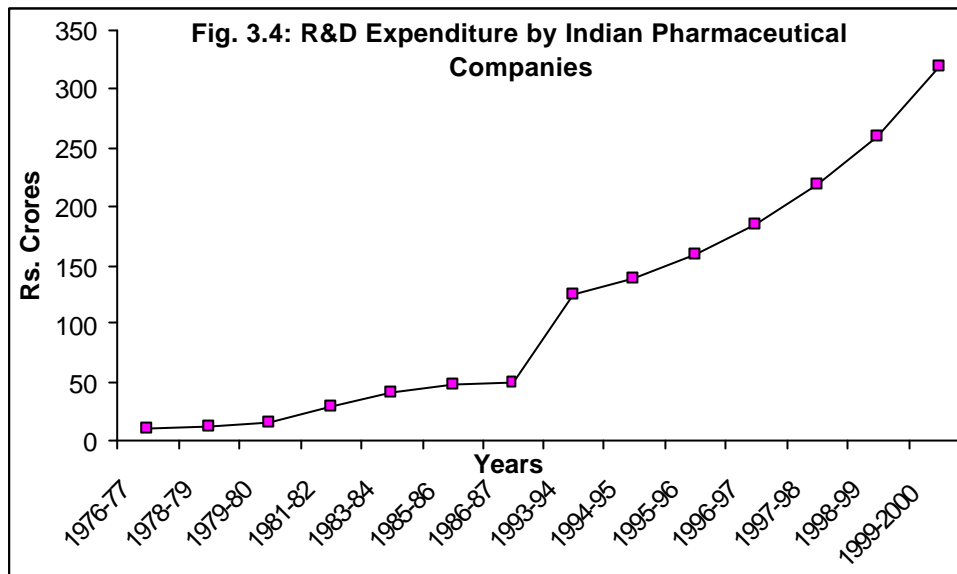
From the fig 3.3 it may be observed that the production of bulk drugs increased more than four fold between 1991-92 and 1999-2000. While, in case of formulations, production increased more than three times during the period under reference.



Again, drug price control and decontrol was a major feature in this trend. In the Drug Price Control Order, 1979, which stayed enforced till 1987, 90% of all drugs were under strict price control. With such massive regulation on the prices of most drugs and thereby on the profitability of the manufacturing companies, the production of scheduled drugs became unfeasible. For instance, no export orders were taken on controlled drugs since their supply had to be under certain parameters. As a result, the level of manufacture by the pharma industry declined. In the DPCO, 1987 and then in the DPCO, 1995, the proportion of drugs under price control declined to 65% and to 40% respectively. With a large number of drugs being taken out of price control, the production of these drugs became feasible again. As a result, the manufacture of these drugs increased.

Investment in research and development has so far not taken off by private sector in pharma sector. While, global pharmaceutical industry spends a much larger percentage of turnover in R&D. For example, in USA, this is as much as 16% of net sales compared to 2% in India. The fig 3.4 describes the investment made by pharmaceutical companies in India on R&D. It is clear from the figure that for the first 7 years, expenditure on R&D was almost stagnant and it was only in the 1990s that expenditure on this front really picked up. The control and decontrol of drug prices is a major explanatory factor of this trend. Until around the 1990s, the drug prices were strictly controlled. This stifled expenditure on R&D in more ways than one. First of all, the profit margin of the industry came down. With an inadequate profit margin, the industry never ventured out in the field of R&D. Second, it dissuaded foreign players

and MNCs from entering the market. In fact, the share of foreign companies in the domestic drug market has continuously declined from 80% in 1970 to 30% in 1994.



Also, the imports and exports were meager as shown in fig. 3.5. With the local players hardly getting any competition from foreign drug manufacturers, they never felt the need of investment in R&D. There were also reasons other than the control of drug prices for the slack R&D expenditure. For instance, process patents had been granted to the industry under the Indian Patent Act of 1970 and the domestic manufacturers simply had to reverse engineer drugs made outside the country. They were able to foray into various therapeutic segments and there was no need to indulge in any R&D.

However, things changed in the 1990s, when controls on drug prices were eased. First of all, profit margin for the domestic drug manufacturers increased thereby enabling local players to provide for R&D. Second, foreign trade in drugs increased thereby raising the level of competition in the domestic and international market and necessitating greater R&D.

However, there were factors other than the decontrol of drug prices, which propelled R&D. For instance, under the TRIPS agreement, process patents were replaced with product patents. This shut the door on reverse engineering and made expenditure on R&D an inevitability for the Indian players.

Price control has direct impact on availability of drugs. Because of the changes in prices by the National Pharmaceutical Pricing Authority (NPPA) many companies have had to alter the contents and nature of their products to meet the requirements of price control. Pfizer has curtailed the production of its popular Vitamin B-complex brand Becosule. Reportedly the company finds the new prices uneconomical. Though the brand was owned by Pfizer it was contracted to another company who manufactured and sold it. Burroughs-Wellcome has changed the contents of Actified substituting Pseudoephedrine with Phenylpropandamine since the former is under price control while the latter isn't. Reportedly Rhone Poulence is believed to have changed the original formulation of Phensydil, a cough expectorant and syrup, to come out of price control. Formulations for which prices have been revised include a range of anti-asthma Deriphyllin dosage forms of German Remedies, Wyeth Lederle's Ledermycin broad spectrum antibiotic.

3.4 Product Patents & Prices Of Medicines

Much of the debate on the impact of product patents on the pharmaceutical industry in India has centred on the issues of price of the patented product and their accessibility. While it is true that a positive association is observed between stronger protection and prices of drugs, it is also true that prices decline with the expiry of patent. In the US, Frank and Salkever (1995) reported a rapid reduction in the price of drugs after the expiration of the patent. Though more competition among generic drug producers results in substantial price reductions for those drugs, yet increased competition from generics does not result in aggressive response in price behaviour by established brand name products. Danzon and Chao (2000) on the contrary observe that generic competition has a significant negative effect on price of the

branded products in the US and other countries with relatively free pricing like UK, Germany and Canada, whereas for the countries with strict price regulation like France, Italy and Japan the number of generic competitors has either no effect or a positive effect on prices of branded products.

In India when amoxicillin was first introduced by a multinational the price of the drug was very high. However, with the local manufacturers stepping in to produce the indigenous version of the amoxicillin, the price of the same declined rapidly. It should be admitted that adoption of the process patents along with the domestic regulations that restricted the role of the multinationals resulted in the growth of the domestic industry. In the late '90s the pharmaceutical industry of India has reached a position of near self-sufficiency in formulations. After a long time experience of having a negative balance of trade in pharmaceutical products, India started enjoying positive balance of trade from the late '80s. In production volume India accounts for 8 per cent of world's pharmaceutical production and is the fifth largest country in the world after the US, Japan, Europe and China. The number of pharmaceutical manufacturers increased from a mere 200 in 1950-51 to more than 6000 in the '80s, which reached a phenomenal figure of 23,790 in 1998-99. Of this a sizeable percentage of firms belong to the small-scale sector. It is estimated that out of the 28.6 million workforces in the pharmaceutical industry, about 4.6 million is employed in the organised units and the rest are engaged in distribution and ancillary industry. These units produce drugs that are not under patent protection and are analogous to products that are already there in the market. Hence, competition is severe among the pharmaceutical units in India, which is one of the important reasons for the relatively lower prices of the medicines in India.

3.4.1 Calculation Of Retail Price Of A Formulation

In fixing the price, the government continued to advocate the profitability ceiling and an upper limit was put on the return on net worth or capital employed for pharma companies. The retail prices of controlled formulations were decided by applying the concept of MAPE (Maximum Allowable Post manufacturing Expenses). It was a mark-up on ex-factory costs, provided to cover selling and distribution costs including retail and wholesale trade margins.

The retail price of a formulation is calculated by the government in accordance with the following formula namely:

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

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

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

The DPCO, 1979 put 347 drugs under price control. These drugs were segregated into three categories, having different MAPE. The latest Drug Price Control Order was passed on 6th January, 1995 (Annexure 1). The basic structure of this DPCO is the same as that of the earlier two orders. Nevertheless, the span of price control under DPCO 1995 has been liberalized considerably from 142 drugs to just 74.

The 74 bulk drugs, the prices of which are controlled under DPCO 1995, have been enlisted in the First Schedule (annexure 2).

It has been advocated that the National List of Essential Medicines (NLEM) should form the basis of drug to be considered for intensive price monitoring, ceiling prices and for imposition of price controls, if necessary. To start the process, the government should announce the ceiling price of all drugs contained in the NLEM on the basis of the weighted average prices of the top three brands by value of single ingredient formulations prevailing in the market as on 01.04.2005 in cases where there are less than three brands, the weighted average of all existing brands would be taken. The ORG-IMS data set can be used for this purpose initially with a 20 percent retail margin provided. There is, however, a need to improve the available data coverage, which should be taken up with ORG-IMS or any other data provider.

NLEM contains list of 354 drugs, 40 are being used in hospitals. For remaining 314 drugs which are not reflected in ORG-IMS data, the NPPA should prepare the necessary information based on market data collection. The Government should specify the reference product in terms of strength and pack size for each product which would form the basis for price determination. The price ceiling would be specified on a per dosage basis, such as per tablet/per capsule or standard volume of injection. The prices of all other strengths and dosages would be determined on the basis of a standard formula, which would be related to the ceiling price of the reference formulation.

Price relaxations may be permitted for non-standard delivery systems, packaging and pack sizes through applications to the negotiations committee, which should become applicable for all similar cases. In the case of formulations which involve a combination of more than one drug in the NLEM, the ceiling price would be the weighted average of the applicable ceiling prices of its constituents. For formulations containing a combination of a drug in the NLEM and any other drug, the ceiling price applicable to the essential drug would be made applicable. However, the company would be free to approach the price negotiations committee for a relaxation of the price on the basis of evidence proving superior therapeutic effectiveness for particular disease conditions.

In order to determine the reasonableness of the ceiling prices fixed as above, the L1 prices quoted in bulk procurement by Government and other designated agencies would be used after the system of bulk procurement is streamlined. Recognizing that retail distribution has costs not reflected in bulk procurement, a mark up of 100

per cent over this reference price is recommended. Since it would take time to streamline the bulk procurement procedures and to generate reliable data on such bulk procurement prices the ceiling prices should be allowed to rise on the basis of the price index manufactured goods (this would be a subset of Wholesale Price Index readily available from the Ministry of industry).

The regulatory body should set up a computer based system which would scan the prices data provided by companies against the ceiling prices determined as above and identify formulations which breach the relevant price ceiling. The company manufacturing or marketing such a product would be required to reduce its price or to face penal action. The companies should be permitted to represent for any price increase on valid grounds, which should then become applicable to the entire class of products.

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

Any new formulation based on existing APIs would be required to submit its intended price along with application for marketing approval regulator, which would be granted only if the indicated price is consistent with the relevant ceiling price. Till such time as the NADT is formed, this function will be carried out by the DCGI and NPPA in a coordinated manner. The NLEM should be revised periodically, say every 2 years, in order to reflect new drugs and significant changes in pattern of drug sales within the therapeutic categories.

Despite the price controls & monitoring the prices have been very poor in India (Rane, 1996) where, significant differences persisted between the prices charged by different manufacturers for the same formulation. Mostly companies with substantial market power charged higher prices and the impact of DPCO did not percolate to the consumers at all (Chaudhuri, 1999). While stressing the fact that the present price controls will be applicable on patented products too and such controls would definitely benefit the customers, Watal (1996) warned that the costs of establishing and maintaining an effective price control over all patented drugs may be very high.

3.5 Drug Pricing In Other Countries

The salient features of drug price control mechanisms in twelve countries are summarized in the following section.

Australia	Germany	Mexico
Brazil	Greece	Poland
Canada	Japan	Switzerland
France	Republic of Korea	United Kingdom

AUSTRALIA

Approximately 95 percent of prescriptions issued in Australia are subsidized by the government under the Pharmaceutical Benefit Scheme (PBS). The remaining 5 percent of prescriptions are those that cost less than the patient co-pay or were private prescriptions. The PBS covered about 80 percent of the cost of the approximately 128 million prescriptions filled in Australia (or about eight prescriptions per year per person). In 2003, this included approximately 600 different pharmaceuticals (many of which were generic brands), presented in some 1,500 forms (e.g., tablet, gels cap, liquid) and 2,500 brands. The price paid included the manufacturer's negotiated price, a 10 percent wholesaler's margin, and a 10 percent markup for the pharmacist, plus the pharmacist's professional fee (\$4.39 per script as of August 1999). Annual inflation adjustments are provided to those at every stage of distribution, except to manufacturers.

The PBS has created two categories for recipients of PBS-subsidized medicines: "general" patients and "concession" patients. The latter are typically low-income workers, the unemployed, the disabled, and senior citizens. As of January 4, 2004, general consumers pay up to \$23.70 for most medicines listed on the PBS, while people with concession cards pay \$3.80. Currently the majority of government expenditure on PBS prescriptions is directed towards concession cardholders (79.8% of the total). The table 3.4 outlines the total expenditure by the Commonwealth on the PBS since 1991:

Date (to June)	Expenditure
1991–92	\$1.11 billion
1992–93	\$1.40 billion
1993–94	\$1.68 billion
1994–95	\$1.88 billion
1995–96	\$2.19 billion
1996–97	\$2.33 billion
1997–98	\$2.52 billion
1998–99	\$2.78 billion
1999–00	\$3.17 billion
2000–01	\$3.81 billion
2001–02	\$4.18 billion
2002-03	\$5.48 billion
2003-04	\$5.61 billion

The PBS growth rate over the last decade has not been uniform. Growth slowed from 20 per cent between 1992-93 and 1993-94, to 6.5 per cent between 1995-96 and 1997-98. After this, growth returned to 20 per cent between 1999-2000 and 2000-01. Since then rates of growth have slowed again, dropping to 9.6 per cent in 2002-03. So, over the last decade, growth rates have fluctuated rather than followed a trend of either slowing or accelerating or remaining the same. This fact should caution against concluding, solely on the basis of recent past experience, that PBS expenditure is likely to continue its growth at an annual average of around 12 per cent.

The three drugs with the highest cost to government in 2003-04 were Atorvastatin (\$352.8 million), Simvastatin (\$324.0 million) and Omeprazole (\$179.6 million). PBS drugs most frequently prescribed are Atorvastatin, followed by Simvastatin and Omeprazole.

Some of the main reasons forwarded to explain the large increase in government expenditure on the PBS include:

- increasingly expensive new drugs being listed
- over-prescribing and leakage
- consumer expectations
- ageing of the population
- aggressive marketing by the Pharmaceutical Industry.

Pharmaceutical Benefits Scheme (PBS) Process

The PBS submission process is complex. A pharmaceutical company seeking to list a drug on the PBS selects a comparator drug, usually the drug that it is seeking to replace. The company must prove that its drug is more cost effective or at least as cost effective than that comparator drug in order to be listed on the PBS. To prove cost-effectiveness, a company must provide data showing incremental cost in dollars of its drug compared with the comparator, and incremental outcomes of its drug compared with the comparator drug. What factors a company is permitted to use when calculating outcomes significantly influences the determination of incremental cost-effectiveness. The sponsors submit their applications to the Pharmaceutical Benefits Advisory Committee (PBAC) and the submission is reviewed by external evaluators and then provided to the PBAC and its economic subcommittee, which analyze the cost effectiveness of the pharmaceutical based on a comparator drug. The PBAC makes a recommendation whether to list, defer or reject a drug. If the recommendation is to list, the recommendation goes to the Pharmaceutical Benefits Pricing Authority (PBPA). The PBPA determines the price at which the government will purchase the drug, taking into consideration a number of factors, most importantly the PBAC's advice on clinical and cost effectiveness. The PBPA then offers a price to the manufacturer and often also seeks price/volume arrangements and limits on the specific indications that will be covered. If no agreement is reached between the PBPA and the drug sponsor, the product will not be listed. If the price is accepted, the PBPA makes a recommendation to the Federal Minister of Health, who has final approval over all PBS listings.

The agency also annually reviews the prices of all products listed as pharmaceutical benefits and can seek price reductions or allow price increases, virtually always the former. The U.S.-Australian Free Trade Agreement included provisions on pharmaceuticals and specific steps to improve the transparency and accountability of

the PBS process. The Australian Government agreed to an independent review of listing decisions, which will enhance the accountability of the process.

BRAZIL

Price controls, in effect since July 2000 and slated to remain in place until the end of 2002, are one of the most significant barriers to the pharmaceutical industry in Brazil. Socalled “voluntary” – in fact, coerced - price controls were imposed in July 2000, and formally extended by presidential decree in December 2000. Those controls were extended again in fall 2001. Pharmaceutical prices in 2001 could not be increased more than 4.4% above August 1999 levels, despite a significant decrease in the value of Brazil’s currency against the U.S. dollar. Prices for 2002 can only be raised 4.5%, clearly inadequate compared to the devaluation of the real. These arbitrary pricing formulas were imposed without input from industry. The price limitation and freeze takes no account of increases in manufacturers’ costs, including Government-mandated salary increases, and the usual increases in the cost of doing business. The decree is completely contrary to the free market principles to which Brazil has committed itself in recent years. It sends an extremely negative message to international investors and bodes ill for other industries as well. This measure violates Brazilian law and will do nothing to improve Brazilian citizens’ access to medicines – the Government’s purported goal in imposing these controls. Pharmaceutical research is enormously expensive and risky; very few products make it from the laboratory bench to market. Price controls threaten biomedical innovation by undercutting the profits needed to finance research and development.

CANADA

The pricing system in Canada is a two-tiered system that relies on negotiated prices. The Patented Medicines Price Review Board (PMPRB) first negotiates a final price for new (or “breakthrough”) prescription drugs, which acts as a price cap for the prices negotiated by each individual province or territory. The intent of the PMPRB is that the price of a new-patented drug at launch should not exceed the average price

established by taking into account the prices in seven other markets (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States). Subsequently, prices are allowed to increase in step with the rate of inflation according to the Consumer Price Index.

For drugs with minor or no innovative therapeutic effect, as deemed by the PMPRB, prices are tied to those of existing drugs with similar effects. Federal prices act as a ceiling on prices nationally and further discounts are negotiated by the provincial and territorial governments. The British Columbian provincial government sets a reimbursement price for all products that are grouped in a specified therapeutic classification. This leaves the manufacturer free to charge any price below the PMPRB price, but it requires the individual patient to pay the difference between the provincial price and the PMPRB price.

FRANCE

The French pricing system allows pharmaceutical companies to sell their products at any price. However, if these companies want the national health care system to reimburse patients for the cost of the drug, the companies must agree to a lower, negotiated price. These negotiated prices and reimbursement rates paid by the healthcare system are based on the therapeutic value of the drug and the price of the drug in other countries. The French pricing system results in brand name drug prices that are an average of 45% lower than prices in the United States. Data from the French pharmaceutical trade association indicate that although the cost of living more than doubled between 1980 and 2000, the retail price of pharmaceutical products increased by only 34 percent over the same period. Overall, French prices are close to the European average. Nonetheless, French patients spend relatively more on pharmaceuticals than other OECD countries and successive governments have pursued cost containment policies as a means to drive down drug spending.

The government regulates the prices of reimbursable drugs. The Social Security Code provides the procedures and criteria for pricing and reimbursement listing. Pricing decisions are jointly agreed between the Ministry of Social Affairs and the Ministry of Economy.

To encourage further generic substitution, the French government implemented a new pharmaceutical distribution margin system. The generic market is currently estimated to account for only 4 to 6 percent of the total prescription market, with sales valued at €800 to €1,000 million.

Pricing of pharmaceuticals

A pharmaceutical company may set its own price for a drug that has received marketing authorisation. For this to be reimbursed by the national health insurance fund, i.e. Caisse Nationale d' Assurance Maladie (CNAM), reimbursement status must be granted by Commission de Transparence (Transparency Commission), and a reimbursement price negotiated with Comité Economique du Médicament (CEM) All registered pharmaceuticals are subjected to Evaluation of Therapeutic Benefit (Amelioration du Service Medical Rendu, or ASMR), that is expressed as a classification between 1 - 6, as follows:

Table 3.5: Classification of drugs

1	innovative product of significant therapeutic benefit
2	product of therapeutic benefit, in terms of efficacy and/or reduction in side effect profile
3	already existing product, where equivalent pharmaceuticals exist; moderate improvement in terms of efficacy and/or reduction in side effect profile
4	minor improvement in terms of efficacy and/or utility
5	no improvement but still granted recommendations to be listed
6	Negative opinion regarding inclusion on the reimbursement list

The ASMR evaluation is based on the expert judgment of the Transparency Commission of the Pharmaceutical Agency (Agence du Medicament). In France, medicines may only be sold at one price; when reimbursement status is obtained and accepted, the price negotiated with CEM becomes the price at which the drug is sold throughout the country, even for private prescriptions.

The Framework Agreement (Accord Cadre)

As a rule, the prices of reimbursable pharmaceuticals are fixed by the state; over the past three years, however, price fixing has been determined to a great extent by negotiations. The prices of reimbursable pharmaceuticals are determined by the interministerial Economic Pharmaceutical Committee (CEM) after negotiations with

the manufacturers and can be fixed in contracts between the CEM and the pharmaceutical company in question. The price depends on

- the ASMR evaluation
- the relevance of the respective pharmaceutical in the market (valuated by the number of packs sold)
- the research expenditure, and
- the advertising costs of the manufacturer

Pharmaceutical companies requesting a reimbursement price for a new drug are requested to provide the prices of that drug in other EU member states. There is no formal mechanism of setting the price of a drug in France on the basis of its price in other European countries. However, CEM is sensitive to accusations that prices in France are low compared to those elsewhere in Europe, and is prepared to bring launch prices closer to the European average. The system of price determination is based on a framework agreement (accord cadre) between the State and the pharmaceutical industry, which in 1994 replaced the price regulation by the State (which had been in use for 25 years). In the accord cadre, manufacturers committed themselves to limiting their advertising expenditures and to inform doctors on a "rational use" of the pharmaceutical in question. This voluntary restriction by the pharmaceutical industry is a pre-requisite for higher selling prices. Any violation by manufacturers of these principles results in the State setting a price as before 1994, i.e. reverting to price regulation, with the price level being lower than before. Prices of reimbursed drugs may not be changed without the authorisation of CEM. Price reductions can be imposed if the sales of a medicine surpass the volumes set out in a price-volume agreement. There are limitations on the industry's promotional expenditure.

For non-reimbursable and hospital-exclusive pharmaceuticals the price regulation by the State was abolished in 1987. For pharmaceuticals in the hospital sector, manufacturers may submit a tender to hospitals, taking into consideration volume variations.

The 1998-99 social security financing bill, has several important implications for pharmaceuticals. The bill focuses on promoting generics and generic substitution from January 1999, and rationalising the reimbursement system. Reimbursement will be focused on "products whose medical efficacy is proven", and the criteria for

reimbursement will be reviewed to take account of the seriousness of the disease and the medical advantages of the product. The government is also poised to pursue an active price policy for innovative medicines, in order to encourage research by French pharmaceutical companies. In particular, the following are being implemented:

Firstly, article 24 of the bill says that the price committee is to monitor pharmaceutical spending on a continual basis to ensure that it is in line with the annual target for national health insurance spending. This would involve at least two annual evaluations of spending trends, after the fourth and eighth months. If these checks showed pharmaceutical spending to be out of line with the overall spending target, the committee would decide what steps to take. It could, for example, tell a company to cut the prices of its reimbursed products (as set under its pricing contract) and publish the new prices in an annex to the contract. If the company refused, the contract could be rescinded, the bill says. This represents a radical departure from the spirit of the pricing system as originally envisaged, which was to have a collaborative price negotiation scheme giving companies a long-term stable framework within which to operate.

Secondly, the bill sets that contracts will be for a maximum of four years, and will cover the price of a company's products and, where applicable, fluctuations in these prices, particularly in terms of commitments on volume sales. It will also cover any rebates payable on excess volumes, and includes commitments on curbing promotional spending in order to ensure the proper use of medicines and meet volume sales commitments.

Thirdly, price-setting will be based on the product's medical value, the prices of comparable medicines, sales volume commitments, and the conditions in which the product is used. Initially, the bill also provided for a payback mechanism on any sales over the annual target which would apply to companies that had not signed contracts. However, the French Parliament adopted an amendment making all companies subject to the spending payback clause. Adopting the bill at first reading on October 30th 1998, the Assembly took on board an amendment by the social affairs committee under which companies that have signed pricing contracts will no longer be exempt from the payback clause. This means that companies must pay back a proportion of their annual sales and sales growth whenever health care

spending is over target. Companies will therefore need to weigh up the drawbacks of signing a contract against the possibility of having to pay back a proportion of their sales each year if spending is over target.

Fourthly, article 26, suggests that the industry would make the 1998 financial contribution to the social security by way of a one-off payment. The payment was based on three factors: industry's French sales of reimbursed products in 1998; any increase (over 2.3%) in these sales compared with 1997; and promotional spending. The payment is due by August 31st 1999. The new pharmaceutical pricing system places more emphasis on the real therapeutic value of products and far less on price/volume trade-offs as a way of restraining prices. In a firm break with the past, the pricing system no longer includes commitments on overall sales, nor is the use of price/volume contracts anywhere as systematic. Such contracts, where companies agree to price cuts when volume sales forecasts are exceeded, will be used only exceptionally. They could, for example, be used for products whose consumption was expected to be very high or which risked being used for un-approved indications - if this happened their price would be cut. Where companies claim higher prices for "innovative" products, the pricing committee will be looking for evidence that this translates into clear clinical improvements over existing products judged to be similar. The product will then get a price that reflects those of similar products in other countries in Europe. Assessing NCEs where no similar products are marketed elsewhere in Europe will be more difficult. For this reason, a group of pharmacoeconomics experts is being set up to look at the possibility of using such studies as a pricing criterion. The new group, which will be independent of the Transparency Commission, is needed because the pricing committee has little experience of such studies. Initially it will only look at the possible use of pharmacoeconomic studies for pricing purposes, but later it may also be able to offer advice to companies wishing to use such studies as a support in their pricing talks.

The committee will be reviewing reimbursement with three criteria in mind:

- 1) Should the products still be reimbursed?
- 2) If so, at what level? and
- 3) Are the products' prices still justified in view of therapeutic progress?

The committee will be taking a much stricter approach to the reimbursement of pharmaceutical products in general, and the scale on which therapeutic progress is

assessed (the ASMR rating) will be tougher. The national health insurance agency, the CNAM, will have a seat on the committee. As an "informed purchaser", the CNAM is expected to be tough on pricing and reimbursement issues.

Prices of generics

In November 1998, the government imposed sharp price cuts of almost 50% on some generic products, after the manufacturers failed to reach agreement on the cuts with the pricing committee by the 30th September 1998 deadline. The government issued a decree cutting the prices of 37 generic products. Generics companies had until the end of September 1998 to cut prices to 30% below those of the original, as set out in relevant legislation, or have the cuts imposed. Some manufacturers have 'voluntarily' reduced the prices of a number of other products (published in the Economy Ministry's official bulletin). All 459 generic products on the most recent generics' list published by the Medicines Agency in July 1998 are now priced at least 30% below the original. Separately, the two pharmacists' associations have drawn up proposals on remuneration to try to ensure, among other things, that they do not lose out financially when dispensing generics. The problem lies in the fact that, under the present margin system, pharmacists are discouraged from substituting generics for the original because the mark-up is lower for generics. One proposal is that pharmacists would apply the same absolute (i.e. financial) mark-up on the generic as on the original.

GERMANY

Germany implemented a reference price system as part of the Health Care Reform Act implemented on January 1, 1989. Reference prices are fixed by the sickness funds for groupings of drugs established by a federal committee of representatives of physicians' associations and the sickness funds. If prices exceed the reference price, the patient is required to pay the difference. In practice, however, it has reportedly not been feasible for suppliers to set prices higher than the reference price because the insured patients were generally not willing to pay the out-of-pocket expenses, and doctors have been reluctant to prescribe drugs priced above the reference price.

Thus, reference prices in practice typically represent the *de facto* upper limit of prices. The system, which covered patent and non-patented pharmaceutical products, had a negative impact on the German pharmaceutical industry. The German government revised the system in 1996. Key changes included removal of patented drugs from reference pricing, cessation of mandatory dispensing of drugs brought into Germany by parallel imports, and the encouragement of biotechnology investment. Seeking to contain growing budgetary pressures, the Germany government revised the system again in 2004. Certain patented pharmaceuticals were again subject to reference pricing. An independent federal committee is currently developing the reference price groups, and the reference pricing including patented pharmaceuticals is to take effect in January 2005. On July 20, 2004, the independent federal committee charged with setting up reference pricing groups, established a pricing group combining generics and patented pharmaceuticals (generally known as “jumbo groups”) for statins (cholesterol control drugs). It intends to announce other jumbo groups in the coming months.

The healthcare reform included an “innovation clause,” which allows pharmaceuticals with special therapeutic qualities to be exempted from reference pricing. However, the criteria for determining whether a drug meets these qualities needs to be clarified further. In addition, since 2003, the German government has required pharmaceutical companies to pay a 6 percent mandatory rebate to statutory health funds. To provide immediate savings to the health fund system while reference pricing is being developed, this rebate was increased to 16 percent in January 2004. The government has stated it intends the rebate to revert to 6 percent once reference pricing is introduced.

GREECE

The Directorate of Prices and Medicinal Products in the Ministry of Development sets pharmaceutical prices. The pricing committee in the Ministry of Development consists of nine members and is responsible for giving expert, nonbinding opinion on pharmaceutical prices. The committee operates under the General Secretariat of Commerce and consists of three representatives from the General Secretariat, a

representative from the National Drug Organization (NDO), a representative from the Ministry of Finance, two pharmaceutical industry representatives, and a pharmacist. Greece follows the EU Directive 89/105, in which drug-pricing decisions must be granted within a 90-day period. However, in practice, these deadlines have not always been met. Prices are published in a Price Bulletin, which is published in the press and the Greek Government Official Gazette. Separate pricing procedures apply to imported and domestically produced pharmaceuticals. The lowest ex-factory European price applies toward imported products, while production and distribution cost factors are taken into account for domestic products.

Greece uses the basic cost formula for locally produced pharmaceuticals; the country will not grant a price unless a product is marketed in one European country. A three-year monitoring period applies after a price is set for a specific product, and the maximum price of the product in Greece is reduced if a lower price is recorded in Europe during that period. Basically, the product's maximum retail price is relative to the price of the same product in neighboring countries. The price is reexamined annually, and the Management of Prices and Industrial Products and Pharmaceutical Products—General Division of Interior Commerce—General Secretariat of Commerce investigates whether the reference prices have fallen in order to readjust. If the Ministry of Health or the National Drug Organization deems the pharmaceutical as a necessity to the public's well-being, the procedure is exempted for the drug.

Generic prices are set at 80 percent of the original product's price, but generic products are not actively promoted by health insurance organizations. The prices of over-the-counter (OTC) products are also regulated and can only be sold by pharmacies.

JAPAN

The Ministry of Health, Labor and Welfare (MHLW), through the Special Committee on Drug Prices (part of the Central Social Insurance Medical Council or Chuikyo), establishes the introductory price of every new prescription brand name drug through negotiation with the manufacturer. Generally, the price of a "comparator" product, which is already on the market, is considered, and overseas prices in four countries

(United States, United Kingdom, Germany, and France) are also taken into account. The Drug Price Organization, which was established in October 2000, is intended to provide the MHLW with advice on the appropriate comparators and premiums. If a comparable product does not exist or if the manufacturer chooses to avoid the comparator-based system, a price can be determined by a cost calculation, but MHLW makes the final decision regarding the actual method used. Drugs are also classified by usefulness and market size.

The “usefulness” categories allow price premiums to be awarded to the new drug. Drugs containing NCEs are added to the National Health Insurance (NHI) drug price list four times annually: March; May; August; and November.

REPUBLIC OF KOREA

After obtaining a product license from the Korea Food and Drug Administration (KFDA), the drug manufacturer/importer must request that MHW list its drug on the Pharmaceutical Reimbursement Schedule (PRS). The PRS lists the ceiling price for each product as determined by consultations between the Ministry of Health and Welfare (MHW) and South Korea’s Pharmaceutical Reimbursement Prices Review Committee. Industry, especially U.S. and other foreign manufacturers of innovative drugs, has lodged numerous complaints about transparency of this process, as well as the methodologies for setting prices. In January 2002, a U.S.-South Korean bilateral working group was formed with the goal of increasing transparency in drug policy and facilitating consultation on a broad range of health care issues. The group is composed of South Korean and U.S. drug companies and South Korean government officials with U.S. government participation.

Attempts to Introduce New Pricing Formulas

Actual Transaction Price: Following discussions in 1999 with the United States, South Korea agreed to allow foreign pharmaceutical products to be sold in the South Korean market. It agreed to set the initial reimbursement prices of innovative drugs at the average ex-factory price of the A-7 countries (The A-7 countries include the United States, United Kingdom, Germany, France, Italy, and Switzerland and

Japan.). In subsequent quarters, reimbursement prices were to be determined based on a sales-weighted average of the actual transaction price (ATP) from the previous quarter. This ATP system was designed to discourage hospitals from demanding discounts when buying drugs and then pocketing the difference between the discounted price and the larger reimbursement price provided by the government-operated health insurance system. However, South Korea's poor enforcement of the ATP system prevented reimbursement prices from settling at levels reflecting the reality of the South Korean market.

Triennial Repricing: In effort to further reduce prices, South Korea adopted the Triennial Repricing system effective on January 1, 2003. Under this system, all registered drugs are subject to repricing every three years. It covers all drugs registered on the national reimbursement list at the end of 1999. The system reduced prices for 2,732 products by an average of 7.2 percent in its first year. U.S. industry has raised concerns that the repricing formula appears to disproportionately reduce the price of innovative drugs compared to the price of generics. In addition, the repricing system does not allow for price increases when data supports such action.

Reference Pricing: The South Korean government has been considering implementation of a reference pricing system since 2001. Such a system faces considerable opposition from doctors, hospitals, patient's associations, and other domestic stakeholders, as well as foreign pharmaceutical companies. The South Korean government shelved the proposal.

Study on Managing Drug Expenditures

The NHI Reform Commission commissioned a study on ways to manage drug expenditures. In August 2004, details of the study became public. They include the following:

1. Establishing a positive list to evaluate the cost effectiveness of a new drug to determine whether reimbursement will be allowed; and
2. Establishing price-volume agreements, which would allow the South Korean government to reduce price reimbursements when sales exceed an estimated level.

MEXICO

The pharmaceutical industry is one of a small number of Mexican industry sectors that is still subject to government price controls, but in recent years the government has loosened price controls to give the industry greater flexibility. Maximum prices are set in consultation with the Secretariats of Health and Economy, as well as Mexico's National Chamber for the Pharmaceutical Industry (Canifarma), the primary industry trade association. Wholesale and retail margins are subject to negotiation between the government of Mexico and the individual manufacturer. The final retail price requires government approval

The prices to the public sector are much lower than those in the private market. In the public market, Mexico's system of price controls mandates that the lowest price criteria be used in purchasing decisions, which may reduce a patient's access to innovative medicines. Seven of the top 20 drugs purchased by the government of Mexico are over 40 years old. In a few cases, patients may receive copy products of the therapies that are best suited for their care. In 2003, the government of Mexico proposed the establishment of a reference pricing system for patented medicines. The details of this system are still under review, but over-the-counter and generic drugs will be exempt from it.

POLAND

Poland operates a reference pricing system of reimbursement. The reimbursement list is operated under the Health Insurance Fund. If the therapeutic group to which the new drugs belong is included on the reimbursement list, the new drug can be added to the same list, but the reimbursement price will be set at the lowest price in the group. Prices of imported generics are set at the level of the cheapest generic equivalent.

Poland has three tier drug-pricing system:

1. **Locally produced reimbursed drugs:** The Ministry of Finance set prices for domestically manufactured prescription medicine. The average prices are usually 20–50 percent of their equivalent in the European Union market. The prices are

calculated based on a “cost-plus” formula. Prices are usually revised once a year; price increases are kept below inflation rates.

2. Imported reimbursed drugs: The Ministry of Health negotiates prices of imported pharmaceuticals. On average, prices are 20–30 percent lower than in the country of origin. Negotiated prices are set in foreign currencies.

3. Non-reimbursed drugs: These pharmaceuticals are not under any price control.

The price setting mechanism has resulted in a wide price differential between imported branded products and domestic generic products, but changes are being made due to Poland’s accession into the European Union. Foreign pharmaceutical companies have raised concerns that the criteria for determining reimbursement pricing are nontransparent. In establishing reimbursement prices, the Polish government takes into account prices in relative low-priced EU markets such as France, Greece, Portugal, Spain, the Czech Republic, Hungary, Slovakia, and Lithuania, but different reference countries are used for different cases. Under the Ministry of Health, the reimbursements are determined based upon the recommendation of a Drug Management Team. The members of the team include three representatives from each of the Ministries of Health, Finance, and Economy and may include representatives from the regional branches of the Health Insurance Fund. The pharmaceutical industry has raised serious concerns about the fairness, transparency, and accountability of this process. The team is obliged to notify the applicant if the application is rejected. Moreover, the industry has raised concerns about the slowness of the process.

A price law, implemented in 2001, aimed at ensuring compliance with the EU Transparency Directives (Directive 89/105/EEC), was supposed to ensure that the decision process did not take longer than 90 days from a price submission, or 180 days if both pricing and reimbursement submissions are made simultaneously. However, these time frames are frequently exceeded. Price increases for compulsory priced drugs have normally been below inflation rates. Prices of domestically produced drugs remain lower than those of equivalent imported drugs. However, the import of foreign drugs has risen, and more drugs are being prescribed. The 1991 Act of Payment for Drugs and Medical Materials limited the cost increase by reducing the numbers of people entitled to state reimbursement. Furthermore, Poland’s accession into the European Union may introduce parallel

trading into the market, and off-patent drugs and drugs fully protected by patents in the accession countries will be potential legal candidates for parallel trade. Multinational pharmaceutical companies worry that the outcome will be an influx of cheap products into the European Union from Poland due to the low drug prices in Poland. This is a misconception because, in general, the price of local products and branded generics in Poland are more inexpensive, but prices of leading branded products (targets of parallel trade) are actually higher in Poland than many other EU countries. Many of these products, in fact, are not reimbursed and sale volumes are low.

SWITZERLAND

The Swiss Federal Office of Public Health manages the pricing and reimbursement of pharmaceuticals. The maximum price for a reimbursed pharmaceutical is based on three criteria:

1. Average price of the product in a group of reference countries (Germany, the United Kingdom, Denmark, and Netherlands).
2. Product's therapeutic and economic value compared to older products of the same therapeutic group.
3. If neither of the two above criteria applies, the manufacturer's suggested price is considered as the maximum price.

New generics are priced at 30 percent below the branded products. Price revisions are conducted every two years after the granting of the initial reimbursement price, and after a patent expires, or after 15 years of reimbursement; factors considered in revision include sales volume and price comparison. Sales of reimbursed drugs account for over two thirds of the country's pharmaceutical expenditure.

In an attempt to prevent price fixing, the Swiss Parliament adopted a revised competition bill, effected on April 1, 2004, that includes the possibility of sanctioning anticompetitive behavior without prior warning. Switzerland is planning to adopt the French's latest initiative on drug pricing, where health insurers will only pay for drugs up to the price of the generic alternative.

UNITED KINGDOM

The Health Departments and the Association of the British Pharmaceutical Industry (ABPI) have a common interest in ensuring that safe and effective medicines are available on reasonable terms to the National Health Service (NHS), and in a strong, efficient and profitable pharmaceutical industry in the United Kingdom (UK).

Such an industry must be capable of sustained research and development (R&D) leading to the future availability of new and improved medicines in this and other countries.

The Pharmaceutical Price Regulation Scheme 2005

The 2005–2010 Pharmaceutical Price Regulation Scheme (PPRS) is an agreement for the purposes of Section 33 of the Health Act 1999. The objectives of the scheme are that it should continue to:

secure the provision of safe and effective medicines for the NHS at reasonable prices;

(b) promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines;

encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

Pricing Of New Products

- New products introduced following the granting of an EU or UK new active substance marketing authorisation from the appropriate Licensing Authority, may be priced at the discretion of the company on entering the market.
- Line extensions relating to such new products, granted on the basis of an abridged application, may also be priced at the discretion of the company provided that the application to market the line extension has been submitted to the appropriate licensing authority within five years of the grant of the original authorisation of the new product.

- Increased strengths of existing formulations may not be priced at a level greater than prorated to existing formulations. The freedom of pricing of reduced strengths should not be coupled with product deletions so as to achieve hidden price increases.
- If forecast sales of any new product in any one year of the first five years following launch is expected to exceed £20 million, a company must inform the Department of both the price and the anticipated level of sales in each of the first five years.
- If a company considers that the rapid uptake of a new product will cause the company to exceed the upper margin of tolerance (MOT), then it is obliged to inform the Department immediately and negotiate a reduction in profitability for the current year to the upper level of the MOT. Similarly, the Department will negotiate a reduction in profitability if it has reason to believe that the rapid uptake of a new product will cause a company to exceed the upper MOT.
- Freedom of pricing at the time of launch of these new products is conditional that it will not cause forecast profits to exceed the target profit MOT.
- A company wishing to introduce a product to the UK market should give the Department a minimum of four weeks notice before the intended date of introduction. The company should supply the Department with details of the product including the NHS list price and Summary of Product Characteristics. The Department will acknowledge the letter and seek confirmation of the new active substance marketing authorisation status from the appropriate licensing authority.
- Once the Department has confirmed the new active substance marketing authorisation status, it will write to the company confirming that the product has freedom of pricing. Where a new product has not been subject to a new active substance marketing authorisation, a company must seek the Department's agreement to the price of the new product. This can include new products regarded by a company as innovative but which are not classified by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA) as new active substances; combination products containing active substances that have been marketed separately; active

substances with new indications; 'complex' branded generics; and variations in formulation, presentation or pack size to existing products.

- In reaching a decision on the acceptability of a price for a new product that is not introduced following the granting of an EU or UK new active substance marketing authorisation, the Department may take into account factors such as the following:
 - the price of other presentations of the same medicine or comparable products;
 - forecast sales and the effect on the NHS drugs bill;
 - the clinical need for the product;
 - any exceptional costs.
- If, following discussions, agreement cannot be reached on the price of the product, a company may decide to go to arbitration

In PPRS 2005 price cut, restraint and reduction have been done on the existing products