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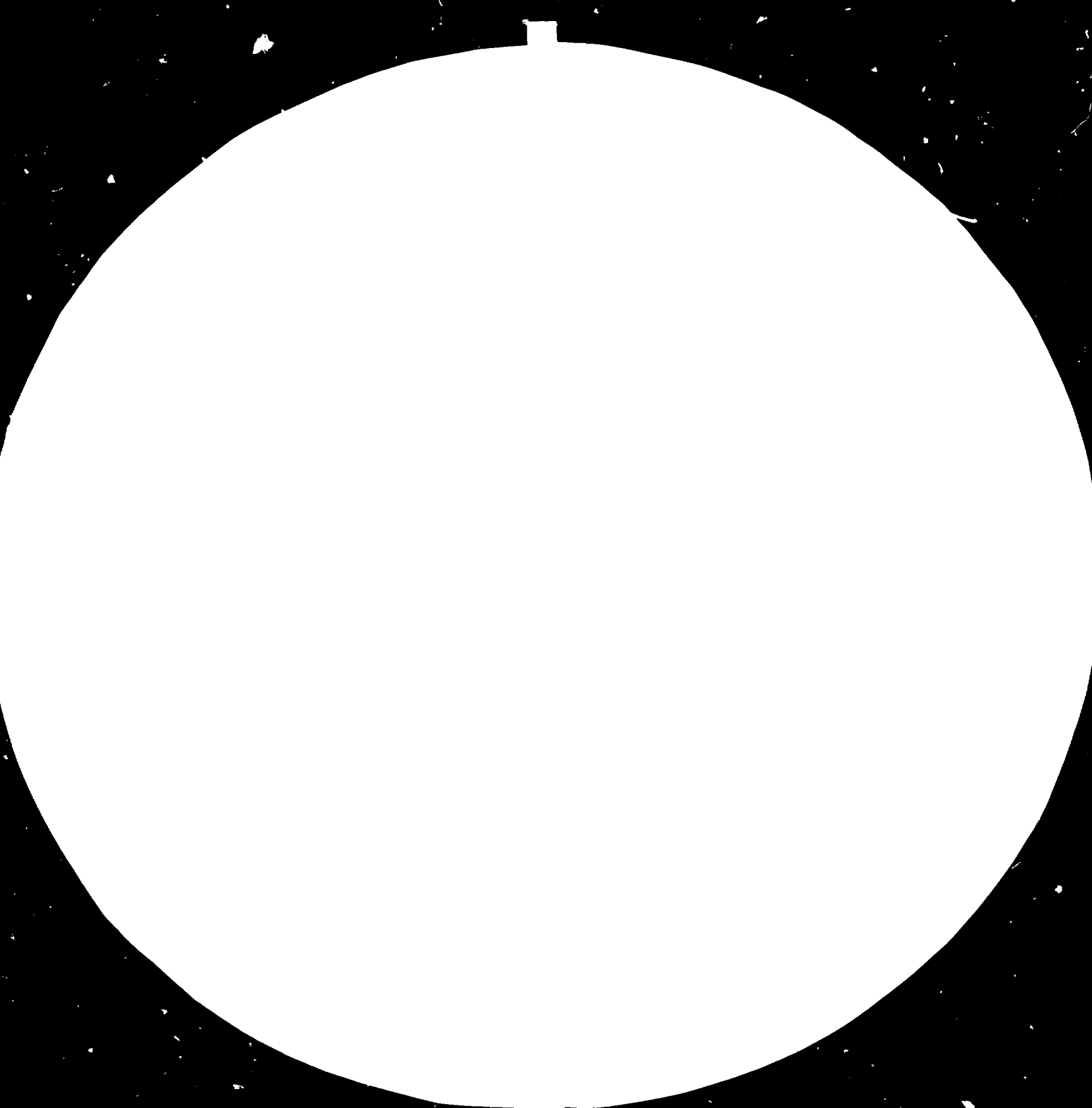

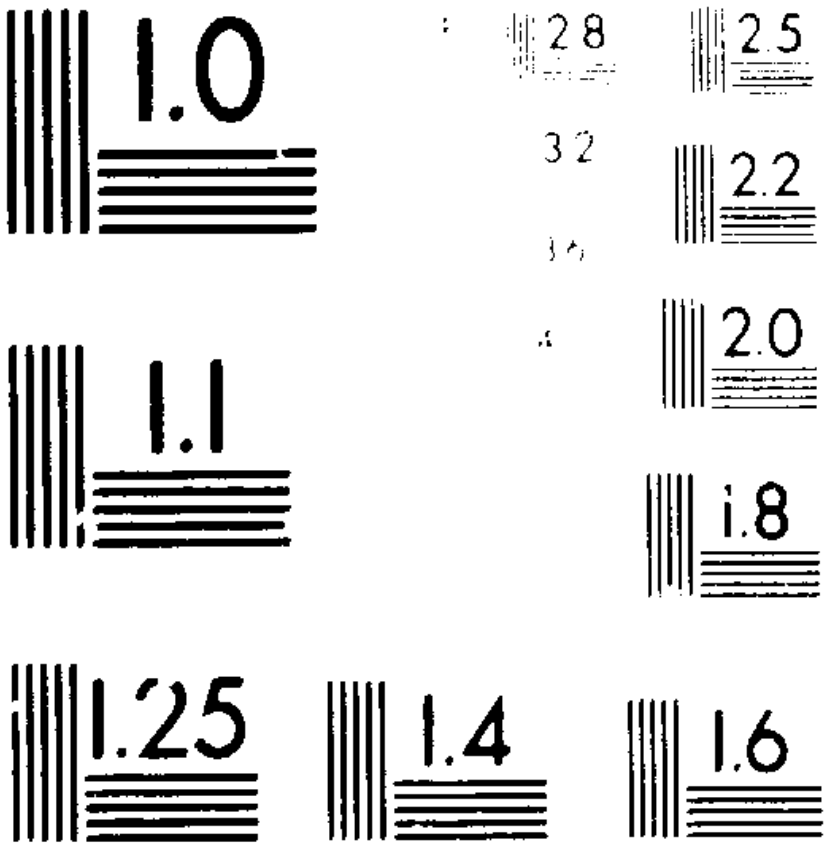

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DRUG PRICE CONTROLS IN INDIA

V.MALIK - N.Delhi

APRIL 1983

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CONTENTS

ANNEXURES

EXPLANATION OF ABBREVIATIONS

Rs	Indian Rupee (Approx US$ 0.10)
BICP	Bureau of Industrial Costs & Prices
DIR	Defence of India Act & Rules
DPCO	Drug Prices Control Order
DCD	Development Commissioner Drugs
EC Act	Essential Commodities Act 1955
GOI	Government of India
HAL	Hindustan Antibiotics Ltd
IDMA	Indian Drug Manufacturers' Association
IDPL	Indian Drugs & Pharmaceuticals Ltd
MU	Mark Up
OPPI	Organisation of Pharmaceuticals Producers of India
RBI	Reserve Bank of India

Lakh	1,00,000	0.1 Million
Ten Lakhs	10,00,000	1 Million
Crore	10,000,000	10 Million

I. BACKGROUND

1. Motivation for Price Controls on Drugs

1.1 The history of price controls on consumer goods in India goes back to the Second World War, when Government authority was used extensively to regulate retail prices of essential common use goods like cloth, foodgrains, sugar and petroleum products etc. The authority was derived from an omnibus wartime legislation called 'The Defence of India Act' (and Rules).

1.2 A new legislation called 'The Essential Commodities Act' was brought on the statute book in 1955 to empower the Government to exercise control over the production, supply and distribution of, and trade in certain selected goods for securing equitable distribution and availability at fair prices. It has been in use for enforcing such

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price controls for nearly three decades now. It enables the Government to promulgate special 'Orders' prescribing specific restrictions on the sale and distribution of what have been listed as 'Essential Commodities'. The restrictions include fixation of controlled sale prices.

1.3 The motivation for the legislation has been the public concern with ensuring availability of common consumer goods to the common man in situations of shortages which the country often faced on account of the increase in demand outpacing the increase in production.

1.4 During the India-China conflict in 1962, the war-time legislation was revived and among other things, came to be used for issue of an order making it compulsory for the manufacturer and pharmacist to publish and display prices of medicines prominently. The same legislation was used later in 1963 (which continued till after the Indo-Pak War of 1965) to freeze drug prices. The Government acted to safeguard exploitation of possible local and/or transient drug shortages by unscrupulous pharmacists.

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1.5 What started as an emergency war-time measure continued upto 1966, by when the country had got used to the application of public controls on drug prices. In 1966, the permanent price control mechanism - the "Essential Commodities Act" came to be used for this purpose when the 'Drug Prices (Control and Display) Order 1966' was issued under it. Subsequently two more price control orders were promulgated under this legislation in 1970 and 1979 (The latter being currently in force).

1.6 A key to the motivation for the continuity and refinement of these controls lies perhaps in the backdrop of the rapid growth of the pharmaceutical industry and products in the previous decade. The capital investment in this industry had more than doubled and the production grown more than threefold during the decade ending 1962. A strong base had been built by Multinational drug companies of British, American, Swiss and German origin in the country. More drugs were being used by more people. Democracy had come of age in India and the second countrywide election had been held in 1962. The Government had embarked upon a "socialistic pattern of society" and consumer inte-

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rest came to attract more public concern than corporate profitability. In fact during these years (1962 to 1965) were laid the foundations of the large Penicillin and antibiotic plants in the Public Sector (HAL & IDPL); which fact is also indicative of the awareness of the Government that essential drugs had to be reached to the masses cheaply and that the existing drug industry had not been able to do that as well as the Government would wish.

1.7 In the decade beginning with 1962, India saw three wars (1962: Chinese aggression; 1965 and 1971: Indo-Pak conflicts). These were years of relative austerity and tighter state controls on business and industry. The socio-political climate favoured increase in checks on large and unrestrained profits in industry. Balance sheets of large industrial houses and Trans-National Corporations attracted critical public scrutiny and discussion. Consequently in 1966, the Government ordered an enquiry (for the first time) into the cost-structure of bulk drugs which was completed in 1968. By 1970, Government had devised and promulgated a more elaborate price control order for drug formulations. It aimed at bringing down prices of essential drugs,

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curbing excessive profits, promoting R&D, and diversification of the range of products.

1.8 In the early seventies, discussions in the Indian Parliament and Press focussed more intensely on the profits earned by the Drug Industry.

1.9 A report on the Pharmaceutical Industry (of India) published in the Eastern Economist (New Delhi) of April 20, 1973 noted :

> "The fact remains that drug prices or the cost of medicines has always been an emotive issue in discussions all over the world. This is due to a number of reasons. In the first place, there is a natural desire among people everywhere that health care should be kept as inexpensive as possible and that commercial interests should not be allowed to exploit ill health or disease for making excessive profits for themselves. Then there is the widespread suspicion that the pharmaceutical industry is so organised that its units are able to enjoy an undesirable immunity from the

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free play of the market forces of supply and demand. In other words, it is widely suspected that there is not enough free competition in this industry and that therefore there is a large element of monopoly entrenched in this industry. Finally, there is the objective fact that the pharmaceutical industry is one of the 'high profit' industries, yielding a larger return on the capital invested than many other industries. Consequently, governments in most countries are under the constant pressure of public opinion to exercise vigilance, if not control, over the prices of drugs and pharmaceuticals.

In our country, there have been some additional reasons for government or public opinion being particularly sensitive to the prices of drugs and medicines. Since there is a large foreign presence in the Indian pharmaceutical industry, it has been tempting to assume that our country's dependence on foreign know-how or technology

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has been or is being exploited for the earning of quick or large profits. Secondly, since foreign participation in the industry involves payment in foreign exchange in the form of royalties or know-how fees or repatriation of dividends, the people and the government of this country are naturally anxious to ensure that the burden of this foreign exchange expenditure is not inflated through high prices for drugs or chemicals or high profit levels for the firms manufacturing them.

Regulation a 'must'

A certain degree of regulation or control of the prices of drugs and pharmaceuticals seems to have become one of the general obligations of governments towards their citizens in all parts of the world. Even in countries where there may be no formal government control over the prices of drugs or pharmaceuticals, there is often either a regular machinery or periodical investigations to

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ascertain facts and exercise vigilance in the public interest on production, prices and profits in this industry. In our own country it would be quite unrealistic to plead that the government should adopt a 'hands off' policy towards drug prices or profits."

1.10 A full-fledged report was commissioned by the Government on all aspects of the Industry ('Hathi' Committee Report) in February 1974 which culminated in the introduction of a more comprehensive price control system for the industry than had existed heretofore. This is presently in force since 1979.

1.11 The Government of India Order constituting this Committee stated :

"In the context of the large-scale expansion of the drugs and pharmaceutical industry envisaged during the Fifth Five Year Plan with a view to ensuring the regulated and rapid growth of drugs manufacture, and further with a view to ensuring that all essential drugs

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are made available to the consumers at reasonable prices, Government have decided to constitute a Committee..."

Among the matters entrusted for examination and report to this Committee were :

"The measures taken so far to reduce the prices of drugs for the consumer"

It was asked to recommend such further measures as may be necessary to rationalise the prices of basic drugs and formulations.

1.12 A popular feeling had grown in the country during the preceding years that despite the efforts at development by planning, a comprehensive public health scheme had not materialised due to constraints of resources. In this background, 'no perspective of a national drug policy had come to be delineated and drug production and distribution had been left to the mechanics of market relations and the profit motives of the drug industry which was dominated by the foreign sector'.*

*Document of the National Convention on Economic Independence and Perspective of Drug Industry - 16 January 1975.

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A national convention on the drug industry attended by eminent and knowledgable persons in December 1974 noted that : 'the question of drugs in one form or the other (has been) exercising all of us at various times. Sometime we face shortages; at other (times), prices rise inordinately; then there is the whole question of adulteration and of excessive profits by some manufacturers and formulators. Indeed the impact of distortions in various aspects of drugs manufacture and trading on the helpless patients and their families is tragic to say the least'.

1.13 While dealing with its task, the Hathi Committee noted* that an important characteristic of the highly competitive pharmaceutical market was the quick product change or product adaptation technique which is only partly based on proven improvements. In a large part, this is essentially a marketing technique used with a view to retaining or augmenting one's share of the market. Such a marketing technique, necessarily involves substantial selling costs which in turn are added to the prices of the drugs. It observed that in advanced countries, the pharmaceutical industry also spends subs-

*Chapter VIII-Page 173-174

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tantial amounts - around 10% of total turn-over - on drug research and product development. But these expenditures are relatively less significant in developing countries, including India, and by and large the multi-national corporations use their research outlays in the parent company to introduce new drugs/formulations by their subsidiaries in developing countries. The use of brand names enables the industry to sell essentially similar drug formulations at widely varying prices. Quite often, it is difficult for the doctor and almost impossible for the patient to have, at their disposal, information which will enable them to compare prices of drugs which are virtually identical. Advertisements rarely mention prices, and in general, the medical representatives canvass the superiority of their particular brand of medicines not on the grounds of prices but on other grounds such as therapeutic effectiveness or advantages of the new or improved drug.

1.14 The Committee also observed that in view of this special feature of the pharmaceutical industry, despite the previous price controls on drugs in India, the increase in the value of produc-

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tion could well be attributable to "the introduction of new products at higher prices"..."while the growth of the pharmaceutical industry over the last 15 years has been quite impressive in terms of output, it has been less so, if one takes into account the product composition and the pricing policies of the industry."

1.15 When it came to defining what ought to be achieved through governmental action in the field of drug prices, it noted that the per capita consumption of modern drugs and pharmaceuticals in India was then estimated to be Rs.6 per year and according to some estimates, only about 20% of the population used modern drugs. The total annual expenditure on drug formulations was roughly estimated to be below Rs.30 per family where the family income was Rs.4,200 per per year.

1.16 The Committee, therefore, concluded :

"The pricing of drugs is thus a socially important issue not because of its effect on the family budget but for certain other considerations. High prices of drugs, for instance, would effect the

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ability of the public hospitals to cater to the needs of the poor; but...the cost of medicines constitutes a relatively small proportion - around 12 to 15 per cent of the total cost of the public health services. The reduction in the prices of drugs, by itself, therefore, will not make much difference to the ability of the municipal or state agencies to provide medical facilities."

"The concern about drug prices, therefore, really arises from the fact that many of them are essential to the health and welfare of the community; and that there is no justification for the drug industry charging prices and having a production pattern which is based not upon the needs of the community but on aggressive marketing tactics and created demand. In other words, the main objective of policy has to be to secure a better convergence

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of commercial considerations and social needs and priorities. The emphasis has to be on increasing the social utility of the industry particularly in the context of extreme poverty and the urgent need for extending as rapidly as possible certain minimum facilities in terms of preventive and curative medicines to the large mass of people both urban and rural."

1.17 An analysis of governmental action shows that the motivation for price control on drugs has been changing from stage to stage.

- In 1962 the problem perceived was only the possibility of Trade malpractices that could arise from sudden increase in demand. It was considered sufficient to insist on printing of retail prices on product labels.

- In 1963 the Government's effort was aimed at containing sudden inflationary trends in the economy. Hence a price 'freeze' was enough.

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- In 1966, prior price approval system was first introduced, albeit in a limited way - only to apply to new products or formulations. This indicates an awareness that the industry exploited new products with high prices.

- The first enquiry into the cost structure of bulk drugs and formulations (by the Tariff Commission) was ordered in the same year (1966) which confirms that the Government had become aware that the industry could not be left to itself in price fixation.

- In 1970 followed the first of the comprehensive price control orders which extended to a large range of retailed products and was inspired by the principle of 'fair' prices, based on the cost of production and a specified return. Apparently the motivation was to 'rationalise' the retail market and prevent undue exploitation of consumers.

- The 1974 action to appoint the 'Hathi Committee' proved that there was a dissatisfaction with the 1970 Pricing Order and its scope.

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- The issue of the culminating order of 1979 shows the desire to re-structure the existing drug market and thereby change the production pattern of the industry in the hope of bringing it more in line with the social requirements of the country.

1.18 Surveying the 20 year long process as a whole, it may be concluded that the instrument of drug price control has been gradually developed, refined and transformed from a mere crude implement for checking inflation to a subtle tool for remoulding and channelling drug production into a new pattern. It is to be noted that each successive price control order (1963, 1966, 1970, 1979) lasted for a longer term than its precursor.

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2. Nature of Price Controls

Compulsory controls

2.1 The present controls on drug and formulation prices as imposed by Drugs Prices Control Order 1979, are compulsory, although they do not cover the entire range of drugs and formulations on sale in the country.

Bulk Drugs :

2.2 Under DPCO 1979, it is compulsory for manufacturers to obtain prior price approvals for price-controlled bulk drugs or to conform to bulk drug prices fixed by the Government based on the costs of others. Under the previous DPCO 1970, initially only a declaration of price was sufficient, except for certain bulk drugs listed as 'essential'.

2.3 New bulk drugs which may be developed through original research and development efforts in the country and have not been earlier produced

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elsewhere, are exempted from price-control for a period of 5 years.

Formulations :

2.4 Both under the above order, and its precursor DPCO 1970, the drug manufacturing units in the Small Scale Sector with annual turnovers of upto Rs.5 million were/are exempted from the requirement of getting Government approval to the prices of their formulations.

2.5 The current price controls extend only to formulations listed under Categories I, II & III in DPCO 1979 and the bulk drugs which are used for their manufacture. The rest (15-20% of the total turnover) of the formulations and bulk drugs are not price-controlled. However, the category of formulations exempted from fixation of price by Government is subject to the general provisions regarding publication and printing of maximum retail prices on the packs. Also the profits earned on these formulations are subject to the overall ceilings (ranging between 8% and 13% on sales turnover pre-tax), as are applicable to the profits earned on price-controlled formulations.

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2.6 All manufacturers of price-controlled drugs and formulations do not require prior Government approvals for prices. In respect of Category I & II formulations, the DPCO 1979 provides for fixation of 'Leader Prices', based on the prices of large-selling packs (assumed to be the most efficient manufacturers). These operate as ceiling prices for all identical formulation packs and strengths including those in the Small Scale Sector. 'Leader Prices' are also fixed in a similar manner for Category III formulations. Manufacturers who wish to adopt these or keep below these do not require to obtain Government approvals.

3. History of Price Control Legislation

The first statutory control; A freeze on formulation prices

3.1 The history of price control legislation in India is precisely 20 years old.

3.2 There had been no statutory control on prices of drugs and formulations before 1962. Following the declaration of a state of emergency in the country in the wake of Chinese aggression, the Defence of India Act was invoked, first to issue the 'Drugs (Display of Prices) Order 1962', and then to promulgate the 'Drugs (Control of Prices) Order 1963', freezing prices of medicines as they stood on 1st April 1963.

3.3 The Defence of India Act & Rules were promulgated during the period of the Second World War; with which India was involved being a part of the British Empire. This Emergency legislation was not specifically concerned with the Drug Industry or Drug Prices but with the equitable distribution of 'essential commodities'. These were defined

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(under Rule 35 clause 5) to mean 'food, water, fuel, light, power or any other thing specified by the Central Government in this behalf as essential for the existence of the community'.

The first scheme of price approvals by the Government

Selective price fixation for formulations

3.4 In 1966 the "Drug Prices (Display & Control) Order 1966" was issued under the "Essential Commodities Act 1955".

3.5 The Essential Commodities Act was promulgated in 1955 with a view to providing a permanent legislative framework for controlling distribution of essential commodities independently of the powers available to the Government during wartime emergencies. It has provisions for distribution and price controls which are basically similar to those of the Defence of India Rules. The list of commodities (Section 2 (9)) includes Textiles, Food-stuffs, Drugs, Paper and Petroleum products etc.

3.6 It had come to be felt by the Govern-

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that the blanket freeze of 1963 had started to affect the growth of the Indian drug manufacturing companies in the Small and Medium Scale Sectors and it was time to allow price increases. The order, therefore, permitted manufacturers to increase prices of formulations on their price-lists on 30th June 1966 subject to prior approval by the Government. Exemptions from such approvals were provided (by separate amendments) to items listed in pharmacopoeias and for new drugs based on original research.

Introduction of price controls on Bulk Drugs
Cost verification and 'fair' return on capital

3.7 In August 1966, the Government also asked the Tariff Commission to examine the cost structure of 18 essential bulk drugs and their formulations, and to recommend fair selling prices for them. This decision followed representation from the industry that while the prices of formulations were controlled, the prices of their inputs were not under control. The Commission presented its report recommending prices of 17 essential bulk drugs and 49 connected formulations. Thus, price controls now came to be extended to bulk drugs.

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Tariff Commission Report (1968)

3.8 The 'Tariff Commission Report' (1968) established that generally the costs (and prices) of bulk drugs manufactured in India were higher than those in the developed countries. The main factors to which these were attributed were (a) smaller and lower plant capacities than those in the developed countries; (b) higher costs of capital goods, intermediates, and other raw materials; and (c) difficulties in obtaining efficient technology and know-how owing to patent laws.

3.9 In the case of formulation prices, it was found that they were comparable to prices in developed countries. The Commission found that production and distribution costs being lower in India than in the developed countries, and the activity not being capital-intensive, there was definite scope for reduction of prices of formulations in several cases - even after allowing for full costs and a reasonable return on investment (15%). Selling expenses being charged were high.

3.10 The Commission took all these aspects into account and adopted generally the principle

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of weighted average for arriving at fair ex-works price for each essential bulk drug where more than one manufacturer was involved. The price of each individual costed unit was built up after a careful analysis of the data collected by them in respect of the years 1965-66 and 1966-67 for the units and after determining the costs on account of materials, manufacturing expenses, packing, royalty, research and selling expenses incurred by them. Provision was also made for a pre-tax return of 15 per cent on capital employed.

3.11 The Commission's findings in respect of selected formulations was that the prices can bear some reduction even after allowing for all costs and a reasonable return on investment. For arriving at the fair retail prices for the selected formulations of each firm, the Tariff Commission computed the factor cost comprising of costs of ma terials and packing materials, conversion cost and packing cost.. As regards selling expenses, the Commission found that their incidence varied from company to company and was "rather on the high side". Accordingly, they restricted it to 15 per cent of the total factory cost. The outward freight and excise duties were added on the

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basis of the then existing rates. They recommended selling prices included in addition to the above items, a 15% mark-up on the total cost of sales, i.e. total factory cost plus freight and the selling expenses corresponding to 15 per cent on capital employed in the case of essential drugs, the commission of the retailers, the wholesalers and other intermediates at differential rates for ethical drugs and non-ethical drugs (i.e. drugs saleable against a doctor's prescription and those saleable without such a prescription).

Drug Prices (Control) Order 1970

3.12 The findings of the Tariff Commission brought home to the Government that firstly there was a divergence in the costs and expenses being charged to various pharmaceutical products by the manufacturers, and secondly some of these charges as well as the 'mark-ups' on the ex-factory costs were too high to be fair. It, therefore, decided to introduce a new legislation - the Drug Prices (Control) Order 1970 which was issued under the Essential Commodities Act to bring down the prices of essential drugs, to curb 'excessive' profits,

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and to promote Research & Development activities and product diversification."

3.13 The DPCO 1970 was promulgated on 16th May 1970. The principal objective of the order was to effect a measure of rationalisation in the prices of drugs and to build up a rational system of price control. The order was also designed :

(i) to bring down the prices of those essential drugs where prices generally remained very high,

(ii) to provide sufficient incentives to the industry to maintain/facilitate its growth from the basic stages and to develop research facilities and expansion in a planned manner,

(iii) to promote diversification of entrepreneurship in the future development of this industry, and thereby provide better opportunities, for Indian personnel with requisite technical qualifications, and

(iv) to curb excessive profits.

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3.14 The Drug (Prices) Control Order 1970 was subsequently amended from time to time in the light of the experience gained in its working and suggestions received from the industry and trade. The salient features of these amendments and Order are as follows :

(i) Selling prices for 17 essential bulk drugs in different forms were fixed by Government taking into account the recommendations of the Tariff Commission.

(ii) Selling prices of other bulk drugs were frozen at the level prevailing immediately before the promulgation of the Order. No manufacturer, importer etc. were to be permitted to increase the selling prices of the bulk drugs without prior approval of the Government for which details were required to be furnished in the prescribed form.

(iii) In regard to formulations, certain norms for conversion charges and packing charges were prescribed for reworking the costs and a for-

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mula was devised for calculating the prices of all formulations having due regard to products of original research and development.

Under the usual scheme, the formulations were priced with a mark-up of 75% on the total ex-factory cost. The mark-up included provision for :

(i) Outward freight,

(ii) Distribution costs and the trade commission,

(iii) Promotional expenses, and

(iv) Manufacturers' margin.

3.15 In case of formulations involving original research, higher rates of mark-up upto 100% were permissible. In respect of formulations involving original research in India on basic drug a mark-up upto 150% was permissible.

3.16 This order also provided for an alternative scheme of pricing. This alternative scheme provided some flexibility in the fixation of prices, subject to certain conditions relating to mark-up applicable to essential and other formulations and

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overall profitability not exceeding 15 per cent on sales turnover.

3.17 It was provided under the 'alternative scheme' that gross profits made by this industry (gross profit before tax) will not exceed 15% of turnover in any year; and any excess thereof; if earned, shall be funded separately which could be utilised with the prior approval of Government, for following purposes :

(a) Research and development;

(b) Adjustments against future profits or losses; and

(c) Such other purposes as may be specified by the Central Government from time to time.

3.18 The Order provided certain time limits for submission of revised price lists supported by complete data for approval by the Government. When it was found that there was a rise in the selling prices of certain products, Government issued an amending order on 18th August 1970 whereby the prices of such products where increases had been effected by the industry after Ist of August, 1970, were

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"frozen" at the level prevailing immediately before the commencement of the Order, pending scrutiny of the pricing data by Government.

3.19 Subsequently, necessary approvals after scrutiny of the detailed cost data, were issued in December 1970. There are over 2,600 drug manufacturing units of various sizes in the country. As it was obviously not possible for the Government to examine the detailed price calculations of all these units in respect of the formulations within the time-limit specified in the Price Control Order, a beginning was made by fixing the prices of the drugs produced by the more important units numbering about 110. It was considered that as a result of operation of the market forces, the prices of formulations manufactured by other units would have to move in sympathy with those of the aforesaid leaders in this industry.

3.20 Details of cost structure of 11,732 packs of formulations as produced by the manufacturers were examined on a quick basis by the Ministry of Petroleum & Chemicals, during a short period by constituting a Drug Prices Review Cell. As a result of this exercise, prices of about 45% of the formu-

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lations/packs were reduced, 36% were kept at the earlier level, and increases were permitted only in respect of 11.45% of packs of finished formulations. At the same time, new introductions accounted for 7.5% of the total number of packs examined. It was then estimated that as a result of the above exercise, the community would have benefited to the extent of Rs.20 crores in a total turnover of about Rs.220 crores.

3.21 In September 1970, a Working Group was set up by the Ministry of Petroleum & Chemicals under the Chairmanship of the Chairman, Bureau of Industrial Costs & Prices to examine the cost structure of 24 bulk drugs and other allied matters. This Working Group also investigated the cost structure of certain connected formulations and developed norms of conversion and packing charges of different packs of these formulations. The Working Group submitted its report in four volumes the first three relating to bulk drugs and the fourth to formulations.

3.22 Reports of the Working Group were submitted to Government between April to October 1972. In April and May 1974, Government announced its deci-

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sions in respect of the recommendations pertaining to norms of conversions and packing charges. As costs of production had undergone a significant change since the initial investigation by the Working Group, the Government asked the Bureau of Industrial Costs and Prices to examine whether and to what extent, the earlier recommendations needed modification. In the light of this examination, later Government announced the revised prices which came into force from Ist May 1975.

3.23 The price control on the Drugs & Pharmaceutical industry has thus been in force in one form or another for two decades. Since 1970, virtually all changes in the prices of drugs and formulations have required prior approval of Government. The operation of the controls upto the 70s, however, had a lesser impact on the structure and level of prices of drugs and formulations than was perhaps expected in view of the very large proportion of items in respect of which reductions in prices were effected.

3.24 As pointed out earlier, the Drug Prices Review Cell undertook a quick examination of the cost structure of 11,732 packs and formulations and

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after discussions with the manufacturers, certain price adjustments mainly downward were effected. In such an exercise, however, it was only to be expected that manufacturers agreed to reduce the prices of those items where the sales value was small and/or growth prospects were limited. While the price reductions covered nearly 45% of the formulations in terms of numbers, in terms of total sales of the 110 companies, the proportion was less than 30%. Similarly, in the case of more than 1/3rd of the formulations, prices were allowed to be kept at the earlier levels. In a large number of cases, these items which together constituted about 6% of the sales were also products which carried a much higher mark-up, and therefore, had a significantly higher margin of profit.

3.25 Rigid control on prices of drugs and formulations had to be modified and selective increase in prices permitted on the merits of each case to take account of any substantial variations in costs of materials including packaging material. But the extent to which such modifications were required was relatively small, until the last quarter of 1973. For instance, the total number of

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applications received for refixation of prices was 759 in 1971, 2716 in 1972 and 2653 in 1973. With the oil crisis and the subsequent spiralling of world prices and also the high rate of domestic inflation, the situation was radically altered by the end of 1973. During the first quarter of 1974, the number of applications for price revision went up to 1469 and increased further to 2151 in the quarter ending June 1974. It was evident that with the steep rise in production costs, the revision of prices both of bulk drugs and formulations was necessary if supplies in the market were to be maintained.

3.26 In July 1974, after detailed discussions with representative associations of manufacturers, the Government evolved a system under which manufacturers could apply for price increases but the extent of such increases was to be limited to the actual increase in costs of materials (including packaging materials) only. Other cost increases such as the ones due to increase in wages, electricity rates, freight charges, distribution costs etc. were not to be taken into account. The salient features of the connected guidelines were to provide :

1. A basis for calculation of escalatory

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effect due to rise in the prices of raw and packing materials over the prices used in the cost data of 1970/the latest cost data approved for price revision prior to May 1974.

2. A simplified procedure for adoption and acceptance of prices for drugs and excipients used in the formulations duly certified by Chartered/ Cost Accountant in the prescribed proforma.

3. Notified rates besides norms for Conversion Costs, Packaging Costs and process loss for overages for working out current ex-factory costs.

4. Provision of an additional mark-up on the escalatory effect to provide for the increased cost of commission, transport and miscellaneous selling and distribution expenses as under :

i) 50% on escalatory effect wherever the existing mark-upwas 75% or less.

ii) 25% on escalatory effect wherever

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the existing mark-up was between 75% to 100%.

iii) Mark-up on escalatory effect upto a maximum of 25% wherever the existing mark-up was between 100 - 150% limited to a maximum mark-up of 100% on the revised ex-factory cost.

iv) No mark-up on escalatory effect for items where the existing mark-up was more than 150%. In such cases, even the escalatory effect would be so restricted as to limit the revised mark-up to 150%.

Further, in order to assist smaller units which, in any case, would have to price their products in relation to the prices charged by the larger manufacturers in the industry, Government also decided to raise the exemption limit from Rs.5 lakhs to Rs.50 lakhs. (Rs 5 Million)

3.27 As a result of these measures, it was possible to deal with the large number of applications received for price revisions much more expe-

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ditiously. In general, decisions on applications were taken within 4 to 6 weeks although the total number of applications was very large. Thus, the monthly receipt of applications which was on an average of 221 in 1973 went up to 603 in the first half of 1974. As a result of the revised procedures, in the course of 3 months between September and November 1974, it was possible to deal with as many as 1466 price revision cases.

The procedure laid down in the guidelines for price revision, however, was intended to be a stop-gap arrangement in order to provide interim relief to the industry in an expeditious manner. The main purpose of this revision was to ensure that there was no serious disruption in supplies on account of the spiralling of production costs and the continuation of uneconomic and low price. This purpose was, by and large, achieved.

Hathi Committee Report

New Drug Policy

3.28 The Committee on Drugs and Pharmaceutical Industry, popularly known as the Hathi

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Committee, which had been set up in 1974, submitted its report and recommendations to the Government in April 1975. It generated a lot of discussion both in the Parliament as well as outside and the Government held several exchanges of views with the representatives of the industry. The proposals based on this could come up to the Cabinet only in early 1977 but they could not be considered as soon thereafter, General Elections were held and the Government changed. The New Drug Policy came to be announced by Government in March 1978.

3.29 It imposed a specific freeze on the prices of bulk drugs and formulations for a period of one year. This period was over in March, 1979 and on 31st March 1979, the Drugs (Prices Control) Order, 1979 was promulgated. The Drugs (Prices Control) Order, 1979 provided for the revision in the prices of bulk drugs and formulations. Government announced increase in the prices of petroleum products in August 1979 which affected the cost/price structure of bulk drugs and formulations. The procedure for allowing price adjustments in bulk drugs and formulations was approved by the Cabinet in August 1980. The price revisions under Drugs (Prices Control) Order, 1979, therefore, started after August 1980.

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3.30 The price revisions of bulk drugs announced since then take into account the escalations in the costs of all inputs upto end of 1979 and those in the cost of major raw materials upto 31st August, 1980. In a few (21) cases (chiefly of fermentation based drugs), Government have also updated the costs of utilities upto 31st December, 1981 taking into account the price hikes in Petroleum Products which the country faced during 1981. In other words, in the prices revised so far, the effect of the increases in the prices of Petroleum products announced by the Government in August 1979 and June 1980 have been taken into account. The effect of the June 1980 escalations on the costs of inputs other than the major raw materials and in a large number of drugs of utilities, is yet to be allowed. The effect of the two subsequent increases in the prices of Petroleum products announced by the Government in January 1981 and July 1981 is yet to be reflected in the prices of ~~the~~ most bulk drugs and formulations.

3.31 The 1980s price increases of bulk drugs and formulations are, therefore, attributable to :

Cont.....40

(i) Increases in the Petroleum product prices announced by the Government in August, 1979 and June, 1980.

(ii) Increases in the rates of Utilities like power, electricity, steam water etc.

(iii) In the case of formulations, the increases in prices are mainly on account of (a) increases in the prices of the connected bulk drugs, (b) increases in the packing material costs.

Decreases

3.32 In the case of some bulk drugs, prices have decreased upon revision under DPCO 1979. These are mostly in cases where the previous prices were the 'declared prices' under DPCO/1970. These drugs were not then specified as essential drugs in Drugs (Prices Control) Order, 1970. The manufacturers were, therefore, allowed to declare their prices on commencement of production. They were brought under price-control in 1979 and their prices

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were fixed on the basis of cost studies.

3.33 A few manufacturers of some of the bulk drugs whose prices have been revised downwards have challenged the revised prices in Courts. The High Courts of Delhi and Calcutta have stayed the implementation of some revised prices of bulk drugs and their formulations.

Recent Reduction in Prices

3.34 Government have recently taken a series of steps to bring down the prices of certain important medicines, which are given below :

i. Reduction in prices of Rifampicin formulations

On account of reduction in the import price of Rifampicin from Rs.5861 per kg. to 4209 per kg., the prices of formulations based on Rifampicin were reduced w.e.f. 16th February, 1983. By this, reduction would range from 25% to 30%.

ii. Ethambutol Formulations

Government have shifted Ethambutol and

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its formulations from Category III to Category II in March, 1983, thereby reducing mark-ups from 100% to 55%.

iii. Trimethoprim and Sulphamethoxazole Formulations

Prices of Trimethoprim were reduced from Rs.2420.67 per kg. to Rs.1055.00 per kg. and that of Sulphamethoxazole from Rs.539 per kg. to Rs.390 per kg. w.e.f. 16th February 1983. This combination is used in anti-bacterial formulations. The prices of important brands of this combination like Septran and Bectrim have already been reduced.

iv. Cimetidine Formulations

The prices of Cimetidine formulations were also reduced in February 1983 by almost 50%.

v. Propranolol Hydrochloride Formulations

In the year 1983, no increase in the price of any major bulk drug have been allowed. However, there have been increases in the prices of a number of formulations based on bulk drugs which were announced earlier in the year.

Chronology of Price Controls on Drugs (and essential commodities)

1942 :	DIR - Cloth (Textiles) Control
1955 :	EC Act framed
1962 :	(China - India War)
	DIR - Display of Prices Order for various commodities Also Drugs
1963 :	Inflationary trend accentuated
1965 :	(Pakistan-India War)
1966 :	EC Act - Price Control Order 1966
1968 :	Tariff Commission enquires into 17 bulk drugs and formulations based on these
1970 :	BICP enquires into another 24 bulk drugs
1970 :	Full-fledged price control order under EC Act : DPCO/1970
1973 :	First petroleum price hike. Inflation accentuated.
1974 :	Parliamentary discussion, Public conventions - Media analyses
1974 :	Constitution of 'Hathi' Committee to report after detailed enquiry into drug industry

Cont.....44

1976 :	Price freeze
1978 :	Report of Hathi Committee
1978 :	Formulation and adoption of a new Drug Policy (23 March, 1978)
1979 :	Promulgation of Drug Prices Control Order 1979 w.e.f. 1.4.1979
1980 :	Procedures regarding pricing under DPCO 1979 finalised by Government
	Price revision of bulk drugs on fresh cost studies commences September 1980
	Formulation price revisions commence December 1980.
1983 :	National Drugs & Pharmaceutical Development Council formed - to assist Government in reviewing existing measures including price controls

DIR	=	Defence of India Rules
EC Act	=	Essential Commodities Act 1955
DPCO	=	Drug Price Control Order
BICP	=	Bureau of Industrial Costs and Prices

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4. The Customers for Drugs

4.1 Market surveys carried out by Operation Research Group specialised in pharmaceutical audit, give the following picture :

	URBAN	RURAL	TOTAL
Number of towns as per 1971 census	2,978	557,013	559.991
Population in the above places in millions	109.06	434.79	543.85
Total retail off-take of Drugs (Jan to Dec '77) in million of rupees	4,030	370	4,400
Trade sales per 1,00,000 population in rupees	37	0.9	38

The survey further indicates that there are 435,321 villages with less than 1,000 population covering 160 million, where regular chemists are not reported to exist.

Cont....46

4.2 There are reported to be over 1,00,000 licensed retailers and wholesalers, 17,000* hospitals and 16,000 dispensaries*, 65,000 primary & Sub health centres*, 1,40,000 doctors' dispensaries and clinics, over 1,00,000 general merchants, licensed to sell home remedies. The number of doctors was 2,68,700 and that of dentists was 8,650 in 1981+.

Hospitals & Government Institutions

4.3 The Government is the biggest single buyer and distributor of drugs. It buys and distributes through its various departments and agencies, such as, Central Government Health Services, Employees' State Medical Services, Defence and Railway Medical Services, etc. Drugs are also required in large quantities for National Programme for eradication of epidemics or other diseases such as malaria, tuberculosis, leprosy, control of blindness and sexually transmitted diseases. In 1979-80, 25 million population was covered by these programmes. The target set for the 1980-1985 Plan

*Health Statistics of India 1982 - Ministry of Health & Family Welfare.

+Medical Council of India and Dental Council of India

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period is a coverage of 35 million population*.

Major Public Health Needs

4.4 Reported Cases (1981)

1. Dysentery	:	6,193,280
2. Gastro-Entritis	:	887,124
3. Malaria	:	2,666,244
4. Leprosy	:	2,674,202
5. S.T.D.	:	557,994

(Source: Health Statistics of India - 1982: Ministry of Health & Family Welfare, New Delhi)

* Sixth Five Year Plan 1980 - Planning Commission of India

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5. The Pattern of Drug Distribution and Sales: Marketing Systems

5.1 Sales of medicines are generally effected by manufacturers through Distributors or Stockists and authorised Wholesalers to retailing druggists and chemists (pharmacists) and the latter dispense them to consumers. In certain cases, sales are organised by a sole selling agent or agents who supply the goods from their regional branches and depots to the wholesalers and retailers. Most leading manufacturers have their own regional offices or depots from where goods are sent to dealers. Some of the manufacturers of basic drugs (such as Boehringer-Knoll, Cyanamid, Hoechst, Pfizer and Wyeth Laboratories) sell their products directly to formulators. Producers claim that by means of continuous contacts and inspection of the depots of the distributors through the manufacturers' own staff appointed for this purpose effective control over the selling system is exercised.

Evolution of Distribution System

5.2 In the forties and early fifties impor-

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ters and manufacturers of drugs and pharmaceuticals predominantly relied on 'Distributing Agencies' to make products available to the trade, hospitals and medical people. Such distributing agencies worked on commission basis and were given territorial rights. As domestic production increased, manufacturers in general set up their own supply points in the form of sales depots. Most of the manufacturers now have such supply points established in every state in the country. Supplies of drugs and medicines flow from these stock points to a large network of wholesalers. These wholesalers are not subjected to any territorial restraint, and are free in turn to supply these drugs and medicines to retailers and doctors as and where needed. Under this system, the resources of the manufacturers have been coupled with the collective resources of thousands of wholesalers working in a climate of competitive trade to effect supplies to a maximum number of consumer outlets.

5.3 Thus the drug industry has already developed a vast distribution network to ensure ready availability of a wide variety of drugs and

Cont.....50

medicines in all parts of the country. A typical example of a large company manufacturing and marketing a number of well-known brand formulations is given below after para 5.17.

The Mode of Transport of Drugs

5.4 Transport of drugs and medicines has progressively changed from carriage by rail to carriage by road transport and, in fact, carriage of drugs by rail has been practically abandoned. This has come about because of the large incidents of breakages and pilferage of goods consigned by rail.

In the recent years, road transport has rapidly developed and today offers safe, speedy and convenient transport services suited to the carriage of drugs and pharmaceuticals even to the remote parts of the country.

5.5 The hospitals under the Government of India (as distinct from the States) receive medicines from the 'Government Medical Stores' run by the Ministry of Health & Family Welfare. Those

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stores invite tenders, and then enter into rate-contracts for a full year's supply - as a rule at the lowest rates.

5.6 State Governments make purchases separately through tenders for lots or annual rate contracts. Indenting Officer can procure medicines directly in accordance with the rate contracts as required. Drugs which may not be on these contracts, or may not be readily available from the contracted suppliers may be bought in immediately required lots by floating local tenders.

5.7 The local tenders are filled by the local distributors or stockists of the manufacturers. The larger contracts are made directly with formulators.

5.8 All other things being equal, the buying departments of the Government of India (not the State Governments) are expected to give a price-preference of 10% to the Public Sector Drug manufacturing units like IDPL & HAL. However, they are also expected to give a 15% price preference to the Small Scale Sector Units.

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5.9 Although under the present Drug Price Control System, the 'maximum retail prices' of most formulations procured by these public institutions are fixed by the Government of India, there is (naturally) no insistence that public sector units may receive these very prices. They have to face competition equally and often lose business to Small Scale Units whose costs are lower on account of lower overheads etc. Drugs and medicines are required to be supplied to these institutions in special packings, with special markings, on credit and at highly competitive rates. These conditions necessitate that supplies are made directly from manufacturers.

Sales Promotion

5.10 The normal means of mass communications are not available/sufficient for the drug industry as pharmaceutical products have to pass through the medical profession before they can reach the consumer. The manufacturers have, therefore, to promote their product sales through other means on which sizeable expenditures are incurred.

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5.11 This is done by various means : appointment of a large number of travelling salesmen (medical representatives), supply of free literature, and free samples to the medical profession, advertisement in medical journals for ethical drugs, and for others as permissible. Manufacturers arrange and finance seminars, work-shops and other 'get-togethers' of doctors which help them build a rapport with the profession.

5.12 The 'medical representatives' travel from town to town, calling on doctors (8 to 10 a day), dealers and hospital administrators (3 to 4 a day). They are large forces (over 10,000) and their cost of travel and stay is considerable.

5.13 The quantum of amounts spent on sales promotion is not relatable to the total turnover of a particular unit or even that of the industry, but is relatable to particular groups of drugs under promotion.

5.14 The costs of sales promotion are however considerably less than in the developed countries. The Tariff Commission had observed in 1968 that, "In

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UK, the number of doctors is about 50,000 and the promotion cost works out to Rs.2,773 per doctor. On the other hand, there a re about 100,000 registered Medical Practitioners in India and the cost comes to Rs.410 per doctor which is almost 1/7th of the figures for UK". It also noted that "this compares with the ratio of the per-capita costs (incurred) of drugs in the two countries."

5.15 Sales promotion expenses actually incurred by a large manufacturer with a wide range of bulk drugs & formulations may be seen below :

[Pages 55 & 56 contain the illustration based on the 'actuals' of another large formulation manufacturer.

Pages 56-A, 56-B, & 56-C contain 'actuals' of a third major Bulk Drug & Formulation manufacturer which is the subsidiary of a US company].

Head of Account	Total Cost Rs./Millions
1. Employees Remuneration & Benefits including Leade & Medical	8.48
2. Incentive to Staff (Achievement related)	0.84
3. Travel & Hotel Expenses	5.66
4. Advertisement	0.13
5. Conferences & Entertainment	0.13
6. Printed Promotional Material, Stationery & Postage	2.76
7. Samples	9.16
8. Gifts	2.00
9. Training & Dev.	0.20
10. Misc. Awards (To Trade)	0.30
	29.66

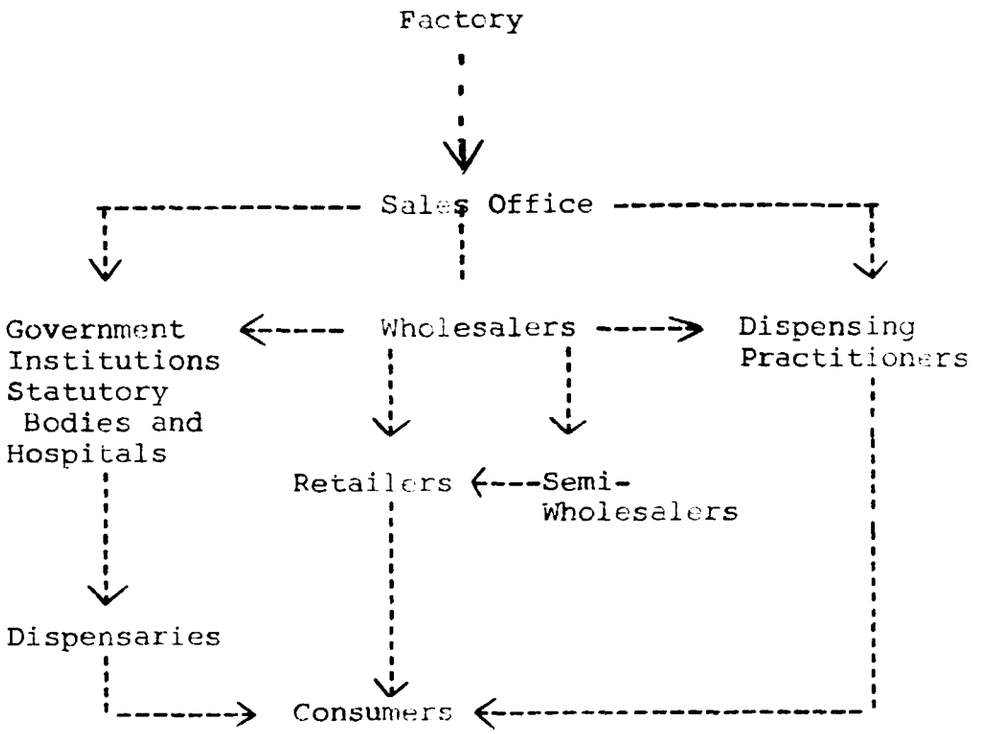
Total No. of Med. Reps.

Human Formulations	350
Vet.	16
Bulk	10
Total :	376

Average Expenditure per Rep. per year Rs.77,290

A TYPICAL CO;--PATTERN OF DRUG DISTRIBUTION AND SALES

1. Distribution Chain :



2. Distribution Set-up :

The country is divided into four Zones - North, South, East and West. The Company runs distribution points called Sales Offices (total 13 in Nos.), which receive stocks from the factory and distribute them to wholesalers and other institutions. As shown in the Distribution chain, the stocks percolate down to the consumer.

3. Margins :

a. Sales Offices - The cost of distribution from factory to wholesalers through the sales offices is borne by the Company. This comprises of sales office overheads, primary transport to stock points and secondary transport to the stockists.

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b. Wholesalers- Minimum wholesalers' margins are stipulated by the Drugs (Prices Control) Order, 1979. The present margins offered by the Company are :

Ethical Products	Categories I, II and III	- 6% of trade price
	Category IV	- 8% " " "
Non-Ethical Products		- 4% " " "

c. Retailers - Minimum retail margins are also stipulated by DPCO. The present levels are:

Ethical Products	Categories I, II and III	- 12% of retail price
	Category IV	- 18% " " "
Non-Ethical Products -		- 10% " " "

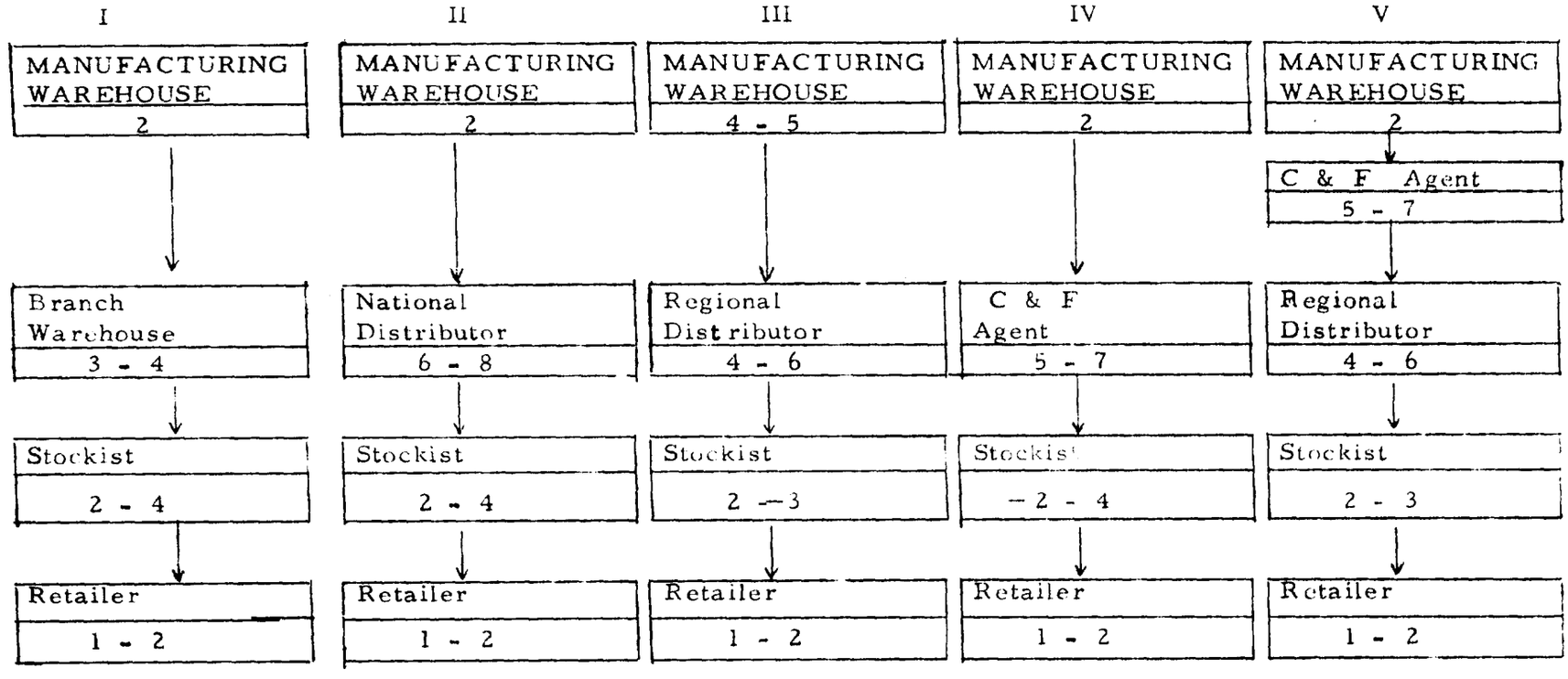
4. Costs incurred by Level :

The Company bears the full cost of transport from factory to sales offices, sales office establishments and the cost of transport from sales offices to wholesalers. The wholesalers and retailers meet their costs out of their own margins. Their margins account for the costs of market credit, quantity discounts and sales service in addition to the costs of their establishments and investment in stocks.

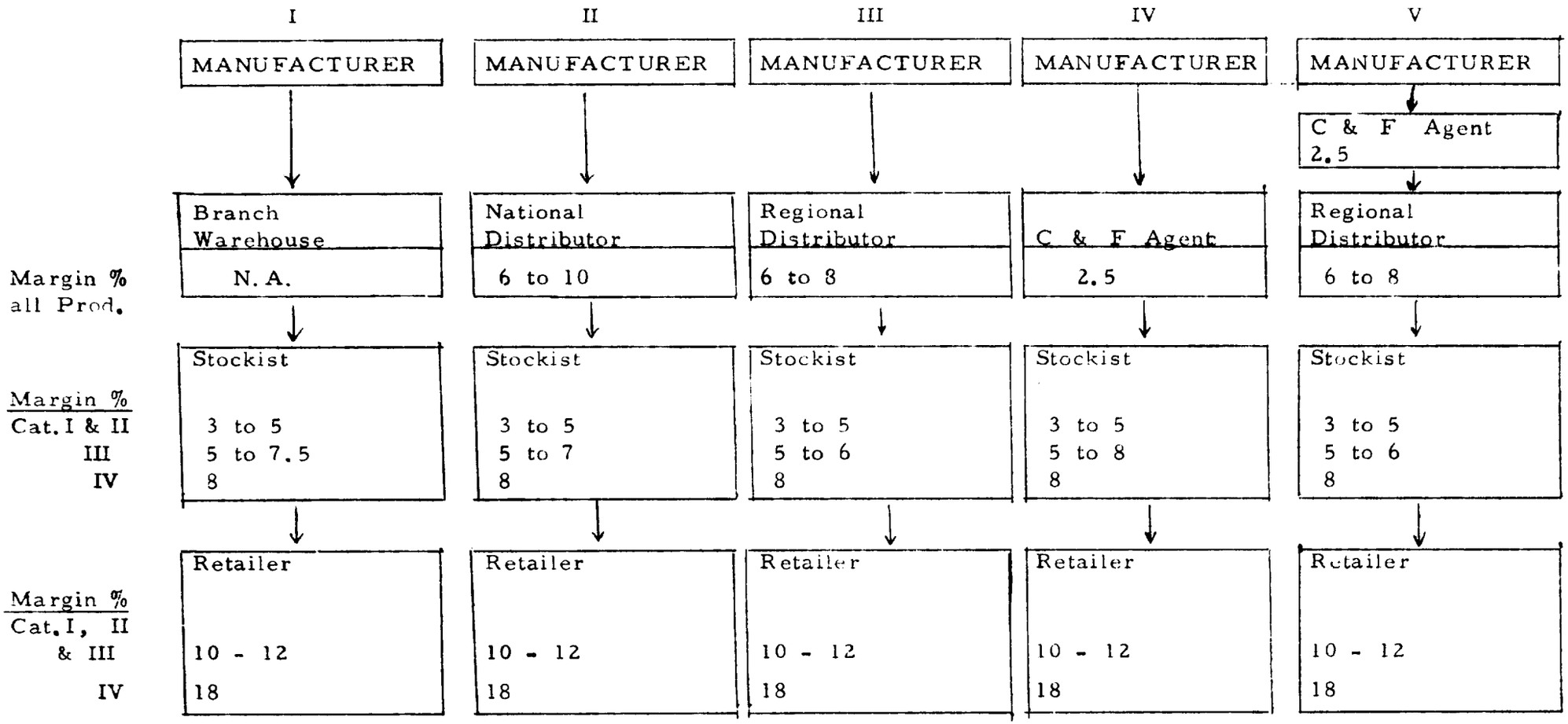
5. Differentiation in Margins :

The basic differentiation in margins is provided for by the DPCO and tripartite agreements between Government, Industry and Trade. In a non-regulatory situation the differentiation is based on product category and the trade practices.

FLOW - CHART OF DISTRIBUTION PATTERNS WITH INVENTORY LEVELS IN WEEKS



DISCOUNT MARGINS ENJOYED BY EACH ON SALES TO NEXT LEVEL CUSTOMER



COMPARISON OF EXPENSES AS % OF SALES VALUE AT VARIOUS LEVELS OF DISTRIBUTION

	NATIONAL DISTRIBUTOR	REGIONAL DISTRIBUTOR	STOCKISTS	RETAILERS
Cost of Capital	1.75	1.50	1.50	1.50
Freight Exp., Delivery cost	1.00	0.75	0.50	0.10
Administration Labour, Rent etc.	1.25	1.00	0.75	0.70
Cost of credit	0.75	0.75	1.00	0.25
TOTAL	4.75	4.00	3.00	2.55
REMARKS:	* High cost of capital. * No own funds. * High freight Exp. due to long distance. * High Admn. cost due better paid employees, better premises.	* Partly own unutilised capital. * Freight lower due smaller area of operation. * Admn. Labour, rent lower being smaller towns.	* Negligible direct credit facility available from Distributor. * Admn., labour cost marginally lower due to less packing cost and less costly labour. * Managerial function by family members.	* Low capital cost due to credit facility from stockists. * Low Admn. cost due to employment of dependents, less qualified persons. * Managerial functions by family members.

II : THE NATIONAL PRICE CONTROL MECHANISM

1. Controlled Prices

1.1 The prices of bulk drugs as well as formulations are controlled in India by a single legislation called the 'Drugs (Prices Control) Order 1979' issued under the 'Essential Commoditis Act 1955' - a well tried and much used legislation, which has stood repeated and varied scrutiny of the country's courts and has been found to be in harmony with the Constitution of India. It is protected by the 9th Schedule of the Constitution.

1.2 The controlled prices are the "maximum selling prices" permissible. They are the retail prices printed on medicine labels in the case of the formulations. However, the minimum margins which must be provided to both the Retailers and the Wholesalers - whether Stockists or Distributors of the manufacturers - have been specified under the DPCO 1979. Thus retailers' and wholesalers'

prices can be derived by discounting the MRP by these margins.

1.3 Most manufacturers base their prices on these discounts although on some products the trade or pharmacist may receive larger margins than the minimum prescribed.

Legal Status of Controlled Prices

1.4 The Indian Courts have examined the question whether control should be exercised on ex-factory prices, wholesale prices or retail prices. The Supreme Court of India has held that "There is no warrant for holding that the Government must not only fix ex-factory prices but also wholesale and retail prices. What prices the Government will fix depend upon their estimate of the situtation which would serve the object of the (Essential Commodities) Act."

"The object of the Act is to secure essential commodities for the consumer, i.e. the general public at fair prices; but it does not follow from this

that the object can be achieved only if retail prices are fixed and that there is no other way of chieving it." (1959 Supreme Court P 629-631).

2. Basis for Controlled Prices: 'Cost-Plus'

2.1 The methodology in drug pricing adopted by the Tariff Commission (1966-68) and later adopted by the BICP and Government under the DPCO 1970 and DPCO 1979 has remained basically unchanged. The cost of production is determined first to which is added a return based on the same, to arrive at the 'maximum selling price'. However, the basis of computing the return to the industry for bulk drugs and formulations is different, the one based on capital employed in business and the other on sales turnover.

2.2 The Tariff Commission had adduced the reasons for adopting this differential basis of computing returns thus:

> "In the case of activity related to the manufacture of basic drugs, heavy capital investment is needed and Return, therefore, can be related to the capital employed. On the other hand in the case of formulations, the industry and consequently the individual units are not capital-intensive and the

proportion of capital employed to sales turnover is very much smaller than in the other case. While it would be quite safe to adopt the capital-employed basis in the case of basic drug manufacture, in the case of formulating activity, the rate of profit cannot be so applied to the employed capital, since the quantum of net assets is small and working capital high. The determination of the working capital in the case of formulating activity would be difficult and even if it is done it will be more or less tantamount to the cost of sales."

Bulk Drugs
Unit Manufacturing Costs

2.3 The actual unit manufacturing cost for the latest available year is collected from the manufacturers. The cost of production (referred to as unit manufacturing cost) takes into consideration raw material cost, cost of utilities and services and conversion cost including depreciation charges. Based on the actual unit manufacturing cost, the proposed costs are projected for the next three

years taking into consideration the installed capacity, likely changes in salaries and wages, additions to plant and machinery etc.

2.4 The costs projected are mostly valid under the normal circumstances and do not require changes. However, in situations of rapidly changing input prices, the adjustments in the projected unit manufacturing cost become necessary at times at shorter intervals and are so made.

Return on Net Worth

2.5 The method of allowing return in respect of bulk drugs is related to Net Worth, which has been defined as Equity Capital + Free Reserves. For the purpose of arriving at Net Worth, net fixed assets for each bulk drug/activity are arrived at on a suitable basis of apportioning. Working capital cost is allowed based on certain specified (usually four) months' cost of production. The sum of net fixed assets and working capital gives the total capital employed for a particular product. This is apportioned in the ratio of debt: equity as available from the latest Balance Sheet. The

equity portion is allowed return and the provision for tax is built separately. The borrowings portion (debt) is allowed interest - based on the average rate of interest paid in the past on long-term borrowings. Return is allowed on net worth @ 14% in respect of Category I & II bulk drugs and @ 12% in respect of Category III bulk drugs.

Formulations
Ex-factory costs plus Mark-ups:

2.6 In so far as formulations are concerned, the ex-factory cost is arrived at by taking into consideration material costs, conversion costs, packing material costs and packing charges. Norms have been notified by the Government for conversion cost and packing charges. In respect of material cost and packing materials, the costs are established by taking into consideration the invoices and bills submitted by the manufacturers in support of their claims and on the ex-factory cost so worked out, a mark-up varying from 40% to 100% in respect of price controlled formulations is allowed depending on the category status of the formulation. The mark-up includes distribution cost, outward freight,

promotional expenses trade commission and manufacturers' margin.

Profit/Margin:

2.7 The actual margin/profit earned by the manufacturer on formulations depends upon the extent upto which the manufacturer is able to economise his expenses. The rates of mark-ups allowed on various categories of formulations are given below:

(a) forty per cent in the case of formulations specified in Category I of the Third Schedule.

(b) fifty-five per cent in the case of formulations specified in Category II of the said Schedule.

(c) upto one hundred per cent in the case of formulations specified in Category III of the said Schedule.

2.8 The Courts in India have ruled that controlled prices can be assailed only if they are "patently arbitrary, discriminatory or demonstrably irrelevant to the policy." It has been held that "Parliament having entrusted the fixation of price

to the expert judgment of the Government it would be wrong (for the Courts) to examine each and every detail pertaining to the Government decision.... The interest of the producer and the investor is only one of the variables in the constitutional calculus of reasonableness and the Court ought not to interfere so long as the exercise of the Governmental power to fix fair prices is broadly within a zone of reasonableness.." (Supreme Court of India - Prag Oil Mills V/s Union of India (1978) 2 Cr.L J. 1281 at pp 1294, 1302 & 1303).

2.9 The clear implication is that the prices may be fixed keeping the balance more in favour of the consumer than the manufacturer - if that has to be done.

3. Prices of New Drugs:

3.1 There was no price control on bulk drugs whether new or existing - before the promulgation of Drugs (Prices Control) Order 1970. Government deputed the Tariff Commission in August 1966 to study the cost structure of18 important bulk drugs. The Commission submitted its report in 1968. The bulk drugs, cost structure of which was studied by the Tariff Commission, were included in the Schedule I of the 1970 Order and were called 'Essential bulk drugs'. Prices for these bulk drugs were notified in the official Gazette of India in 1970 by the Government and were revised thereafter. In respect of these bulk drugs the prices as notified by the Government were the maximum selling prices and no manufacturer could sell such bulk drugs at prices exceeding the prices as notified by the Government.

3.2 In respect of remaining bulk drugs at the time of commencement of Drugs (Prices Control) Order 1970 in May 1970, the manufacturers were free to make declaration of the selling prices or the notional prices within 15 days of the commencement

of Order and subsequent increase, if any, of the prices of bulk drugs so declared could only be effected by the manufacturers with the prior approval of the Government. In respect of new bulk drugs production of which was commenced subsequently, manufacturers were free to declare prices within two weeks of commencement of production, but, subsequent increases, if any, could be effected only after approval of the Government.

3.3 Under the Drugs (Prices Control) Order1979 the manufacturers cannot opt to have their declared prices as selling prices of notional prices. The list of price controlled bulk drugs has also been enlarged and there are at present over 300 bulk drugs included in the list. Out of these about 200 bulk drugs are indigenously produced in the country. In a majority of the cases (184 in April 1983), Government have notified the prices of indigenously produced bulk drugs. The notified prices of the bulk drugs are binding on the new manufacturers.

3.4 In respect of bulk drugs for which there are no notified prices the manufacturers are required within 14 days of the commencement of production to

furnish the details of cost of production, plant and machinery, borrowings etc. in the proforma specified in the Drugs (Prices Control) Order 1979. After verification of the details relating to cost, Government fixes a provisional price of new bulk drugs under the said Order. The price fixed by the Government is normally fixed for a period of six months. After completion of six months, the manufacturers are once again required to furnish details about the cost of production, depreciation, plant and machinery cost, borrowings etc in the specified Form. These details are based on the actual cost and actual working experience which becomes available to the manufacturers by then. After scrutiny of the details furnished and a detailed study of technical aspects and other parameters, the final price is fixed and published by the Government in the Official Gazette.

3.5 The Drugs (Prices Control) Order 1979 also deals with the new bulk drugs produced through original research and development efforts in the country. In respect of such bulk drugs which are not produced elsewhere i.e. in other parts of the world, exemption from price control for a period of five

years from the date of commencement of production of such bulk drugs is available under the said Order. Necessary certificates to the effect whether a particular bulk drug is produced elsewhere or not is issued by the Department of Science & Technology of the Government in consultation with the Organisation of Drug Controller (India) in the Ministry of Health and Family Welfare. The prices of formulations based on such bulk drugs are, however, price controlled.

4. The Controlling Authority: Its Tasks:

4.1 The final authority for fixing/revising the prices of bulk drugs and formulations rests with the Central Government. The Development Commissioner (Drugs) in the Ministry of Chemicals and Fertilizers has the responsibility to operate the scheme of pricing under the Drug (Prices Control) Order.

4.2 The basic costing work is done by the Bureau of Industrial Costs & Prices - an expert body of the Government which receives and collects data from the manufacturers, examines it and presents its cost-study reports and recommendations to the Development Commissioner Drugs, who scrutinises them and notifies them in the Official Gazette after obtaining approvals of the Minister for Chemicals and Fertilizers in each case.

4.3 The work in the BICP is overseen by a Committee called the 'Drug Prices Review Committee' on which are represented the Development Commissioner Drugs, the Drug Controller, Ministry of Health and Family Welfare, and the Economic Adviser in the Ministry of Industrial Development.

4.4 A Sub-Committee of the DPRC meets every week to scrutinise the price recommendations regarding formulations before they are sent to the Development Commissioner Drugs. Since the DPCO 1979 provides for higher mark-ups on formulations which are market leaders, a Working Group constituted by the Development Commissioner identifies 'market leaders' from monthly market survey reports (Operations Research Group).

4.5 Thus the BICP does the initial costing on each drug and formulation. The Development Commissioner Drugs finalises the prices, obtains Government approvals, and publishes them in the Official Gazette. The other tasks of the Development Commissioner's Organisation are to collect constant intelligence about imports of drugs and raw materials from the ports and to keep a track of the C.i.f. prices as well as domestic market prices. Whenever these prices change significantly, revisions are initiated by it. Early in 1983, prices of popular formulations based on Trimethoprim-Sulphamethoxazole combinations, Rifampicin and Cemetidine were revised downwards when sharp falls in bulk drug prices and imports were observed.

4.6 The Development Commissioner Drugs operates the Drug Prices Equalisation Account established under DPCO 1979. He mops up any unexpected savings that may accrue to a manufacturer if his costs fall well below those taken for pricing him.(e.g. in a case where a drug priced on the basis of basic-stage production is manufactured temporarily from and intermediate stage). This fund is also operated where two or more manufactuers of the same bulk drug have to be provided a 'retention' price whereas the sale is at a 'common' sale-price. He also initiates penalties/punitive action against violations of the price-order.

5. METHOD OF CALCULATING THE COST OF IMPORTED RAW MATERIALS

Finished & Packed Products

5.1 Import of only those finished and packed pharmaceuticals is permitted which are not produced in the country. Most of the medicines imported in the finished and packed form are essential and life saving medicines. The requirements are small, but these are important for treating major diseases like Cancer, Leprosy, Perkinsonism. The c.i.f. import price of the finished and packed product is verified from the proforma invoice and bill of entry. Duty of customs is allowed over the c.i.f. cost at the prevalent rates-which are nil in respect of essential and life saving medicines,and are allowed on other medicines on slab basis specified by the Government from time to time. Letter of Credit opening charges, voyage interest and other incidentals are allowed subject to a ceiling of 2% on the c.i.f. price. The sum total of c.i.f. import price + duty of customs + letter of credit opening charges etc. gives the costs of the imported finished and packed medicines.

5.2 The prices of finished and packed medicines

are also fixed under the Drugs (Prices Control) Order 1979. In fixing their prices, a mark-up of 50% on the cost indicated above and also referred to as landed cost of imports is allowed. The mark-ups besides distribution cost, freight, trade commission and promotional expenses includes the profit margins of the importers.

Bulk Drugs

5.3 The c.i.f. import price of the bulk drug is verified with the help of proforma invoices and bills of entries. Over the 101% c.i.f. price of the bulk drug, duty of customs is calculated. Customs duty levied on drugs at present varies from 0% to 105%. LC opening charges and voyage interest etc are allowed subject to a ceiling of 2% on the c.i.f. cost. The sum total of the c.i.f. cost, duty of customs and the above charges establishes the landed cost of import on a bulk drug. This landed cost normally forms the basis for fixing the prices of formulations under the Drugs (Prices Control) Order 1979.

5.4 The imports of bulk drugs are made by formulators from different sources at diverse prices. Not only the sources of imports, but, the prices of imports

are also monitored and scrutinised from time to time. This scrutiny reveals the lowest and the highest cost paid for the import of a bulk drug. Data relating to import of drugs is also collected by the Officers of the Drug Controller (India) stationed at various Ports and International Airports of the country. Based on the collected data, the average c.i.f. import price for a complete year or for a limited period is determined and such a price with prevailing rates of duty of customs and LC opening charges etc. calculated on the above basis gives the landed cost of imports. Such landed cost of import is also used for the purpose of regulating the prices of formulations in those cases where imports of bulk drugs are significant and are arranged by the importers from different sources at different prices.

5.5 At times model values of c.i.f. import prices are also used to determine the landed cost of imports for regulating the prices of formulations.

Intermediates used in Drug Synthesis

5.6 The range of intermediates used for the production of bulk drugs is quite large. Intermediates which are not available in the country or the production of which is not adequate, are imported for

production of bulk drugs. The rates of duty of customs on intermediates are also levied on a slab basis and vary from 25% of the c.i.f. price to much higher percentages. The procedure for working out the landed cost of imports of the intermediates is the same as for the bulk drugs. The landed cost + transport charges incurred on their transportation to the factory of the producer of the bulk drug form the basis for adopting the rates for such intermediates while working out the cost of the bulk drugs.

5.7 The import of finished and packed medicines, bulk drugs and intermediates is regulated under the Imports & Export Policy issued early year by the Government of India. In the Import Policy restrictions varying from absolute ban, limited permissible imports, to imports under Open General Licences have been imposed. Such restrictions are imposed keeping in view the indigenous production, capacity installed etc.

How is the Level of Above Prices Calculated for the Purpose of:

Calculating Customs Tarrif and other duties:

5.8 Duty of customs on imports is levied ad valorem;

the value that forms the basis for levy of such duty is the c.i.f. price. The various elements of the duty of customs are the basic rate of duty of customs, auxiliary rate of duty of customs and counter-vailing rates of duty of customs. All these duties are calculated on ad valorem basis.

Transfer prices for inter-companies transactions

5.9 In India for the purpose of fixing prices of imported finished medicines, bulk drugs and intermediates used in drug synthesis, the principles of cost + margin of the transferer is not recognised. The charges that are recognised have already been indicated in the above discussion, and the cost incurred by the transferer, if any, over and above these charges is not recognised. The principle of transfer price is, however, relevant in respect of production of certain intermediates/chemicals required for indigenous production of bulk drugs. In those cases where one company produces intermediate alone and the other company produces bulk drug out of those intermediates, the cost of such intermediates is first studied and after verification such cost is allowed for determining the price of a bulk drug.

6. METHOD OF CALCULATING OTHER AVAILABLE COSTS:

Research & Development

6.1 Research Cost is defined as 'the cost of searching for new or improved products, new applications of materials, or new or improved methods of production'. On the other hand development cost is the cost of the process which begins with the implementation of the decision to produce a new or improved product or to employ a new or improved method and ends with the commencement of formal production of that product by that method. In other words, development starts where research ends.

6.2 In so far as drug industry in India is concerned, about two decades back, there were no major research and development centres to undertake basic research. Basic research centreshave since been set up by M/s Hoechst Pharmaceuticals Limited M/s Hindustan Ciba-Geigy, M/s Ambalal Sarabhai Enterprises Ltd, IDPL, HAL and a number of other units. Most of the other units have undertaken applied research which is aimed at improvement of existing products, methods or equipments, exploring or establishing new products, processes and research for raw materials and other

resources utilisation. In so far as applied research and development costs are concerned, they are mostly incurred at the place where production of the products is undertaken. These costs are, therefore, apportioned to the products on which such costs are incurred or sometimes are included in the factory overheads.

6.3 Basic research is not connected with any specific product. The benefits of such research, therefore, cannot be assessed against particular products. The salient features of such a research which is undertaken to acquire better basic knowledge and know-how are as follows:

(i) Expenditure is incurred ahead of actual production and may not, therefore, be charged to current production.

(ii) The amount of expenditure is heavy.

(iii) Sometimes the expenditure is entirely infructuous, research being unsuccessful or yielding no worthwhile results.

(iv) Benefit of R&D is received over a number of future years.

(v) Difficulty in fixation of proper standards for control of Research & Development expenditure.

(vi) The objectives for which research & development is undertaken are varied and, therefore, different accounting treatments are required for different circumstances.

6.4 Budgets for research & development are drawn in advance. The costs incurred on basic research are on capital account and revenue account. The total expenditure incurred on R&D and the projections indicated for the future are taken into consideration to arrive at the figure apportionable to the cost of various products produced by a company. The total R&D costs so arrived at are apportioned to the various products on the basis of conversion cost incurred in their manufacture. This practice is being followed since 1970.

License Cost

6.5 This cost relates to the cost of acquiring a brand name or a process to produce a drug. Foreign brand names are now mostly not allowed for use in the country. In so far as the cost of acquiring process of mnufacture is concerned, the owner of such a process is either allowed a lumpsum payment or royalty or both, in lieu of parting with the

process know-how. The lumpsum cost allowed is a specific percentage of the saleable value of the product and is allowed for a period of five years.

6.6 These costs are absorbed in product pricing based on the production likely to be achieved and the sale value relatable to such production etc.

Sales Promotion Cost

6.7 These costs are also called in common parlance 'selling and distribution costs'. Most of the items constituting selling and distribution costs are not identifiable with the individual products and, therefore, these costs are call-ed 'indirect costs'. All expenses incurred for the purpose of selling to the existing customers or for increasing sales to the existing and potential customers are grouped together under the head 'Selling Costs'. The various elements constituting selling costs are direct selling costs on functions like soliciting and obtaining orders, market investigations to ascertain size, nature and expenditure of the market and costs of issuing goods to the customers, costs on advertisements and sales promotion, costs of credit and credit calculation and costs of financial and general administration.

These costs are accounted for by any of the well-known methods, namely, by cost centres, by functions, by products or by costs units and are then apportioned to the products on an acceptable basis. In so far as the drugs & pharmaceuticals industry is concerned, details of costs incurred in the past, and the future projections of these costs are obtained from the manufacturers and are then apportioned to the products.

6.8 In respect of formulations such costs form a part of the mark-up and are not separately allowed while fixing the prices of formulations. In so far as bulk drugs are concerned, the costs actually incurred or 5% of the cost of sales, whichever is lower, forms the basis for allocation of such costs.

6.9 In so far as distribution costs are concerned, they include cost of packing materials, transportation costs warehousing and storage cost and costs of financial and general administration. These costs are allowed on the basis of actuals incurred in the past. In respect of formulations, they are included in the overall percentage of mark-up on the ex-factory cost allowed by the Government under Drugs (Prices Control) Order 1979.

Other allowable costs

6.10 The other allowable costs are administration overheads, bonus, cost on quality control. Administration cost or administrative overheads are the expenses incurred on the administration division of a concern responsible for planning and control of the organisation. The administration costs are allocated to product cost based on any acceptable basis, namely, as a portion of selling cost, sales value, conversion cost or product units. The method followed for allocating administration overheads cost to product cost is any one of the above well recognised bases of allowcation.

6.11 In so far as drug formulations are concerned, the administration overheads costs are included partly in conversion cost and partly in the mark-up on the ex-factory cost as allowed on the various categories of formulations under the Drugs (Prices Control) Order 1979.

6.12 While determining prices of bulk drugs, bonus is allowed at the minimum statutory rate of 8.33% of salaries & wages. In fixing prices of formulations, bonus is not separately allowed but, it forms a part of the overall mark-up allowed on the ex-factory cost.

6.13 Quality control costs are allowed based on the actuals of the cost and projections for the future, and are allocated to various bulk drugs based on quantum of production. In formulations, such costs form a part and parcel of the mark-up allowed on the ex-factory cost as explained above.

7. Publication of Controlled Prices

7.1 The publication of the controlled prices is the responsibility of the Development Commissioner Drugs. Under DPCO 1979, a controlled price may be fixed for a particular drug irrespective of its being manufactured by one or more than one manufacturer (Paras 3,5,6). However where the objective of the Government may be to encourage a new manufacturer to enter into the manufacture of a drug already under manufacture in the country it may fix separate 'retention' prices for various manufacturers and a 'common sale price' at which they may sell the drug (Para 4). Similarly, 'retention' prices and 'pooled' prices may be fixed (Para 7) where a drug is sold to the formulators from indigenous production as well as imports.

7.2 Where a controlled drug price is applicable to a drug and is not exclusive to a particular manufacturer, it is invariably published in the Official Gazette of the Government. When a price is specific to a manufacturer the order may be communicated directly to him.

7.3 The formulation prices are also published on the same basis and in the same manner in the Official Gazette. There is no prescribed frequency for such publication. Prices are published as soon as fixed and are effective immediately on publication. They apply to all unsold stocks held by the manufacturer or Trade and Pharmacists on the day of publication.

CONTROLLED PRICES OF DRUGS - SINCE 1970

(a selection)

Sl No.	Drug	Unit	Maximum sale price fixed by the Government (Rupees)
1	2	3	4
	Analgesics		
1.	Acetyl Salicylic Acid	Kgs	13.97 (18.5.1970)
			18.62 (19.4.1974)
			20.90 (11.6.1974)
			23.84 (4.3.1975)
			24.58 (19.5.1976)
			32.71 (8.1.1981)
			43.00 (5.7.1982)
2.	Paracetamol	Kgs	50.00 (18.5.1970)
			78.08 (19.4.1974)
	Anti-Leprosy		
3.	Dapsone	Kgs	90.00 (18.5.1970)
			113.35 (19.4.1974)
			133.91 (22.8.1974)
			156.47 (6.12.1980)
	Cardiovascular		
4.	Propranolol Hcl	Kgs	2000.00 (1975)
			2415.00 (16.2.1983)

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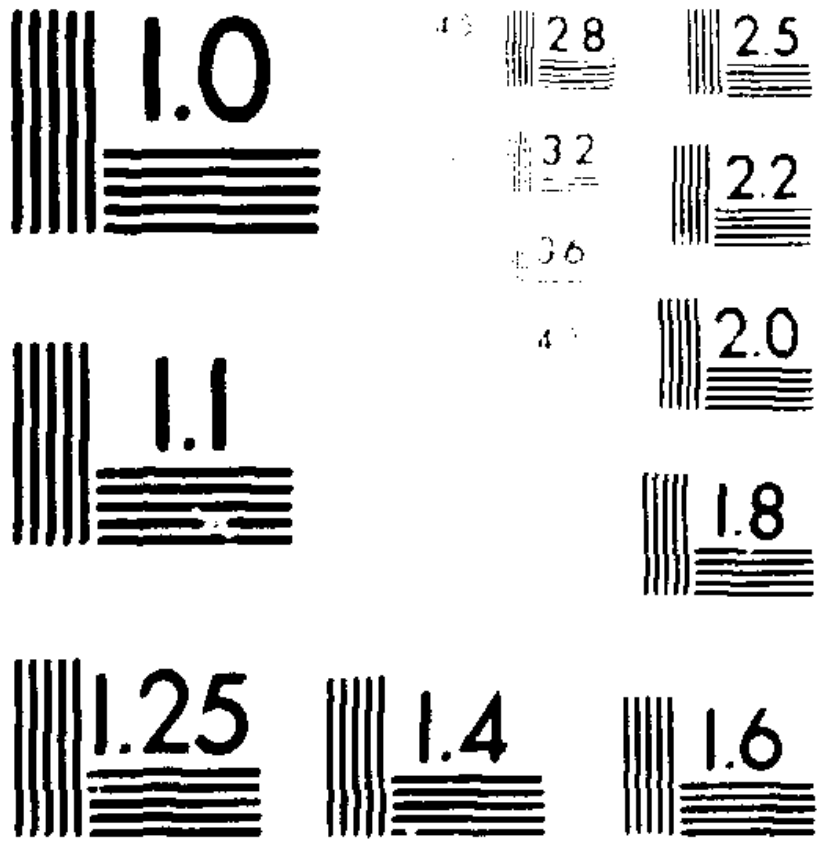


1	2	3	4
	Antifilarial		
5.	Diethylcarbamazine Citrate	Kgs	190.00 (18.5.1970)
			257.88 (19.4.1974)
			281.19 (10.2.1975)
			171.51 (29.12.1980)
			177.23 (17.2.1981)
	Anti-diabetic		
6.	Insulin	MU	4900.00 (18.5.1970)
			6680.00 (2.8.1972)
			8898.00 (21.1.1974)
			9869.74 (5.9.1974)
			12637.25 (30.7.1975)
	Anti-malarial		
7.	Chloroquin Phosphate	Kgs	259.53 (18.5.1970)
			311.40 (20.1.1975)
			352.00 (1976)
			476.00 (18.6.1982)
8.	Amodioquin Hcl	Kgs	106.91 (18.5.1970)
			177.86 (3.11.1970)
			216.86 (14.7.1971)
			282.72 (5.9.1974)
			367.00 (1976)

1	2	3	4
			468.00 (22.1.1982)
			525.00 (26.6.1982)
	Antibacterial drugs		
9.	Sulphadimidine	Kgs	77.00 (18.5.1970)
			131.70 (19.4.1974)
			161.41 (22.8.1974)
			178.56 (7.12.1980)
			192.18 (17.2.1981)
			199.00 (20.5.1982)
10.	Sulphacetamide Sodium	Kgs	62.50 (18.5.1970)
			87.69 (19.4.1974)
			102.25 (22.8.1974)
			113.10 (4.10.1980)
			119.62 (4.1.1981)
11.	Sulphasomidine	Kgs	99.90 (18.5.1970)
			105.37 (19.4.1974)
			116.17 (17.7.1974)
12.	Sulphaguanidine	Kgs	44.00 (18.5.1970)
			66.63 (19.4.1974)
			89.74 (22.8.1974)
			103.32 (29.1.1981)
			121.00 (20.5.1982)

1	2	3	4
	Corticosteroids		
13.	Betamethasone Alcohol	Gm	176.00 (18.5.1970)
			119.88 (19.4.1974)
			134.28 (22.8.1974)
			113.34 (12.5.1981)
14.	Prednisolone	Kgs	11946.21 (18.5.1970)
			14266.21 (17.6.1970)
			17100.00 (8.8.1974)
	Anti-tuberculosis		
15.	Isonicotinic Acid Hydrazide	Kgs	126.16 (18.5.1970)
			130.32 (22.7.1970)
			153.17 (4.3.1975)
16.	Ethambutol	Kgs	730.00 (1978)
			620.00 (19.12.1980)
			837.00 (9.8.1982)
			804.00 (21.3.1983)
	Vitamins		
17.	Vitamin A	1000MMU	391.00 (18.5.1970)
			452.54 (20.1.1971)
			562.00 (4.3.1975)
			555.00 (28.1.1981)
18.	Vitamin B2	Kgs	1300.00 (1975)
			1417.95 (13.11.1980)

1	2	3	4
19.	Vitamin B12	Gm	100.00 (18.5.1970)
			95.00 (1976)
			98.70 (16.12.1980)
			124.87 (27.9.1982)
20.	Vitamin C	Kgs	72.70 (18.5.1970)
			90.72 (8.8.1974)
			104.00 (1975)
			115.48 (29.12.1980)
			127.54 (25.2.1981)

III. NATIONAL PRICES & FOREIGN PRICES : A COMPARISON

3.1 The price control authority uses the actual verified costs of production within the country for pricing the drugs and formulations. It does not, therefore, require to collect information on prices of these products in other countries for the purposes of pricing. However, in the process of looking at the invoices and other documentation relating to materials imported by the manufacturers, it is able to collect and scrutinise a vast amount of data on such prices. This applies to intermediates also. The Development Commissioner Drugs does, however, collect information on international prices of bulk drugs and intermediates as also formulations, being charged with the scrutiny of the cost actually incurred by the manufacturers after the fixation of the price. He is also responsible for the imports to be made by the centralised canalising agency (State Trading Corporation of India Limited) for distribution of intermediates and bulk drugs to

manufacturers. The levels of the duty of customs to be charged on drugs, intermediates and formulations is also fixed and varied from time to time by the Government on his recommendations. Similarly the restrictions on imports of drugs and pharmaceuticals are also based on his recommendations. In this connection, therefore, that office studies and has uptodate information on prices of imports made into India. At times, special studies are undertaken with reference to specific products during the course of which worldwide prices are scrutinised.

3.2 There is no system of regular sharing of cif price information with other countries. Exchange of such information on a bilateral basis can, however, be made subject to its being kept confidential and confined to a limited number of major items of import.

3.3 In a few cases where requests have been made from the developing countries, the controlling authority has responded positively; from which it would appear that it would be willing to share this information,-if approached,-with UNIDO and/or developing countries subject to confidentiality and reciprocity.

IV. IMPACT OF PRICE CONTROL

1.1 Since 1978 when the present Drug Policy of the Government of India was announced, a number of controls on licensing of new products, ceilings on capacities of production, ratios of production between bulk drugs and formulations, etc. have been in implementation besides the drug price control. It is, therefore, obvious that the changes that have occurred since then are attributable to a mix of all controls although the impact of the latter is definitely the prominent one. The most noticeable impact is that the drugs price index has not mounted at the same rate as the price index for all commodities. The accompanying chart shows how the divergence between the two has somewhat increased. Prices of a much wider range of formulations now stand rationalised on the basis of updated costs and the new scale of mark-ups. The sectorwise production of drugs and formulations has changed in the favour of the large and medium scale units of the Indian sector and the small scale units (which are entirely in the Indian sector) whose share of the total produc-

VALUE OF PRODUCTION OF BULK DRUGS & FORMULATIONS

CHANGES IN SECTORAL SHARES

US$/Millions

Sector	1978-79	1979-80	1980-81*
BULK DRUGS			
1. Public Sector	49	59	63
2. Foreign sector	56	53	53
3. Indian organised Private Sector	75	90	98
4. Small Scale Sector	20	24	26
TOTAL: BULK DRUGS	200	226	240
FORMULATIONS			
1. Public Sector	60	72	80
2. Foreign Sector	800	778	790
3. Indian Organised Private Sector			
4. Small Scale Sector	190	300	330
TOTAL; FORMULATIONS	1050	1150	1200

* Estimated

Source: Ministry of Chemicals & Fertilizers (GOI)

tion has increased. Serious efforts have been made by the manufacturers to reduce their costs and improve production as well as marketing efficiencies. Some major manufacturers have reduced the number of employees. Many others are restraining themselves in wage increases although the industry still pays by and large a better wage than most other sectors. Packaging costs have been reduced by discontinuing avoidable frills.

Wholesale Price Index of Medicines

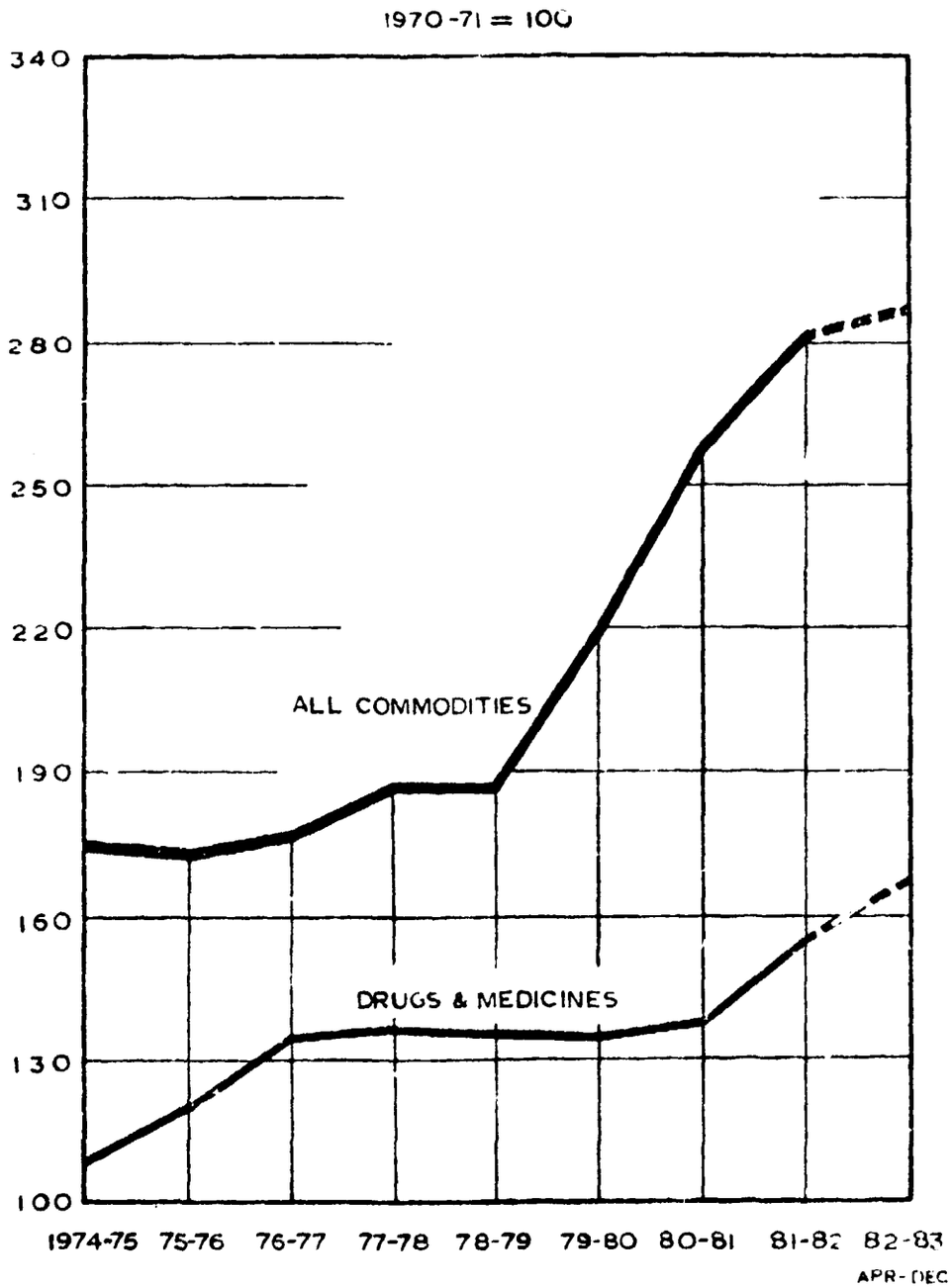
1.2 The wholesale price index for drugs and medicines exhibits more steadiness as compared to other commodities. This may be seen from the following Table :-

1970-71 = 100 = Base Year

Year	Drugs & Medicines	All commodities taken together
1975-76	118.7	173.0
1976-77	139.9	176.6
1977-78	136.3	185.8
1978-79	136.3	185.8
1979-80	135.2	217.6
1980-81	137.5	257.1
1981-82	151.6	280.4
1982-83 (Apr. to Jan. 1983)	176.0	288.1 (provisional)

INDIA

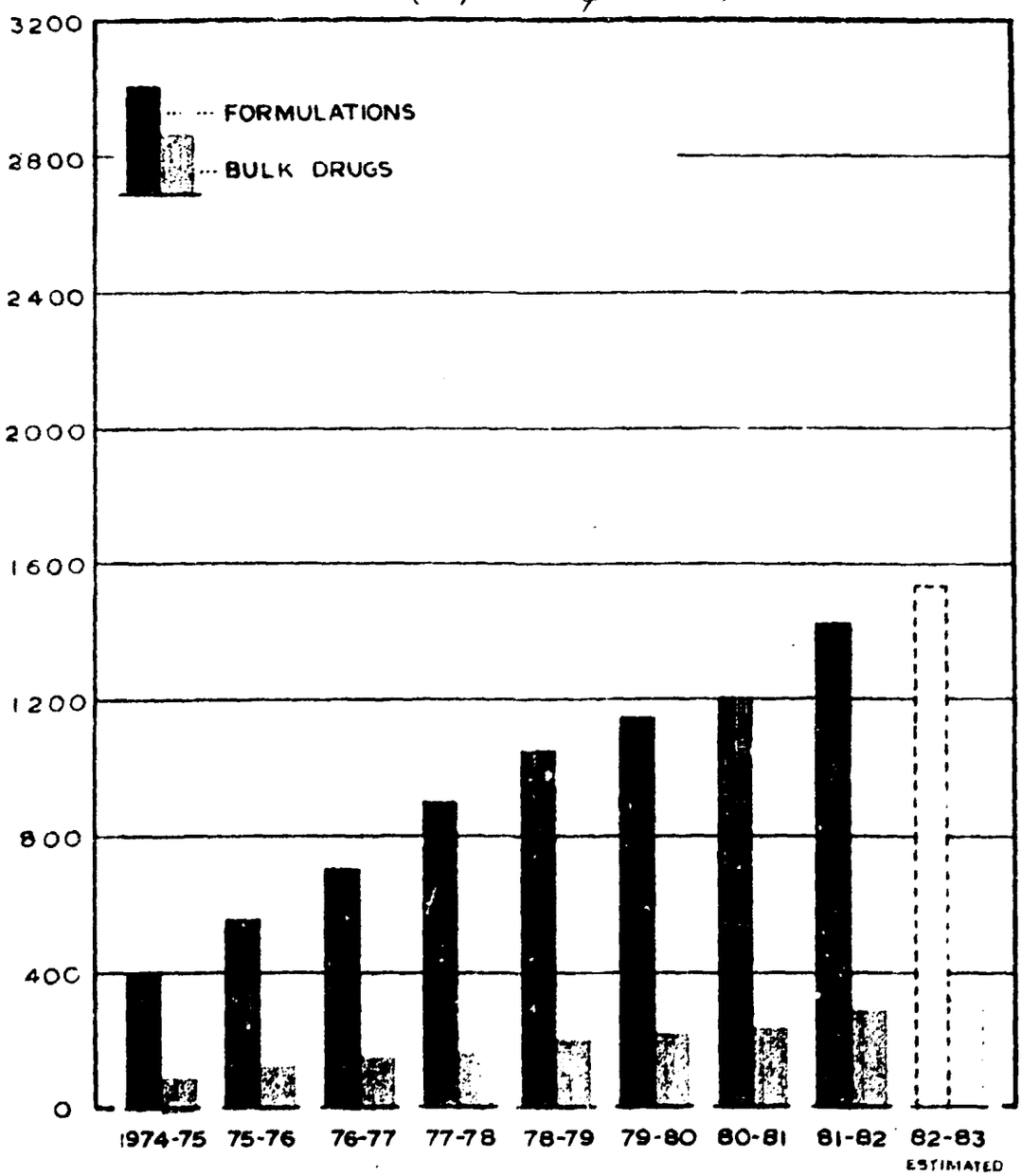
DRUGS PRICE INDEX



M. E. D., C. & F.
DEV. COMMISNR DRUGS

INDIA

PRODUCTION OF BULK DRUGS & FORMULATIONS



DEV. COMM. DRUGS
M.E.D., C.& F.

1.3 On the negative(?) side, as the industry has been complaining, profitability has generally decreased or not improved and the rate of investment has been slow. The extremist representatives of the industry at times claimed that the industry is going sick. This is, however, not supported by the overall profitability of the industry and the expansion of the medium level Indian sector units. The rate of growth in production both of bulk drugs and formulations also does not support this view.

Year	Bulk drugs	Formulations
	(Rs./00,000)	
1979-80	226	1150
1980-81	240	1200
1981-82	289	1430
1982-83 (anticipated)	325	1545

Source : Annual Report 1982-83, Ministry of Chemicals and Fertilizers, New Delhi

Profitability

1.4 A survey conducted by the Economic Times, Bombay, on finances of 20 large pharmaceutical companies during 1980-81 brought out the following data. The survey being limited to a few companies - mostly multi-national subsidia-

ries who are subject to growth and capacity controls - is only indicative and not representative of the whole industry. Currently, a more representative survey (mix of over 40 companies) is being carried out by the National Council for Applied Economic Research, the results of which will be available this year.

1.5 According to the ET Survey, sales income of 20 large and medium pharmaceutical companies increased from Rs.433 crores in 1979-80 to Rs.474 crores in 1980-81 or by 9.5 per cent. Their gross profits declined from Rs.61 crores in 1979-80 to Rs.54 crores in 1980-81. The decline in profits was due to rising cost of inputs such as raw materials, power and fuel, salaries and wages etc. Expenditure on raw materials as a percentage of the value of production increased from 48.9 per cent in 1979-80 to 52.6 per cent in 1980-81, and that of wage bills from 15.3 per cent to 15.7 per

cent during the same period. With the sharp decline in profits, profitability ratios showed a decline. The ratio of gross profits to total capital employed declined from 20.2 per cent in 1979-80 to 15.8 per cent in 1980-81. The ratio of gross profits to net sales also declined from 14.3 per cent in 1979-80 to 11.3 per cent in 1980-81. Ratio of profit after tax to net worth declined to 15.3 per cent in 1979-80 and to 11.8 per cent in 1980-81 (Table 1.5 - A to D).

1.6 The profits before tax of the 20 companies declined by 25.2 per cent from Rs.51.9 crores in 1979-80 to Rs.38.8 crores in 1980-81. Profits after tax also declined by 15.7 per cent from Rs.19.9 crores in 1979-80 to Rs.16.8 crores in 1980-81. The impact of the decline in net profits was reflected in retained profits which fell from Rs.9.4 crores to Rs.7.3 crores. Total borrowings went up from Rs.70.5 crores in 1979-80 to Rs.87.6 crores in 1980-81 or by 24.2 per cent mainly as a result of an increase in bank borrowings from Rs.47.0 crores in 1979-80 to Rs.54.5 crores in 1980-81. Consequently, interest charges spurted from Rs.9.4 crores to Rs.14.8 crores. Gross fixed assets rose by 18.3 per cent

from Rs.147.9 crores in 1979-80 to Rs.174.9 crores in 1980-81. Some companies undertook diversification and expansion programmes. Inventories went up from Rs.134.3 crores in 1979-80 to Rs.149 crores in 1980-81, the share of this in the total assets having gone up fractionally from 43.9 per cent to 44.1 per cent. Sundry debtors increased from Rs.47.4 crores in 1979-80 to Rs.53.5 crores in 1980-81, their share in the total assets having gone down from 15.6 per cent to 12.9 per cent during the year.

1.7 A balance-sheet study of the same 20 companies made in the Ministry of Chemicals and Fertilizers with reference to years 1980-81 and 1981-82 shows a different level of profits. (Please see Table 1.7-A). These leading private sector companies are, by and large, in a sound financial health.

Source : The Economic Times dated January 28, 1982

Table 1.5-A

Selected Financial Data Of 20 Pharmaceutical Companies During 1979-80 And 1980-81

(Rs/ 00,000)

Name of companies	Total capital employed		Net Worth		Net Sales *		Gross Profits		Profits before tax	
	1979-80	1980-81	1979-80	1980-81	1979-80	1980-81	1979-80	1980-81	1979-80	1980-81
	1	2	3	4	5	6	7	8	9	10
1. Albert David	274	304	4	30	632	1120	41	69	13	27
2. Alembic	2394	2475	714	684	3188	3387	203	143	51	- 72
3. Bayer	3404	3701	1472	1528	4688	4954	651	522	493	257
4. Boehringer-Knoll	575	637	194	204	821	895	70	73	40	34
5. Boots	940	1660	376	409	1533	1828	221	234	202	204
6. Cyanamid	1509	1509	957	975	1947	1606	415	57	415	48
7. Duphar-Interfran	486	481	196	217	713	669	109	97	93	75
8. Glaxo	5087	6155	2759	2881	7114	7249	1093	1157	1006	1029
9. German Remedies	1045	1227	349	391	1563	1786	323	285	268	194
10. Hoechst Pharma	2530	3148	1030	1148	4054	4657	573	482	486	329
11. May & Baker	1978	1368	385	512	1644	1969	99	71	75	49
12. Nicholas Lab.	297	387	100	201	621	788	92	102	85	96
13. Pfizer	2865	2897	2004	1952	3898	3829	703	584	697	579
14. Ranbaxy Lab.	913	1178	254	300	1282	1664	172	194	108	104
15. Raptakos-Brett	795	1259	172	505	1336	1543	102	125	54	56
16. Richardson Hind.	732	943	226	246	1176	1432	129	222	96	175
17. Sandoz	2852	3150	950	1076	4207	4677	710	526	629	356
18. Searle (India)	358	464	203	243	455	633	91	128	82	112
19. Unichem Lab.	648	853	233	242	1071	1303	78	100	42	49
20. Warner Hind.	745	757	398	410	1350	1424	262	196	260	183
Total 20 pharmaceutical companies	30427	33953	12976	14154	43293	47413	6137	5367	5195	3884

* Net Sales are exclusive of Excise Duty and Sales Tax

Table 1.5-B

Cost structure (as percentage of Value of Production) of 20 Pharmaceutical Companies

Item	1979-80	1980-81
1. Raw materials consumed	48.9	52.6
2. Power and fuel	2.1	2.4
3. Other mfg. expenses	6.1	4.8
4. Wage bills	15.3	15.7
5. Other expenses	14.3	14.3
6. Depreciation	1.8	2.0
7. Interest	2.1	3.0
8. Profit margin	9.4	5.2
Total	100.0	100.0

Table 1.5-C

Combined Profits & Loss Accounts of 20 Pharmaceutical Companies: 1979-80 and 1980-81

(Rs. 00,000)

Income	1979-80	1980-81
1. Net Sales income	43292	47409
2. Other income	990	1360
3. Closing stock of finished goods	7012	8216
Total:	51294	56985
Expenditure & Appropriation		
4. Opening stock of finished goods	5650	6982
5. Raw materials consumption	21857	25569
6. Power and Fuel	938	1189
7. Other mfg. expenses	2725	2327
8. Salaries & wages	5642	6342
9. Welfare expenses	1181	1318
10. Other expenses	6379	6942
11. Depreciation	785	951
12. Gross Profits	6157	5365
13. Less interest	941	1483
14. Profits before tax	5196	3882
15. Less tax provision	3204	2204
16. Profits after tax	1992	1678
a. Dividends	1054	951
b. Retained profits	938	727
Total	51294	56985

Table 1.5-D

Profitability, Ratios of Pharmaceutical Companies.

Percentage

	GP / TCE	GP / Net Sales	PAT / Net Worth
1975-76 (a)	18.2	13.0	12.0
1976-77 (a)	21.3	14.2	14.6
1977-78 (a)	21.4	14.2	16.5
1978-79 (a)	25.3	15.7	16.3
1979-80 (c)	20.2	14.3	15.3
1980-81 (c)	15.8	11.3	11.8

Notes:

GP - Gross profit

TCE - Total capital employed

PAT - Profits after tax

(a) - Estimate as given in the RBI survey on 52 companies vide RBI bulletin May and July, 1980.

(c) - ET estimates.

TABLE : 1.7 – A

SAMPLE BALANCE SHEET STUDY

Selected Data of 20 Pharmaceutical Companies 1980-81 and 1981-82

(Rs./in 00,000)

Name of the Companies	Gross Profits		Profits before Tax		Gross Profits as % of Total Capital Employed		Profits after tax as % of Net Worth	
	1980-81	1981-82	1980-81	1981-82	1980-81	1981-82	1980-81	1981-82
1. Albert David	69	65	27	21	33.8	24.7	90.0	31.3
2. Alembic	143	469	(-) 72	256	8.6	25.9	(-) 10.5	26.1
3. Bayer	472	329	208	112	15.3	11.9	4.7	2.3
4. Boehringer Knoll	74	78	35	18	15.9	13.7	10.8	8.4
5. Boots	235	250	205	226	35.5	36.3	19.0	19.9
6. Cyanamid	57	48	48	2	4.9	3.5	2.7	0.2
7. Duphar Interfran	97	58	75	26	28.4	12.4	14.7	5.8
8. Glaxo	1155	1027	1028	800	35.8	26.7	16.0	15.2
9. German Remedies	282	366	191	268	27.1	33.6	16.9	20.2
10. Hoechst	512	566	359	358	24.5	23.8	17.3	15.5
11. May & Baker	74	207	52	175	9.2	23.3	5.7	14.1
12. Nicholas Lab.	102	89	96	85	50.5	41.8	15.8	15.0
13. Pfizer	586	583	581	583	29.2	28.2	11.2	12.6
14. Ranbaxy	196	271	112	167	21.7	25.2	20.3	29.6
15. Raptakos Brett	122	156	54	77	13.2	12.6	5.1	8.8
16. Richardson Hindustan	222	232	174	159	40.7	37.2	22.0	20.2
17. Sandoz	521	730	352	545	24.6	35.4	21.9	14.1
18. Searle (India)	128	195	111	149	40.0	37.8	24.3	24.6
19. Unichem Lab.	88	96	36	30	14.4	14.0	7.8	7.3
20. Warner Hindustan	196	208	183	186	40.9	35.4	10.6	17.7
Total (1 to 20)	5331	6031	3855	4243	23.3	23.9	11.4	13.5

Data for both the years has been compiled in Ministry of Chemicals & Fertilizers (GOI)

INVESTMENT IN DRUGS & PHARMACEUTICALS

US$/Millions

Year	Investment
1952	24
1962	56
1967	150
1971	200
1973	225
1975	250
1977	450*
1980 (Estimated)	500

* Including equity, reserves and long-term loans

Source: Ministry of Chemicals & Fertilizers

RESEARCH AND DEVELOPMENT EXPENDITURE

* Handbook of Research & Development Statistics 1976-77, Deptt of Science & Technology (GOI)

** OPPI Estimate

US$/Millions

Year	R & D Expenditure
1972-73*	5.86
1973-74*	6.28
1974-75*	7.29
1975-76*	8.00
1976-77**	10.50
1977-78**	12.00
1978-79**	14.75

Efforts to Improve Cost Efficiency

2.1 One impact of the expansion of the range of price controls and introduction of differentiated mark-ups on formulations has been that a large number of manufacturers have been forced to improve their cost efficiencies. An illustration is provided by a report of a very large bulk drug and formulation producer which reads as below:

> "The remedial measures proposed to be taken up by the Plants and the Marketing Organisation in this regard are as follows:
>
> Plants Level
>
> i) Maximum utilisation of capacity after removing built-in imbalances and re-adjusting them to market demands;
>
> ii) Reduction in variable costs and better utilisation and control of raw materials and utilities;
>
> iii) Improving production efficiency for attaining higher yields; and
>
> iv) Economising in administrative overheads and cutting down unproductive expenditure.
>
> Marketing Level
>
> (a) Short Term:

i) Minimising inventory of finished products by selling them at reasonable prices and not just for the purposes of liquidation; and

ii) Realisation of outstanding payments from the State Governments for institutional sales.

(b) Long Term:

i) Maximising trade sales;

ii) Reducing institutional sales unless the State Governments assure purchase of their medicinal requirements in our range at the prices fixed by the Government and prompt payments;

iii) Increasing the range of pharmaceutical specialities under Category III and IV; and

iv) Introduction of house-hold remedies and OTC products."

3. THE COSTS OF DRUGS:

Cost of Drugs to the Consumer:

3.1 Maximum retail prices fixed for formulations under the Drugs (Prices Control) Order 1979 (Paras: 12 to 16) are the ceilings and no manufacturer or importer or distributor can sell a formulation at a price higher than the price fixed by the Government. The manufacturers or importers are, however, free to seek revision in prices from the Government from time to time based on changes in the costs. The cost of a formulation to the consumer is the retail price including excise duty fixed by the Government plus sales tax and local taxes. Normally, the incidence of these two taxes is 5% to 9% of the retail price. A statement showing the changes in the price to the consumer in respect of 10 important formulations during the last decade is attached.

Cost of Drugs to the National Health Service

3.2 Drugs for major diseases like Malaria, Leprosy Filaria, STD, TB, etc. are supplied by (Government) Medical Stores/Depots. These Depots purchase the bulk drugs and have the various dosage forms manufactured for themselves by exclusive arrangement.

The objective is to reduce the cost to the minimum. Medicines are supplied to the consumer free of cost from Government hospitals and dispensaries and the entire cost is borne by the Government.

Cost of Drugs to Hospitals

3.3 Director General Supplies and Disposals invites open tenders for supply of medicines from the manufacturers in the country. The manufacturers quote the rates and lowest tender consistent with the quality and the standing of the manufacturer is normally accepted. Government hospitals purchase at the rates negotiated by the Director General Supplies and Disposals. The System of tendering ensures that purchases are made at the best prices. Retail prices fixed by the Government serve only as a guide. In respect of those medicines where there is no rate-contract entered into by DGS&D, tenders are directly invited by hospitals.

Cost of Imported Bulk Drugs and Medicines

3.4 Imports of bulk drugs and intermediates are permitted to the actual users for use in their factories. A statement giving the import prices of 10 bulk drugs and 5 intermediates over a period from 1970 is attached. (Annexure 2(A)).

4. COST AUDIT ON BULK DRUGS AND INTERMEDIATES REQUIRED FOR THE PRODUCTION OF BULK DRUGS

4.1 Cost audit (under Cost Accounting Record Rules 1968) was extended to bulk drugs w.e.f. 1st April 1974. This audit is already in existence in respect of a number of other industries. It is undertaken under the Company's Act 1956. Statutory cost audit i.e. compulsory audit of cost accounts by an ex ernal and independent accountant under the provisions of Law, is special to India. Though internal verification of cost accounting records as a part of a good known accounting system; or specific cost studies conducted at the instance of managements, either by company's own selected staff or outside consulting accountants, for improving operational efficiency or profitability or for securing cost reduction are routine in the advanced countries.

4.2 So far Cost Audit of companies engaged in the production of bulk drugs is being under taken on a selective basis by the Central Government Department of Company Affairs. It has now been suggested that such an audit should be undertaken on a regular basis so that in addition to the data furnished to the

Government by the manufacturers from time to time, a separate set of data duly verified by independent external statutory Auditors becomes available to the Government. It has been possible with the help of Cost Audit to watch the progress and cost efficiency achieved by bulk drugs manufactured by various units.

4.3 It has also been suggested that audit of cost of selected intermediates used in the production of major bulk drugs should also be undertaken. This proposal is, however, still under consideration.

Expenditure on Drug Promotion

Please see page 52 (Paras 5.10 to 5.15)

Return on Investment of Companies

Please see page 99 (Paras 1.4 to 1.7)

ANNEXURE I

Extracts from the Drug Prices Control Order, 1970

ORDER

S.O. 1752.—In exercise of the powers conferred by Section 3 of the Essential Commodities Act, 1955 (10 of 1955), and in supersession of the Drugs Prices (Display and Control) Order, 1966, the Central Government hereby makes the following Order, namely:—

1. **Short title, extent and commencement.**—(1) This Order may be called the Drugs (Prices Control) Order, 1970.

(2) It extends to the whole of India.

(3) It shall come into force on the date of its publication in the Official Gazette.

4. **Power to fix the maximum sale price of an essential bulk drug.**—(1) The Central Government may, with a view to regulating equitable distribution of essential bulk drug and making the same available at a fair price, from time to time fix, by notification in the Official Gazette, the maximum price at which the said essential bulk drug shall be sold:

10. **Special provisions in respect of new packs, new formulations and new manufacturers.**—(1) No manufacturer or importer shall market a new formulation or a new pack of his existing formulation except with the prior approval of the Central Government.

(2) For the purpose of applying for the approval of the Central Government, the manufacturer or importer, as the case may be, shall furnish information and details of calculations regarding retail price as in Form 3.

(3) The Central Government shall accord the approval subject to such modification as may be considered necessary having regard to the provisions contained in paragraphs 6, 7, 11 and 14 for the calculation of retail price within four months of the receipt of the application complete in all respects.

(4) The manufacturer or importer shall issue a price list or supplementary list in respect of the formulations or packs for which the approval is accorded by the Central Government within a fortnight of the receipt of approval by him. Where the approval is not accorded within the specified time-limit, the manufacturer or importer shall market the new formulation or new pack at the price calculated by him and shall issue price list or supplementary price list accordingly.

(5) The provisions of sub-paragraphs (1) to (4) shall apply to a new manufacturer or importer who markets his formulations for the first time.

11. **Power of the Central Government to fix retail prices of formulations.**—(1) If on the scrutiny of the price lists and the information and details of calculations furnished to it under paragraph 9, the Central Government is of the opinion that the retail price of any formulation has not been fixed in accordance with paragraph 6 or 7, it may fix the retail price of such formulation in accordance with the provisions of the said paragraphs and communicate the retail price so fixed to the manufacturer or importer, who shall amend the relevant price list and communicate the same to the dealers:

Provided that before fixing the maximum price in respect of an essential bulk drug, it shall be the duty of the Central Government to institute such inquiry as it deems fit for the purpose.

Provided further that, as regards the fixation of the maximum price of the essential bulk drugs included in Schedule I at the commencement of this Order, the recommendations made in this behalf by the Tariff Commission in its Report of August, 1968 shall form the basis and no such inquiry as aforesaid shall be necessary.

(2) No persons shall sell an essential bulk drug at a price exceeding the price fixed for the same under this paragraph plus local taxes payable if any.

5. **Maximum selling prices of bulk drugs.**—(1) Every manufacturer or importer of a bulk drug, shall report to the Central Government within two weeks of the commencement of this Order, the name of the bulk drug marketed by him or used exclusively by him for formulations, and its maximum selling price or the notional price as the case may be, at the time of the commencement of this Order, and he shall not thereafter increase the said selling price or notional price of such bulk drug without the prior approval of the Central Government for which purpose he shall also furnish information as required in Form No. 1.

Provided that the Central Government may for sufficient cause, either generally or in individual cases, extend the said period of two weeks to four weeks.

Provided further that every importer of a bulk drug shall report to the Central Government within 15 days of every import, the landed cost of the imported bulk drug and the selling price thereof and he shall not thereafter increase the said selling price without the prior approval of the Central Government.

(1-A) Notwithstanding anything contained in sub-paragraph (1), the Central Government may, after calling for such information as may be necessary, fix the selling price of any imported bulk drug having regard to its landed cost, handling charges, storage expenses, distribution costs, and reasonable return on capital invested.

(2) The provisions of sub-paragraph (1) shall apply also to bulk drugs introduced after the commencement of this Order except that the said period of two weeks shall be computed from the date of introduction of the said bulk drug.

(3) No person shall sell a bulk drug at a price exceeding the price referred to in sub-paragraph (1) plus local taxes payable if any.

Explanation.—Landed cost for the purpose of this paragraph means the cost of import inclusive of customs duty and clearing charges.

Provided that the Central Government shall have the power to accept such mark-up within the ceilings mentioned in paragraph 7, as may be expedient in the public interest in the case of any particular formulation having regard to all relevant factors such as changes in the cost of raw materials, promotional expenses, volume of sales and the mark-up approved in the case of other similar or comparable formulations.

(2) The retail price of any formulation fixed by the Central Government under sub-paragraph (1) and the said amended price list shall come into force not later than fifteen days from the receipt of the aforesaid communication by the manufacturer or importer.

(3) The power under sub-paragraph (1) to fix the prices of formulations shall be exercised by the Central Government within four months from the date of receipt by it of the intimation of retail price for any formulation together with the information and details of calculations referred to in paragraph 9:

Provided that the said period of four months may be extended by the Central Government to six months in the case of formulations involving detailed examination.

Provided, however, that an intimation that the period has been extended to six months shall be sent by the Central Government before the expiry of the said period of four months to the manufacturer or importer concerned.

(4) Notwithstanding anything contained in sub-paragraph (1) and paragraphs 6, 7, 10, 13, and 14, the Central Government may either generally or in individual cases, by order, fix, in the public interest, the retail price of any formulation or class of formulations essential to the life of the community.

(5) The price fixed under sub-paragraph (4) shall be in force until altered or cancelled by the Central Government.

12. **Determination of a new formulation.**—(1) The manufacturer or importer of a new formulation may, before introducing such a new formulation for sale or including the retail price of such a new formulation in the price list, apply to the Central Government for a decision as to whether the formulation constitutes a new formulation within the meaning of clause (i) (a) or clause (i) (b) of paragraph 7.

(2) Where an application is received under sub-paragraph (1), the Central Government may within a period of forty-five days of the receipt of the said application, by order, inform the applicant of its decision as to whether or not the formulation constitutes a new formulation as aforesaid.

(3) The manufacturer of such a new formulation may—

(i) on receipt of the order of the Central Government that the formulation constitutes a new formulation, or

(ii) where no such order is sent by the Central Government, before the expiry of the period of forty-five days referred to in sub-paragraph (2), follow the procedure laid down in paragraph 9 or 10, as the case may be, for introducing the new formulation for sale or including the retail price of such new formulation in the price list and the provisions of paragraph 7 shall in so far as they relate to the fixation of retail price apply to the said new formulation.

13. **Revision of Prices.**—(1) The retail price of a formulation once fixed in accordance with the provisions of this Order shall not be increased except with the prior approval of the Central Government.

(2) Every application for increase in the retail price of a formulation shall be accompanied by information and details of calculations as required in Form 3.

(3) It shall be lawful for the Central Government to revise the retail price of any formulation *suo moto*.

(4) For the purpose of such revision, the Central Government may call for such information regarding cost structure of any formulation as it may consider necessary from any manufacturer or importer and fix the retail price in accordance with paragraphs 6 and 7 in which case the manufacturer or importer shall within fifteen days from the date of receipt of the Central Government's communication fixing the retail price of such formulation amend the price list and market the said formulation at the retail price fixed by the Central Government:

Provided that if the manufacturer or importer fails to furnish the required information within the time stipulated, the Central Government may on the basis of such information as is available with it, fix the retail price of the said formulation and communicate the same to the manufacturer or importer and the manufacturer or importer shall within 15 days of the receipt of the aforesaid communication revise the price list accordingly, and market the formulation at the retail price so fixed.

14. **Alternative scheme of pricing.**—(1) Notwithstanding anything contained in the other provisions of this Order, the manufacturer or importer may, if he so chooses, submit to the Central Government for approval a scheme of prices covering all of the formulations marketed by him so that the overall gross profit before tax does not exceed 15 per cent of the sales turn-over as estimated by him and submit the price list resulting therefrom, alongwith such other information as is required in Schedule III for the purpose:

Provided that the scheme shall be subject to the following conditions, namely. –

(i) the formulations based on the essential bulk drugs shall be priced in accordance with the provisions of paragraphs 6 and 7;

(ii) the formulations based on the bulk drugs other than the essential bulk drugs shall be priced in accordance with the formula in paragraph 6, in such a way that the mark-up in any individual case does not exceed 150 per cent of such lower or higher mark-up as the Central Government may permit in any case having regard to the circumstances of that case;

(iii) The manufacturer or importer shall, on choosing the scheme, undertake and maintain separate accounts for formulations based on essential bulk drugs and the formulations based on other bulk drugs, and submit them for scrutiny in such manner as may be specified by the Central Government;

(iv) in case the actual gross profit before tax for any particular year as shown in the audited accounts of the manufacturer or importer exceeds 15 per cent of the sales turn-over of the year, as certified by the auditor, the excess shall be funded separately and shall not be utilised for distribution of dividends but shall be utilized with the prior approval of the Central Government, for any of the following purposes, namely:—

(a) research and development expenditure;

(b) adjustments against future profits or losses;

(c) such other purposes as may be specified by the Central Government from time to time.

Explanation.—"the formulation based on the essential bulk drugs" means the formulation which contains one or more of the essential bulk drugs as major therapeutic ingredient.

(2) The option referred to in sub-paragraph (1) shall be exercised and the price lists under the alternative pricing scheme accompanied by information and details of calculations regarding retail price as required in Form No. 3 shall be submitted to the Central Government by the manufacturer or importer, as the case may be, within two months of the commencement of this Order:

Provided that the Central Government may for sufficient cause, either generally or in individual cases, extend the said period of two months to such further period or periods as it may deem fit so however, that the period or periods so extended shall not exceed four months from the date of commencement of this Order in any case.

(3) Pending the decision of the Central Government on the price lists submitted to it under sub-paragraph (2), the manufacturer or importer may market his formulations as per price lists submitted by him under the said sub-paragraph:

Provided that in any case where the price for any formulation calculated in accordance with the provisions of sub-paragraph (1) is higher than the price prevailing on the 15th May, 1970, for such formulation, then until such time the decision of the Central Government on the

price list submitted under sub-paragraph (2) is received, such formulation shall be marketed only at the price prevailing on the date aforesaid.

(4) The Central Government shall have the power to approve or modify the price of any formulation included in the price list submitted to it under sub-paragraph (2) and shall communicate its decision to the manufacturer or importer not later than the 31st December, 1970:

Provided that in cases where the communications regarding such decisions are not issued by the aforesaid date, the price lists submitted under sub-paragraph (2) shall be deemed to have been approved by the Central Government and shall be deemed to be valid price lists for the purpose of this paragraph.

(5) For the purpose of approval or modification of the price of any formulation included in the price list submitted to it under sub-paragraph (2) it shall be lawful for the Central Government to take into consideration all relevant factors such as product-mix, material costs, the number and nature of specialised formulations, if any, export performance during the preceding three years, amount and nature of expenditure on research, trend of gross profits before tax during the immediately preceding three years of the manufacture and the prices approved for similar or comparable formulations of other manufactures or importers as the case may be.

(6) The prices of the formulations under this paragraph shall take effect within fifteen days of the receipt of the communication regarding decision of the Central Government relating to approval or modification of the price of any formulation by the manufacturer or importer.

(7) Where the Central Government modifies the price of any formulation, it shall communicate in writing the reasons for such modification to the manufacturer or importer unless such modification follows from the revision made by the manufacturer or importer himself in consultation with the Central Government.

(8) The provisions of paragraph 13 shall so far as may be, apply to revision of prices of formulations fixed under this paragraph.

(9) The provisions of paragraph 10, shall so far as may be, apply to new packs of existing formulations and new formulations to be marketed by a manufacturer or importer who opts for the alternative scheme of pricing.

(10) The option once exercised by the manufacturer or importer shall not be changed without the previous approval of the Central Government.

(11) If any difficulty arises in giving effect to the provisions of this paragraph, the Central Government may, from time to time, issue such orders, directions or instructions, not inconsistent with the provisions of this Order as appear to it to be necessary or expedient for the removal of such difficulty.

ANNEXURE 2(A)

IMPORT PRICES - BULK DRUGS AND INTERMEDIATES - AN ILLUSTRATIVE LIST

C.i.f. Import Price (Rs)

Sl No	Product	Unit	1971-72	1973-74	1975-76	1977-78	1979-80	1981-82
1	2	3	4	5	6	7	8	9
	Bulk Drugs							
	Analgesic & Antipyretic							
1.	Analgin	Kg	43.26	29.38	61.99	66.99	66.85	68.85
	Antibacterial							
2.	Chloramphenicol Powder	Kg	257.16	120.10	281.49	185.00	357.73	379.48
3.	Tetracycline	Kg	262.39	136.23	232.89	238.07	256.82	281.86
4.	Streptomycin	Kg	203.22	121.55	226.14	328.12	376.50	245.50
	Antifungal							
5.	Griseofulvin	Kg	205.26	357.28	969.19	756.05	724.24	Nil
	Anti-malarial							
6.	Chloroquin Phosphate	Kg	145.93	125.55	172.52	260.22	276.66	247.53
7.	Primaquin	Kg	379.66	850.78	787.52	1248.52	1183.88	1067.69

1	2	3	4	5	6	7	8	9
	Anti-diabetics (Oral)							
8.	Chlorpropamide	Kg	58.15	67.02	97.62	Nil	Nil	Nil
	Antidiuretics							
9.	Hydrochlorthiazide	Kg	81.12	55.00	226.00	207.50	NA	205.16
	Vitamins							
10.	Vitamin B6	Kg	120.33	138.36	328.47	328.09	370.46	347.18
			Drug Intermediates					
1.	Metaminophenol	Kg	Nil	16.54	Nil	Nil	Nil	Nil
2.	Betapicoline	Kg	Nil	11.66	Nil	13.03	NA	NA
3.	L Base (Amiodiol)	Kg	NA	NA	261.53	300.76	385.00	400.00
4.	8-Hydroxyquinoline	Kg	NA	NA	74.41	68.98	82.18	76.23
5.	4-7 Dichloroquinoline	Kg	NA	NA	224.19	293.40	NA	Nil

ANNEXURE - 2(B)

PRICES OF SOME MAJOR FORMULATIONS AS APPROVED BY THE GOVERNMENT

Sl No	Name of the formulation	Pack size	Retail Price in 1971	Retail Price in 1976	Retail Price in 1983
1.	Althrocin Tablets 250mg/tab (Erythromycin Estolate)	10's Strip	16.72	14.91	14.91
2.	Lasix Tablets 40mg/tab (Frusemide)	25x10's	170.00	52.26	29.28
3.	Resochin Tablets 250mg/tab (Chloroquin)	10x10's	14.36	19.54	27.56
4.	Dapsone Tablets 100mg/tab	1000's	22.28	24.42	24.42
5.	Chloramphenicol Capsules 250mg/Cap	12's Strip	4.12	4.15	4.73
6.	Neurobion (B1, B6 & B12)	10x3ml	25.00	25.89	25.89
7.	Novalgin Tablets 500mg/Tab (Analgin)	10x10's	19.38	18.27	22.74
8.	Terramycin 250mg/Cap (Oxytetracycline)	100 Caps	63.00	46.19	44.05
9.	Tetracycline Capsules 250mg/Cap	100 Caps	61.50	45.89	41.56
10.	Streptomycin Injection 1gm	1 Vial	1.11	1.19	2.57

ANNEXURE 3

रजिस्ट्री सं. डी. (डी.एन.)-72

REGISTERED No. D. (D.N.)-72

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (ii)
PART II—Section 3—Sub-section (ii)

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके

Separate paging is given to this Part in order that it may be filed as a separate compilation

MINISTRY OF CHEMICALS & FERTILIZER

Office of the Development Commissioner (Drugs)

NOTIFICATION

New Delhi, the 19th April, 1983

S.O. 321(E).—In exercise of the powers conferred by section 6 of the Industries (Development and Regulation) Act, 1951 (65 of 1951), read with rules 2, 3, 4 and 5 of the Development Councils (Procedural) Rules, 1952, the Central Government hereby establishes a Development Council for the Drugs and Pharmaceuticals Industry. The said Development Council shall be known as the National Drugs and Pharmaceuticals Development Council and shall consist of the members specified in Annexure I to this Order, whose tenure of appointment shall be for a period of two years from the date of publication of this Order in the Official Gazette.

2. The said Development Council shall perform functions as are specified in Annexure II to this Order.

3. Shri Vinay Malik, Joint Secretary and Development Commissioner (Drugs), Ministry of Chemicals and Fertilizers, New Delhi is hereby appointed to carry on the functions of the Member-Secretary to the said Development Council.

[No.7(7)/83-D.II]
VINAY MALIK, Jt. Secy.

ANNEXURE-I

List of the Members of the Development Council for Drugs and Pharmaceuticals Industry.

1. Shri Vasant Sathe, Minister of Chemicals & Fertilizers — Chairman
2. Shri Ram Chandra Rath, Minister of State in the Ministry of Chemicals and Fertilizers — Vice-Chairman
3. Shri S. Ramanathan, Secretary, Ministry of Chemicals & Fertilizers — Member
4. Dr. I.D. Bajaj, Director General of Health Services, Ministry of Health. — Member
5. Dr. S.S. Gothoskar, Drug Controller, Ministry of Health. — Member
6. Shri Krishan Mohan Bhamidipati, Member of Parliament from Rajya Sabha. — Member
7. Shri Mahendra Prasad, Member of Parliament, Lok Sabha. — Member
8. Dr. V. Ramalingaswami, Chairman, Indian Council of Medical Research. — Member
9. Prof. Sharma, Department of Chemical Technology, Bombay University, Bombay. — Member
10. Dr. Nam Joshi, Specialist in Indigenous Medicines, Bombay. — Member
11. Dr. Nityanand, Director, Central Drug Research Institute, Lucknow. — Member
12. Dr. M.G. Garg, President, Indian Medical Association, Delhi. — Member
13. Mr. George Daniel, President, Organisation of Pharmaceutical Producers of India, Bombay. — Member
14. Shri J.B. Modi, President, Indian Drug Manufacturers Association, Bombay. — Member
15. Shri Jagmohan Singh Kochar, All India Small Scale Drug Manufacturers Association, Delhi. — Member
16. Shri Y.H. Gharpure, Managing Director, Hindustan Antibiotics Ltd., Poona. — Member
17. Shri Vinoobhai Shah, President, All India Organisation of Chemists & Druggists. — Member
18. Dr. B.B. Gaitonde, New Delhi. — Member
19. Shri Raja Kulkarni, Labour Leader, Bombay. — Member
20. Dr. M.P. Ballal, Chief Cardiologist Silver Jubilee Cardiac, Rehabilitation & Research Centre, Project Sadar, Nagpur. — Member
21. Shri Yashodhan Kale, Chartered Accountant, Bombay. — Member
22. Shri M. Satyapal, Secretary, DGTD. — Member
23. Shri D. Zaveri, Chairman, Export Promotion Council, Bombay. — Member
24. Dr. V. Venkitanarayanan, Joint Secretary (Drugs), Ministry of Chemicals & Fertilizers. — Member
25. Shri Vinay Malik, Joint Secretary and Development Commissioner (Drugs), Ministry of Chemicals & Fertilisers. — Member-Secretary

ANNEXURE-II

Functions of the Development Council for Drugs and Pharmaceuticals Industry

(1) Recommending targets for production, co-ordinating production programmes and reviewing progress from time to time.

(2) Suggesting norms of efficiency with a view to eliminating waste, obtaining maximum production, improving quality and reducing costs.

(3) Recommending measures for securing the fuller utilisation of the installed capacity and for improving the working of the industry, particularly of less efficient units.

(4) Promoting arrangements for better marketing and helping in the *devising of a system of distribution* and sale of the produce of the industry which would be satisfactory to the consumer.

(5) Promoting standardisation of products.

(6) Assisting in the distribution of controlled materials and promoting arrangements for obtaining materials for the industry.

(7) Promoting or undertaking, inquiry as to materials and equipment and as to methods of production, management and labour utilisation, including the discovery and development of new materials, equipment and methods and of improvements in those already in use, the assessment of the advantages of different alternatives and the conduct of experimental establishments and of tests on a commercial scale.

(8) Promoting the training of persons engaged or proposing engagement in the industry and their education in technical or artistic subjects relevant thereto.

(9) Promoting the retraining in alternative occupations of personnel engaged in or retrenched from the industry.

(10) Promoting or undertaking scientific and industrial research, research into matters affecting Industrial Psychology and research into matters relating to production and to the consumption or use of goods and services supplied by the industry.

(11) Promoting improvements and standardisation of accounting and costing methods and practice.

(12) Promoting or undertaking the collection and formulation of statistics.

(13) Investigating possibilities of decentralising stages and process of production with a view to encouraging the growth of allied small scale and cottage industries.

(14) Promoting the adoption of measures for increasing the productivity of labour, including measures for securing safer and better working conditions and the provision and improvement of amenities and incentives for workers.

(15) Advising on any matters relating to the industry (other than remuneration and conditions of employment) as to which the Central Government may request the Development Council to advise and undertaking inquiries for the purpose of enabling the Development Council so to advise, and

(16) Undertaking arranagments for making available to the industry information obtained and for advising on matters with which the Development Council are concerned in the exercise of any of their functions.

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ANNEXURE 4

(Pl. see P. 347 inside) DPCO/79

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (ii)

PART II—Section 3—Sub-section (ii)

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।

Separate paging is given to this Part in order that it may be filed as a separate compilation.

पेट्रोलियम, रसायन और उर्वरक मंत्रालय

(रसायन और उर्वरक विभाग)

आदेश

नई दिल्ली, 31 मार्च, 1979

का०आ० 190(अ).—केन्द्रीय सरकार, आवश्यक वस्तु अधिनियम, 1955 (1955 का 10) की धारा 3 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, निम्नलिखित आदेश करती है, अर्थात्:—

1. संक्षिप्त नाम, विस्तार और प्रारम्भ —(1) इस आदेश का नाम औषधि (कीमत नियंत्रण) आदेश, 1979 है।

(2) इसका विस्तार सम्पूर्ण भारत पर होगा।

(3) यह राजपत्र में प्रकाशन की तारीख को प्रवृत्त होगा।

2. परिभाषाएं—इस आदेश में, जब तक कि संदर्भ से अन्यथा अपेक्षित न हो,

(क) "अपूंज औषधि" से, औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) के अधीन स्वीकार औषध संग्रह या अन्य मानका के अनुरूप कोई भी पदार्थ अभिप्रेत है, जिसके अंतर्गत भैषजिक, रासायनिक, जैव या वनस्पति उत्पाद अथवा औषधीय गैस भी हैं। इनका प्रयोग उसी रूप में या किसी संरूपण में संघटक के रूप में किया जाता है;

(ख) 'व्यवहारी' से ऐसा व्यक्ति अभिप्रेत है जो थोक या फुटकर में तथा किसी अन्य कारबार के साथ या उसके बिना, औषधियों के क्रय-विक्रय का कारबार करता है। इसके अन्तर्गत व्यवहारी का अभिकर्ता भी है;

(ग) 'वितरक' से ऐसा कोई औषधि वितरक या उसका अभिकर्ता या स्टाकिस्ट अभिप्रेत है जिसे, किसी व्यवहारी को उनका पुनःविक्रय करने के लिए ऐसी औषधियों के किसी विनिर्माता या आयातकर्ता द्वारा नियुक्त किया गया है;

(घ) 'औषधि' के अंतर्गत,—

(1) मानव प्राणियों या जीवजन्तुओं के आन्तरिक या बाह्य प्रयोग के लिए कोई औषधि और ऐसे सभी पदार्थ है जो मानव प्राणियों या जीव जन्तुओं के रोगों के निदान, इलाज शमन या उनसे बचाव के लिए प्रयोग किए जाने के लिए आशयित हैं;

(2) ऐसे पदार्थ हैं जो सरकार द्वारा समय-समय पर राजपत्र में अधिसूचना द्वारा विनिर्दिष्ट किए जाते हैं और मानव या जीव-जन्तु के शरीर की संरचना या किसी कार्य को प्रभावित करने के लिए आशयित हैं या उन पीड़क जन्तु या कीटाणुओं को नष्ट करने के लिए आशयित हैं जो मानव प्राणियों या जीव जन्तुओं में रोग उत्पन्न करते हैं;

(3) अपूंज औषधियों और विनिर्मितियां;

(ङ) "प्ररूप से" चौथी अनुसूची में विनिर्दिष्ट प्ररूप अभिप्रेत है;

(च) 'विनिर्मिति" से किसी भैषजिकी सहायता से या उसके बिना, मानव प्राणियों या जीव-जन्तुओं के रोगों में आन्तरिक या बाह्य प्रयोग के लिए या उसके निदान, इलाज, शमन या उनसे बचाव के लिए एक या अधिक अपूंज औषधि

या औषधियों से मिलाकर तैयार की गई औषधि अभिप्रेत है, परन्तु इसके अन्तर्गत निम्नलिखित नहीं है, अर्थात :—

(i) आयुर्वेदिक प्रणाली (जिसके अन्तर्गत सिद्ध भी है) या यूनानी (तिब्ब) प्रणाली की कोई सदभाविक औषधि;

(ii) होमियोपैथिक प्रणाली की कोई औषधि ;

(iii) ऐसा कोई पदार्थ जिसे औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) के अपबन्ध लागू नहीं होते ;

(छ) "मुक्त आरक्षिति" से लाभों के विनियोजन में सृष्ट कोई आरक्षिति अभिप्रेत है, किन्तु इसके अन्तर्गत आकस्मिक दायित्व, विवादग्रस्त दावे, गुडविल, पुनर्मूल्यन और ऐसी ही अन्य आरक्षितियाँ नहीं है;

(ज) "सरकार" से केन्द्रीय सरकार अभिप्रेत है;

(झ) "आयात" से, इसके व्याकरणिक रूपभेदों और सजातीय पदों सहित, भारत के बाहर किसी स्थान से भारत में लाना अभिप्रेत है; और किसी भी समय किन्हीं वस्तुओं के आयात और उपभोग के दौरान उनके संबंध में, "आयातकर्ता" के अंतर्गत, कोई स्वामी या कोई ऐसा व्यक्ति है जो अपने आप को आयातकर्ता घोषित करे ;

(ञ) 'अग्रणी कीमत' से ऐसी कोई कीमत अभिप्रेत है जो सरकार ने ऐसी विनिर्मितियों के मुख्य विनिर्माताओं की लागत या कार्यकुशलता या दोनों को ध्यान में रखते हुए, पैरा 10 और पैरा 11 के उपबन्धों के अनुसार तृतीय अनुसूची के प्रवर्ग 1, प्रवर्ग 2 या प्रवर्ग 3 में विनिर्दिष्ट विनिर्मितियों के लिए नियत की है ;

(ट) किसी औषधि के संबंध में, 'विनिर्माण' के अंतर्गत है ऐसी कोई प्रक्रिया या उसका कोई भाग जो किसी औषधि के विक्रय और वितरण को ध्यान में रखते हुए, उसके बनाए जाने, परिवर्तित किए जाने, परिष्कृत किए जाने, पैक किए जाने, उस पर लेबल लगाए जाने, उसके विश्लेषित किए जाने या अन्यथा उसके अभिक्रियागत या अंगीकार किए जाने के लिए की जाती है, किन्तु इसके अन्तर्गत किसी औषधि का आमिक्षण या नुस्खा बनाना या फुटकर कारबार के साधारण अनुक्रम में उसका पैक किया जाना नहीं है, और "विनिर्मित करना" का तदनुसार अर्थ लगाया जाएगा;

(ठ) "विनिर्माता" से वह व्यक्ति अभिप्रेत है जो कोई औषधि विनिर्मित करता है;

(ड) 'शुद्ध मालियत' से किसी कम्पनी की मुक्त आरक्षिति, यदि कोई हो, सहित उसकी अंश-पूंजी है;

(ढ) "नव प्रपुंज औषधि' से, इस आदेश के प्रारम्भ के पश्चात् देश के भीतर पहली बार विनिर्मित प्रपुंज औषधि अभिप्रेत है;

(ण) प्रपुंज औषधि के सम्बन्ध में, "पूलकृत कीमत" से, पैरा 7 के अधीन नियत की गई कीमत अभिप्रेत है;

(त) 'कर-पूर्व विवरणी' से, आय-कर और अतिकर के संदाय से पूर्ववर्ती लाभ अभिप्रेत हैं और इसके अन्तर्गत ऐसे अन्य व्यय भी सम्मिलित हैं जो विनिर्मिति की लागत के भागरूप नहीं हैं;

(थ) "मूल्य सूची" से, इस आदेश में निर्दिष्ट मूल्य सूची अभिप्रेत है और इसके अन्तर्गत पूरक मूल्य सूची भी है;

(द) "फुटकर कीमत" से इस आदेश के उपबंधों के अनुसार किसी औषधि की नय या नियत की गई अभिप्रेत है और इसके अन्तर्गत अग्रणी कीमत भी है ;

(ध) "फुटकर विक्रेता" से ऐसा व्यवहारी अभिप्रेत है जो ग्राहकों को औषधियों के फुटकर विक्रय का कारबार करता है ;

(न) किसी प्रपुंज औषधि के सम्बन्ध में 'प्रतिधारण कीमत' से ऐसी प्रपुंज औषधियों के व्यक्तिगत विनिर्माताओं या आयातकर्ताओं या वितरकों के लिए पैरा 4 और 7 के अधीन नियत की गई कीमत अभिप्रेत है ;

(प) "विक्रय आवर्त" से किसी लेखा वर्ष में, विक्रय-कर सहित फुटकर कीमत से गुणित किसी विनिर्माता या किसी आयातकर्ता द्वारा, यथास्थिति, सीधे विक्रय की गई विनिर्मित के एककों का योग अभिप्रेत है किन्तु ऐसी कीमत के अंतर्गत उत्पाद-शुल्क और स्थानीय कर, यदि कोई हो, नहीं है;

(फ) "अनुसूची" से इस आदेश से उपाबद्ध अनुसूची अभिप्रेत है;

(ब) "थोक विक्रेता" से औषधियों का ऐसा कोई थोक विक्रेता या उसका अभिकर्ता, अथवा स्टाकिस्ट अभिप्रेत है जिसे किसी फुटकर विक्रेता को ऐसी औषधियों विक्रय करने के लिए ऐसी औषधि के किसी विनिर्माता या आयातकर्ता द्वारा नियुक्त किया गया है।

3. प्रथम अनुसूची या द्वितीय अनुसूची में विनिर्दिष्ट देश में विनिर्मित प्रपुंज औषधियों की अधिकतम विक्रय कीमत नियत करने की शक्ति (1) सरकार, प्रथम अनुसूची या द्वितीय अनुसूची में विनिर्दिष्ट देश में विनिर्मित किसी प्रपुंज औषधि के न्यायोचित वितरण को विनियमित करने और उपपैरा (2) में दिए गए उपबंधों के अधीन इसे उचित कीमत पर उपलब्ध कराने की दृष्टि से तथा ऐसी जाँच कराने के पश्चात, जैसी वह ठीक समझे, ऐसी अधिकतम कीमत जिस पर ऐसी प्रपुंज औषधि बेची जाएगी, समय-समय पर राजपत्र में अधिसूचना द्वारा नियत कर सकेगी।

(2) सरकार, उपपैरा (1) के अधीन किसी प्रपुंज औषधि की कीमत नियत करते समय, किसी दक्ष विनिर्माता द्वारा विनिर्मित ऐसी प्रपुंज औषधि के उत्पादन की औसत लागत को ध्यान में रख सकेगी और शुद्ध मालियत पर उचित प्रतिफल अनुज्ञात कर सकेगी।

स्पष्टीकरण—इस उप-पैरा में, "दक्ष विनिर्माता" पद से ऐसा विनिर्माता अभिप्रेत है,—

(1) जिसका देश में, ऐसी प्रपुंज औषधि के कुल उत्पादन के सम्बन्ध में, ऐसी प्रपुंज औषधि का उत्पादन अधिक है; या

(2) जो ऐसी प्रपुंज औषधि के उत्पादन में दक्ष प्रौद्योगिकी लगाता है।

(3) कोई भी व्यक्ति किसी प्रपुंज औषधि को उपपैरा (1) के अधीन अधिसूचित कीमत से ऊपर ह्रदयग्रहणीय स्थानीय करों के अतिरिक्त, अधिक कीमत पर नहीं बेचेगा।

परन्तु जब तक प्रपुंज औषधि की कीमत इस प्रकार अधिसूचित नहीं की जाती तब तक ऐसी प्रपुंज औषधि की कीमत वह कीमत होगी जो इस आदेश के प्रारम्भ से ठीक पूर्व विद्यमान थी और ऐसी प्रपुंज औषधि का विनिर्माता ऐसी प्रपुंज औषधि को यथा पूर्व विद्यमान कीमत से अधिक कीमत पर नहीं बेचेगा।

(4) (क) जहां कोई विनिर्माता, प्रथम अनुसूची या द्वितीय अनुसूची में विनिर्दिष्ट किसी ऐसी प्रपुंज औषधि का उत्पादन इस आदेश के प्रारम्भ के पश्चात् आरम्भ करता है, जिसकी कीमत सरकार द्वारा पहले

ही अधिसूचित की जा चुकी है, वहां वह प्रपुंज औषधि को इस प्रकार अधिसूचित कीमत से अधिक कीमत पर नहीं बेचेगा।

(ख) जहां किसी प्रपुंज औषधि की कीमत सरकार द्वारा अधिसूचित नहीं की गई है, वहां विनिर्माता ऐसी प्रपुंज औषधि के उत्पादन के प्रारम्भ से चौदह दिन के भीतर सरकार को प्ररूप 1 में आवेदन देगा और सरकार को वह कीमत सूचित करेगा जिस पर उसका उस प्रपुंज औषधि को बेचने का विचार है, और सरकार, ऐसी जांच करने के पश्चात् जैसी वह ठीक समझे, आदेश द्वारा ऐसी अनन्तिम कीमत नियत कर सकेगी जिस पर ऐसी प्रपुंज औषधि बेची जाएगी।

(ग) इस उपपैरा में निर्दिष्ट विनिर्माता ऐसी उत्पादन के प्रारम्भ से छह मास के भीतर, सरकार को प्ररूप 1 में एक और आवेदन देगा, और सरकार, ऐसी जांच करने के पश्चात्, जैसी वह ठीक समझे, राजपत्र में अधिसूचना द्वारा ऐसी प्रपुंज औषधि की कीमत नियत कर सकेगी।

4. प्रतिधारण कीमत और सामान्य विक्रय कीमत नियत करने की शक्ति—पैरा 3 में किसी बात के होते हुए भी, यदि सरकार, प्रथम अनुसूची या द्वितीय अनुसूची में विनिर्दिष्ट देश में विनिर्मित किसी प्रपुंज औषधि के उत्पादन को बढ़ाने के लिए ऐसा करना आवश्यक या समीचीन समझती है, तो आदेश द्वारा :—

(क) ऐसी प्रपुंज औषधि की प्रतिधारण कीमत नियत कर सकेगी;

(ख) खण्ड (क) के अधीन नियत की गई प्रतिधारण कीमत के भारित औसत को ध्यान में रखते हुए, ऐसी प्रपुंज औषधि के लिए सामान्य विक्रय कीमत नियत कर सकेगी।

5. नई प्रपुंज औषधि की अधिकतम विक्रय कीमत नियत करने की शक्ति—(1) किसी नई प्रपुंज औषधि का प्रत्येक विनिर्माता ऐसी नई प्रपुंज औषधि के उत्पादन के प्रारम्भ से चौदह दिन के भीतर सरकार को प्ररूप 1 में आवेदन करेगा, और सरकार, ऐसी जांच करने के पश्चात् जैसी वह आवश्यक समझे, ऐसी नई प्रपुंज औषधि को इस आदेश में सम्मिलित करने का विनिश्चय करेगी और आदेश द्वारा, एक अनन्तिम कीमत नियत करेगी जिस पर ऐसी नई प्रपुंज औषधि बेची जाएगी;

(2) (क) प्रत्येक मामले में, जहां किसी नई प्रपुंज औषधि के लिए अनन्तिम कीमत नियत कर दी गई है, ऐसी नई प्रपुंज औषधि का प्रत्येक विनिर्माता, ऐसी नई प्रपुंज औषधि के उत्पादन से छह मास पूरे हो जाने पर, सरकार को प्ररूप 1 में एक और आवेदन देगा।

(ख) खण्ड (क) के अधीन किसी आवेदन की प्राप्ति पर, सरकार, ऐसी जांच करने के पश्चात् जैसी वह ठीक समझे, राजपत्र में अधिसूचना द्वारा, ऐसी प्रपुंज औषधि की कीमत नियत कर सकेगी।

(ग) खण्ड (ख) के अधीन नियत कीमत, ऐसी नई प्रपुंज औषधि की अधिकतम विक्रय कीमत होगी और कोई व्यक्ति (जिसके अन्तर्गत वह व्यक्ति भी है जो उसके बाद ऐसी नई प्रपुंज औषधि का विनिर्माण करता है) ऐसी नई प्रपुंज औषधि को इस प्रकार अधिसूचित कीमत से अधिक कीमत पर नहीं बेचेगा।

6. प्रथम या द्वितीय अनुसूची में विनिर्दिष्ट आयातित प्रपुंज औषधि की अधिकतम विक्रय कीमत नियत करने की शक्ति—(1) प्रथम अनुसूची या द्वितीय अनुसूची में विनिर्दिष्ट किसी प्रपुंज औषधि का प्रत्येक आयातकर्ता, ऐसी प्रपुंज औषधि के आयात से चौदह दिन के भीतर, सरकार को प्ररूप 2 में एक आवेदन देगा।

(2) (क) सरकार, प्ररूप 2 में की गई जानकारी को ध्यान में रखते हुए, ऐसी औषधि की कीमत, आदेश द्वारा, नियत कर सकेगी।

(ख) खण्ड (क) के अधीन नियत की गई कीमत ऐसी प्रपुंज औषधि की अधिकतम विक्रय कीमत होगी और कोई भी व्यक्ति ऐसी प्रपुंज औषधि को इस प्रकार नियत की गई कीमत से अधिक कीमत पर नहीं बेचेगा।

7. देश में विनिर्मित और आयातित, प्रथम अनुसूची और द्वितीय अनुसूची में विनिर्दिष्ट प्रपुंज औषधियों के विक्रय के लिए प्रतिधारण कीमत और पुलित कीमत नियत करने की शक्ति—(1) जहां प्रथम अनुसूची और द्वितीय अनुसूची में विनिर्दिष्ट कोई प्रपुंज औषधि देश में विनिर्मित की जाती है और आयातित भी होती है, वहां सरकार देश में विनिर्मित प्रपुंज औषधियों और आयातित प्रपुंज औषधियों के बारे में समय-समय पर विद्यमान विक्रय कीमतों को ध्यान में रखते हुए, ऐसे समायोजनों सहित, जैसे सरकार आवश्यक समझे, आदेश द्वारा—

(क) ऐसी प्रपुंज औषधियों के अलग-अलग विनिर्माताओं, आयातकर्ताओं या वितरकों के लिए प्रतिधारण कीमतें नियत कर सकेगी;

(ख) ऐसी प्रपुंज औषधियों के विक्रय के लिए पुलित कीमत नियत कर सकेगी;

(2) जहां विनिर्मितियों का कोई विनिर्माता अपने उत्पादन से या किसी अन्य स्रोत से प्राप्त किसी प्रपुंज औषधि को, जिसकी कीमत उस कीमत से निम्नतर है जो उसे उसकी विनिर्मितियों के लिए अनुज्ञात की गई है, अपनी विनिर्मितियों के उपयोग में लाता है, वहां सरकार ऐसे विनिर्माता से अपेक्षा कर सकेगी कि वह—

(क) सरकार द्वारा अवधारित की गई अधिक राशि औषधि कीमत समायोजन लेखा में निक्षिप्त करे; या

(ख) विनिर्मितियों को ऐसी कीमतों पर बेचे जो सरकार नियत करे।

8. देश में किए गए अनुसंधान और विकास द्वारा उत्पादित प्रपुंज औषधि की कीमत—(1) मूल अनुसंधान और विकासी प्रयासों द्वारा देश में, न कि और कहीं उत्पादित नई प्रपुंज औषधियों के विनिर्माताओं को प्रोत्साहन देने की दृष्टि से, ऐसी प्रपुंज औषधियों को, ऐसी नई प्रपुंज औषधियों के उत्पादन के प्रारम्भ की तारीख से पांच वर्ष की अवधि के लिए, इस आदेश के उपबन्ध लागू नहीं होंगे :

परन्तु ऐसी नई प्रपुंज औषधि का प्रत्येक विनिर्माता, ऐसी नई प्रपुंज औषधि के उत्पादन के प्रारम्भ से चौदह दिन के भीतर, सरकार को प्ररूप 1 में, विज्ञान और प्रौद्योगिकी विभाग द्वारा प्रमाणपत्र सहित जिसमें उसके इस दावे का अधिप्रमाणन होगा कि वह पूर्णतः नई प्रपुंज औषधि है, आवेदन देगा और वह सरकार को उक्त प्रपुंज औषधि का नाम, वह कीमत जिस पर उसके द्वारा विक्रय किया जा सकता है या आबद्ध उपभोग के लिए उसके द्वारा उपभोग किया जा सकता है या ऐसी अतिरिक्त जानकारी देगा जिसकी सरकार अपेक्षा करे:

परन्तु यह और कि उक्त नई प्रपुंज औषधि के बारे में सरकार को प्रस्तुत की गई कीमत सरकार की पूर्व मंजूरी के बिना बढ़ाई नहीं जाएगी।

(2) उपपैरा (1) में निर्दिष्ट पांच वर्ष की अवधि की समाप्ति के पश्चात् इस आदेश के उपबंध, उस उपपैरा में निर्दिष्ट नई प्रपुंज औषधि को लागू होंगे।

9. विनिर्मितियों के विनिर्माताओं को प्रपुंज औषधियों का विक्रय करने के लिए प्रपुंज औषधियों के विनिर्माताओं को निदेश देने की शक्ति—(1) सरकार समय-समय पर, साधारण या विशेष आदेश द्वारा, किसी प्रपुंज औषधि के किसी विनिर्माता को ऐसी प्रपुंज औषधि, विनिर्मितियों के ऐसे विनिर्माताओं को विक्रय करने के लिए ऐसा निर्देश दे सकेगी जैसा ऐसे आदेश में विनिर्दिष्ट किया जाए :

परन्तु ऐसा कोई आदेश देते समय, सरकार निम्नलिखित बातों में सभी या किन्हीं को विचार में रखेगी, अर्थात्:—

(क) ऐसे विनिर्माता के आबद्ध उपभोग की अपेक्षाएं;

(ख) विनिर्मितियों के अन्य विनिर्माताओं की अपेक्षाएं ;

(ग) समय-समय पर सरकार की नीति के अनुरूप भेषजीय उद्योग योजनाबद्ध अभिवृद्धि ।

(2) उपपैरा (1) के अधीन कोई आदेश करने के प्रयोजन के लिए, सरकार प्रपुंज औषधियों के विनिर्माताओं, आयातकर्ताओं या वितरकों से ऐसी जानकारी मांग सकेगी जैसी वह आवश्यक समझे और ऐसे विनिर्माता, आयातकर्ता या वितरक ऐसे जानकारी, ऐसी समय के भीतर जैसा सरकार विनिर्दिष्ट करे, देने के लिए बाध्य होंगे।

10. विनिर्माताओं की फुटकर कीमत की संगणना—किसी विनिर्मिति की फुटकर कीमत निम्नलिखित सूत्र के अनुसार संगणित की जाएगी, अर्थात् :—

$$\text{फु०की०} = \frac{(\text{सा०ला०} + \text{सं०ला०} + \text{पै०सा०} + \text{पै०प्र०}) \times (1 + \text{व०की०})}{100} + \text{उ०शु०}$$

यहां—

"फु० की०" से फुटकर कीमत अभिप्रेत है।

"सा०ला०" से सामग्री की कीमत अभिप्रेत है और इसके अन्तर्गत, सरकार द्वारा इस बारे में समय-समय पर राजपत्र में अधिसूचना द्वारा विनिर्दिष्ट किए गए ऐसे मानों के अनुसरण में औषधियों की लागत और अतिरिक्त माल, यदि कोई हो, सहित प्रयुक्त अन्य भेषजीय सहायता, तथा उस पर प्रक्रियागत हानि भी है ।

"सं० ला०" से ऐसे मानो के अनुसार निकाली गई वह संपरिवर्तन लागत अभिप्रेत है जो सरकार इस बारे में समय-समय पर राजपत्र में अधिसूचना द्वारा विनिर्दिष्ट करे।

"पै०सा०" से ऐसे मानो के अनुसार निकाली गई पैकिंग सामग्री की लागत, जिसके अन्तर्गत उस पर हुई प्रक्रियागत हानि भी है, अभिप्रेत है जो सरकार इस बारे में समय-समय पर राजपत्र में अधिसूचना द्वारा निनिर्दिष्ट करे।

"पै० प्र०" से ऐसे मानो के अनुसार निकाले गए पैकिंग प्रभार अभिप्रेत हैं जो सरकार इस बारे में समय-समय पर राजपत्र में अधिसूचना द्वारा विनिर्दिष्ट करे।

"व०की०" से पैरा 11 में विनिर्दिष्ट वर्धित कीमत अभिप्रेत है।

"उ०शु०" से उत्पाद-शुल्क अभिप्रेत है:

परन्तु किसी आयातित विनिर्मित की दशा में, उसके उतरने तक की लागत ऐसे मार्जिन सहित जैसा समय-समय पर अनुज्ञात करे, उसकी कीमत नियत करने का आधार होगी :

परन्तु यह और कि जहां कोई आयातित विनिर्दिष्ट पुनः पैक की जाती है, वहां उसकी कीमत नियत करने का आधार वह योग होगा जो ऐसे मानो के अनुसार, जैसे सरकार समय-समय पर राजपत्र में अधिसूचना द्वारा विनिर्दिष्ट करे, उसके उतरने तक की लागत, पैकिंग सामग्री की लागत और पैकिंग प्रभार को जोड़कर आए।

स्पष्टीकरण—इस पैरा के प्रयोजनों के लिए, "उतरने तक की लागत" से सीमा-शुल्क और निकासी प्रभारों सहित औषधि के आयात की लागत अभिप्रेत है।

11. वर्धित कीमत—पैरा 10 में निर्दिष्ट वर्धित कीमत के अन्तर्गत है, वितरण लागत, जावक भाड़ा, उन्नयन व्यय, विनिर्माता का मार्जिन और व्यवसाय कमीशन और यह निम्नलिखित से अधिक नहीं होगी :—

(क) तृतीय अनुसूची के प्रवर्ग 1 में विनिर्दिष्ट विनिर्मितियों की दशा में ..... चालीस प्रतिशत।

(ख) उक्त अनुसूची के प्रवर्ग 2 में विनिर्दिष्ट विनिर्मितियों की दशा में ..... पचपन प्रतिशत ;

(ग) उक्त अनुसूची के प्रवर्ग 3 में विनिर्दिष्ट विनिर्मितियों की दशा में .... शत प्रतिशत।

12. तृतीय अनुसूची के प्रवर्ग 1 और 2 में विनिर्दिष्ट विनिर्मितियों की अग्रणी कीमत नियत करने की सरकार की शक्ति.—(1) सरकार, तृतीय अनुसूची के प्रवर्ग 1 और प्रवर्ग 2 में विनिर्दिष्ट किसी विनिर्मिति की अग्रणी कीमत समय-समय पर राजपत्र में अधिसूचना द्वारा नियत कर सकेगी और ऐसी अग्रणी कीमत ऐसी विनिर्मितियों के प्रत्येक विनिर्माता के लिए अधिकतम विक्रय कीमत के रूप में रहेगी।

(2) उपपैरा (1) में अन्तर्विष्ट किसी बात के होते हुए भी, जहां इस आदेश के आरम्भ की तारीख को किसी विनिर्माता की विनिर्मिति की विक्रय कीमत उपपैरा (1) के अधीन नियत की गई अग्रणी कीमत से कम है, वहां ऐसा विनिर्माता सरकार के पूर्व अनुमोदन के बिना अपनी विनिर्मिति की विक्रय कीमत में वृद्धि नहीं करेगी।

(3) सरकार, स्वप्रेरणा से या इस निमित्त विनिर्माता द्वारा, यथास्थिति, प्ररूप 3 या प्ररूप 4 में किए गए आवेदन पर, ऐसी जानकारी प्राप्त करने के पश्चात् जैसी वह आवश्यक समझे, आदेश द्वारा किसी विनिर्मिति की पुनरीक्षित अग्रणी कीमत नियत कर सकेगा।

13. तृतीय अनुसूची के प्रवर्ग 3 में विनिर्दिष्ट विनिर्मितियों की फुटकर कीमत नियत करने की सरकार की शक्ति.—(1) सरकार, पैरा 10 और 11 के उपबन्धों के अनुसार तृतीय अनुसूची के प्रवर्ग 3 में विनिर्दिष्ट विनिर्मितियों की फुटकर कीमत समय-समय पर आदेश द्वारा नियत कर सकेगी।

(2) जहां सरकार इस आदेश के उपबन्धों के अधीन किसी प्रपुंज औषधि की कीमत नियत या पुनरीक्षित करती है और कोई विनिर्माता तृतीय अनुसूची के प्रवर्ग 3 में विनिर्दिष्ट अपनी विनिर्मिति में ऐसी प्रपुंज औषधि का उपयोग करता है तो वह ऐसे नियतन से पुनरीक्षण 30 दिन के भीतर, सरकार को यथास्थिति, प्ररूप 3 या प्ररूप 4 में आवेदन करेगा और सरकार यदि वह आवश्यक समझे तो, ऐसी विनिर्मिति की कीमत नियत या पुनरीक्षित कर सकेगी।

(3) कोई विनिर्माता उपपैरा (1) के अधीन किसी विनिर्मिति की सरकार द्वारा एक बार नियत की गई फुटकर कीमत में सरकार के पूर्व अनुमोदन के बिना वृद्धि नहीं करेगा।

(4) यदि कोई विनिर्माता उपपैरा (1) के अधीन नियत की गई किसी विनिर्मिति की फुटकर कीमत का पुनरीक्षण कराना चाहता है तो वह सरकार को, यथास्थिति, प्ररूप 3 या प्ररूप 4 में आवेदन करेगा और सरकार, ऐसी जानकारी प्राप्त करने के पश्चात् जो वह आवश्यक समझे, आदेश द्वारा, ऐसी विनिर्मिति की पुनरीक्षित कीमत नियत कर सकेगी।

(5) पूर्वगामी उपपैरा में अन्तर्विष्ट किसी बात के होते हुए भी, तृतीय अनुसूची के प्रवर्ग 3 में विनिर्दिष्ट विनिर्माता की किसी विनिर्मिति को फुटकर कीमत, जब तक कि उसकी फुटकर कीमत इस आदेश के उपबन्धों के अधीन नियत नहीं कर दी जाती, वह कीमत होगी जो इस आदेश के प्रारम्भ के तुरन्त पूर्व विद्यमान थी और ऐसी विनिर्मित का विनिर्माता ऐसी विनिर्मिति को पूर्वोक्त रूप में विद्यमान कीमत से अधिक विक्रय नहीं करेगा।

(6)(क) पूर्ववर्ती उपपैराओं के उपबन्धों पर प्रतिकूल प्रभाव डाले बिना, सरकार यदि वह ऐसा करना आवश्यक या समीचीन समझे तो, राजपत्र में अधिसूचना द्वारा तृतीय अनुसूची के प्रवर्ग 3 में विनिर्दिष्ट किसी विनिर्मिति की अग्रणी कीमत नियत कर सकेगी और ऐसी विनिर्मिति का विनिर्माता ऐसी विनिर्मिति का विक्रय इस प्रकार अधिसूचित कीमत से अधिक पर नहीं कर सकेगा और तदनुसार सरकार को सूचित करेगा।

(ख) उपपैरा (2) के उपबन्ध ऐसे विनिर्माता को लागू नहीं होंगे।

14. विनिर्मितियों की कीमत से संबंधित साधारण उपबन्ध.—(1) कोई भी विनिर्माता या आयातकर्ता सरकार से उसकी कीमत का पूर्व अनुमोदन प्राप्त किए बिना किसी नई विनिर्मिति का या तृतीय अनुसूची के प्रवर्ग 1 या प्रवर्ग 2 या प्रवर्ग 3 में विनिर्दिष्ट उसकी विद्यमान विनिर्मिति का नए पैक या नए मात्रा निर्धारण में विक्रय नहीं करेगा।

(2) कोई भी व्यक्ति, तृतीय अनुसूची के प्रवर्ग 1 या प्रवर्ग 2 या प्रवर्ग 3 में विनिर्दिष्ट किसी आयातित विनिर्मिति का विक्रय या व्ययन सरकार से उसकी कीमत का पूर्व अनुमोदन प्राप्त किए बिना नहीं करेगा।

(3) कोई भी ऐसा विनिर्माता या आयातकर्ता जो उपपैरा (1) या उपपैरा (2) में निर्दिष्ट किसी विनिर्मिति की कीमत की बाबत सरकार का अनुमोदन प्राप्त करना चाहता है, सरकार को यथास्थिति, प्ररूप 3 या प्ररूप 4 में आवेदन करेगा और सरकार आवेदन प्राप्त करने से चार मास की अवधि के भीतर अपना अनुमोदन ऐसे उपान्तरों के अधीन रहते हुए देगी, जो वह आवश्यक समझे :

परन्तु जहां चार मास का उक्त अवधि के भीतर अनुमोदन नहीं दिया जाता है वहां, यथास्थिति, विनिर्माता या आयातकर्ता उपपैरा (1) में निर्दिष्ट नई विनिर्मिति या नए पैक या नई डोज/नए मात्रा निर्धारण का विक्रय आवेदन पत्र में अपने द्वारा घोषित कीमत पर कर सकेगा और तुरन्त कीमत सूची जारी करेगा और तदनुसार सरकार को सूचित करेगा :

परन्तु यह और कि सरकार यदि वह आवश्यक समझे, तो यथास्थिति विनिर्माता या आयातकर्ता द्वारा इस प्रकार घोषित की गई कीमत का, आदेश द्वारा, पुनरीक्षण कर सकेगी और ऐसे पुनरीक्षण के पश्चात् विनिर्माता या आयातकर्ता ऐसी विनिर्मिति का विक्रय इस प्रकार पुनरीक्षित कीमत से अधिक कीमत पर नहीं करेगा ।

15. विनिर्मितियों की कीमत पुनरीक्षित करने की शक्ति.—इस आदेश में किसी बात के होते हुए भी,

(क) सरकार, विनिर्माता या आयातकर्ता से ऐसी जानकारी प्राप्त करने के पश्चात जैसी वह आवश्यक समझे, ऐसे विनिर्माता या आयातकर्ता द्वारा विक्रय की जाने वाली एक या अधिक विनिर्मितियों की जिसके अन्तर्गत तृतीय अनुसूची के प्रवर्गों में से किसी भी प्रवर्ग में विनिर्दिष्ट न की गई विनिर्मिति भी आती है, फुटकर कीमत ऐसी रीति में नियत या पुनरीक्षित कर सकेगी कि ऐसे विनिर्माता या आयातकर्ता के विक्रय आवर्त पर कर पूर्व प्रत्यागम पांचवीं अनुसूची में विनिर्दिष्ट अधिकतम कर पूर्व प्रत्यागम से अधिक न हों।

(ख) सरकार, यदि वह ऐसा करना लोकहित में आवश्यक समझे, तो, तृतीय अनुसूची के प्रवर्गों में से किसी प्रवर्ग में विनिर्दिष्ट किसी विनिर्मिति की फुटकर कीमत को आदेश द्वारा पुनरीक्षित कर सकेगी।

16. कुछ परिस्थितियों में कीमत नियत करना.—जहां किसी प्रपुंज औषधि या विनिर्मिति का कोई विनिर्माता, आयातकर्ता या वितरक इस आदेश के अधीन अपेक्षित रूप में और समय के भीतर जानकारी देने में असफल रहता है तो सरकार, अपने पास उपलब्ध जानकारी के आधार पर, यथास्थिति, ऐसी प्रपुंज औषधि या विनिर्मिति की बाबत आदेश द्वारा कीमत नियत कर सकेगी ।

17. औषधि कीमत समकारी लेखा :- (1) सरकार औषधि कीमत समकारी लेखा नामक एक लेखा रखेगी जिसमें

(क) यथास्थिति, विनिर्माता, आयातकर्ता या वितरक द्वारा

(i) पैरा 7 के पैरा के उपपैरा (2) के अधीन अवधारित रकम ;

(ii) अपनी प्रतिधारण कीमत के ऊपर यथास्थिति सामान्य विक्रय कीमत या पूलित कीमत का आधिक्य जमा किया जाएगा ; और

(ख) ऐसी अन्य धन राशियां जमा की जाएंगी जो इस निमित्त संसद द्वारा किए गए सम्यक विनियोग के पश्चात, सरकार समय समय पर अनुदत्त करे ।

(2) उपपैरा (1) के अधीन जमा की गई रकम केवल निम्नलिखित के लिए खर्च की जाएगी, अर्थात:-

(क) औषधों के उत्पादन में वृद्धि करने या उसका उचित वितरण निश्चित करने और उचित दर पर उन्हें उपलब्ध कराने के प्रयोजन के लिए यथास्थिति, विनिर्माता, आयातकर्ता या वितरक को, उसकी प्रतिधारण कीमत और यथास्थिति, सामान्य विक्रय या पूलित कीमत के बीच कमी का संदाय करने के लिए :-

(ख) इस पैरा के अधीन कृत्यों के निर्वहन में सरकार द्वारा उपगत खर्च के लिए ।

(3) प्रत्येक विनिर्माता, आयातकर्ता या वितरक, यदि उपपैरा (2) के खण्ड (क) के अधीन उसका कोई दावा है तो सरकार को आवेदन कर सकेगा और सरकार दावे को तय करने के लिए यथास्थिति विनिर्माता आयातकर्ता या विरक से यह अपेक्षा कर सकेगी, कि वह उसे ऐसे ब्यौरे दे जो इस निमित्त सरकार द्वारा विनिर्दिष्ट किए जाएं;

(4) सरकार औषधि कीमत समकारी लेखा में जमा की गई और उसमें से खर्च की गई सभी राशियों का और उक्त लेखे से संबंधित ऐसी अन्य रिपोर्टों और विवरणियों का जो वह आवश्यक समझे लेखा रखेगी ।

18. उस आदेश के कुछ उपबंधों का उन विनिर्मितियों को लागू होना जो तृतीय अनुसूची के प्रवर्ग 1 प्रवर्ग 2 या प्रवर्ग 3 में सम्मिलित नहीं है :-

इस आदेश के उपबंध पैरा 10 से 14 (दोनों सम्मिलित है) में अंतर्विष्ट उपबंधों को छोड़कर ऐसी किसी विनर्मित को लागू होंगे जो तृतीय अनुसूची के प्रवर्ग 1, प्रवर्ग 2 या प्रवर्ग 3 में विनिर्दिष्ट नहीं है ।

19 व्यवहारियों को विनिर्माता या आयातकर्ता द्वारा कीमत सूची का दिया जाना .—(1) विक्रय के लिए आशयित किसी विनिर्मिति का प्रत्येक विनिर्माता या आयातकर्ता, व्यवहारियों, राज्य औषधि नियंत्रकों और सरकार को एक कीमत सूची देगा, जिसमें वह कीमत (जिसमें उत्पाद शुल्क भी सम्मिलित है) जिस पर विनिर्मिति फुटकर विक्रेता को विक्रय की गई है और ऐसी विनिर्मिति को फुटकर कीमत दिखाई जाएगी और ऐसी सूची प्ररूप 5 में इस आदेश के प्रारम्भ से 30 दिन के भीतर व्यवहारियों को दे दी जाएगी :

परन्तु जहां विनिर्माता या आयातकर्ता ऐसी कीमत सूची देता है, वहां ऐसे विनिर्माता या आयातकर्ता के लिए प्रत्येक पश्चात्वर्ती विक्रय के समय व्यवहारी को एक नई कीमत सूची देना तब तक बाध्यकर नहीं होगा जब तक कि उस सूची में परिवर्धन, लोप या परिवर्तन के रूप में कोई संशोधन न किया जाए और इस दशा में एक अनुपूरक कीमत सूची दी जाएगी जिसमें ऐसे परिवर्धन, लोप या परिवर्तन का भी उल्लेख होगा।

(2) प्रत्येक विनिर्माता या आयातकर्ता समय समय पर सरकार द्वारा यथा-अनुमोदित परिवर्तित कीमतों की उस संसूचना की प्राप्ति से 15 दिन के भीतर, प्रभावी बनाएगा जो इस निमित्त सरकार ऐसे विनिर्माता या आयातकर्ता को दे ।

(3) प्रत्येक व्यवहारी कीमत सूची को परिसर के, जहां वह कारबार करता हो ऐसे सहज दृश्य भाग में ऐसी रीति से प्रदर्शित करेगा कि उसे देखने की इच्छा रखने वाला प्रत्येक व्यक्ति जब तब सुगमता से पहुंच सके ।

20. आधान के लेबल पर फुटकर कीमत प्रदर्शित करना .— विक्रय के लिए आशयित विनिर्मिति का प्रत्येक विनिर्माता, आयातकर्ता या वितरक, विनिर्मित के आधान के लेबल पर या फुटकर विक्रय के लिए दिए गए उसके छोटे से छोटे पैक पर, अमिट मुद्रण चिह्न उस विनिर्मिति की अधिकतम फुटकर कीमत निम्न प्रकार वर्णित करेगा अर्थात्, "खुदरा कीमत से अधिक नहीं होगी ।" "स्थानीय कर अतिरिक्त" ।

21. तृतीय अनुसूची में विनिर्दिष्ट विनिर्मितियों की विक्रय कीमतों पर नियंत्रण :—कोई भी थोक विक्रेता किसी व्यक्ति को तृतीय अनुसूची के प्रवर्गों में से किसी प्रवर्ग में विनिर्दिष्ट किसी विनिर्मिति का विक्रय चालू कीमत—सूची में विनिर्दिष्ट कीमत या आधान या उसके पैक के लेबल पर प्रदर्शित कीमत से, इनमें से जो भी कम है, अधिक कीमत पर विक्रय नहीं करेगा । स्थानीय कर, यदि कोई हैं, भी संदेय होंगे ।

स्पष्टीकरण :—इस पैरा के प्रयोजनों के लिए, 'स्थानीय कर' में, किसी विशिष्ट क्षेत्र में तत्समय प्रवृत्त किसी विधि के अधीन थोक विक्रेता द्वारा वस्तुतः संदत्त कोई विक्रय कर और चुंगी भी है ।

22. विनिर्मितियों की विभक्त क्वालिटी का विक्रय :—कोई भी व्यवहारी ऐसी विनिर्मिति के बोतल पैक में ली गई किसी विनिर्मिति का खुली मात्रा में विक्रय उस कीमत से अधिक कीमत पर नहीं करेगा जो उस विनिर्मिति की उस मात्रा की आनुपातिक कीमत और उसके 5 प्रतिशत से अधिक है :

परन्तु इससे संबंधित कोई बात व्यवहारी के परिसर में संयोजित विनिर्मिति को लागू नहीं होगी ।

23. विनिर्माता, वितरक और व्यवहारी औषधियों का विक्रय करने से इंकार नहीं करेंगे :—औषधि और प्रसाधन अधिनियम, 1940 (1940 का 23) के उपबंधों के अधीन रहते हुए,—

(क) कोई भी विनिर्माता या वितरक किसी व्यवहारी को कोई औषधि विक्रय करने से विधारण या इंकार, तब तक नहीं करेगा जब तक कोई उचित और पर्याप्त कारण न हो ।

(ख) कोई भी व्यवहारी कोई औषधि क्रय करने की वांछा रखने वाले किसी ग्राहक को अपने पास उपलब्ध किसी औषधि का विक्रय करने से विधारण या इंकार नहीं करेगा ।

24. थोक विक्रेता और फुटकर विक्रेता के लिए कीमतें (1) :—कोई भी विनिर्माता, आयातकर्ता या वितरक किसी थोक विक्रेता को, जब तक कि इस आदेश या किसी अन्य आदेश के अधीन बनाए गए उपबंधों के अधीन अन्यथा अनुज्ञात न हो, किसी विनिर्मिति का विक्रय निम्नलिखित से अधिक कीमत पर नहीं करेगा, अर्थात् :—

(क) नैतिक औषधि की दशा में फुटकर कीमत में से उसके 14 प्रतिशत को घटाकर, आई कीमत और

(ख) नैतिकेतर औषधि की दशा में, फुटकर कीमत में से उसके 12 प्रतिशत को घटाकर आई कीमत ।

(2) कोई भी विनिर्माता, आयातकर्ता, वितरक या थोक विक्रेता, किसी फुटकर विक्रेता को, जब तक कि इस आदेश या किसी अन्य आदेश के अधीन बनाए गए उपबंधों के अधीन अन्यथा अनुज्ञात न हो, किसी विनिर्मिति का विक्रय निम्नलिखित से अधिक कीमत पर नहीं करेगा, अर्थात् :—

(क) नैतिक औषधि की दशा में, फुटकर कीमत में से उसके 12 प्रतिशत को घटाकर आई कीमत ; और

(ख) नैतिकेतर औषधि की दशा में, फुटकर कीमत में से उसके 10 प्रतिशत को घटाकर आई कीमत ।

स्पष्टीकरण :—इस पैरा के प्रयोजनों के लिए,—(i) "नैतिक औषधि" के अन्तर्गत वे सभी औषधियां हैं जो औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) के अधीन निर्मित औषधि और प्रसाधन सामग्री नियम से संलग्न अनुसूची ग, अनुसूची ग(1) की प्रविष्टि सं० 1, [illegible], 7, 8 और 9 अनुसूची ड, अनुसूची छ अनुसूची ज और ठ में विनिर्दिष्ट की गई हैं ; और

(ii) नैतिकेतर औषध' से नैतिक औषधियों में भिन्न सभी औषधियां अभिप्रेत हैं ।

(3) उप-पैरा (1) और (2) में अन्तर्विष्ट किसी बात के होते हुए भी, सरकार, थोक विक्रेता या फुटकर विक्रेता को ऐसी किसी विनिर्मिति की बाबत, जिसकी कीमत इस आदेश के अधीन नियत या पुनरीक्षित हो चुकी है, कीमत लोक हित में साधारण या विशेष आदेश द्वारा, नियत कर सकेगा ।

25 अभिलेखों को रखना और निरीक्षण के लिए उन्हें पेश करना :—(1) प्रत्येक विनिर्माता अपने द्वारा विनिर्मित हरेक प्रपुंज औषधि के विक्रय आवर्त और विनिर्मितियों के विक्रय आवर्त का पैकों के हिसाब से ऐसे अन्य अभिलेख भी, जो समय समय पर सरकार द्वारा निर्दिष्ट किए जाएं, ऐसे प्ररूप में रखेगा जो सरकार द्वारा विनिर्दिष्ट किया जाए और ऐसे अभिलेख सरकार के निरीक्षण के लिए खुले रहेंगे ।

(2) प्रत्येक विनिर्माता लेखा वर्ष की समाप्ति से छह मास के भीतर सरकार को उस वर्ष के लिए प्ररूप 6 में जानकारी देगा ।

(3) प्रत्येक व्यवहारी या विनिर्माता औषधियों के क्रय और विक्रय के केश मेमो या उधार मेमों, लेखा-बहियां और अन्य अभिलेख रखेगा और उक्त अभिलेख सरकार के निरीक्षण के लिए उपलब्ध कराएगा ।

26. प्रवेश तलाशी और अभिग्रहण की शक्ति :—(1) केन्द्रीय सरकार या राज्य सरकार का कोई ऐसा राजपत्रित अधिकारी, जिसे इस निमित्त यथास्थिति केन्द्रीय सरकार या राज्य सरकार द्वारा किसी साधारण या विशेष आदेश द्वारा प्राधिकृत किया जाए, इस आदेश का पालन सुनिश्चित करने की दृष्टि से या अपना यह समाधान करने की दृष्टि से कि इस आदेश के उप-बंधों का अनुपालन किया गया है,—

(क) किसी स्थान में प्रवेश कर सके और उसकी तलाशी ले सकेगा;

(ख) किसी ऐसी औषधि को, जिसकी बाबत उसे यह संदेह है कि इस आदेश के किसी उप-बंध का उल्लंघन किया गया है, किया जा रहा है या किया जाने वाला है, उसके ऐसे आधानों, पैकों या आवेष्टनों सहित, जिसमें वह औषधि है, अभिग्रहीत कर सकेगा और तत्पश्चात् इस प्रकार अभिगृहीत की गई औषधि आधानों, पैकों या आवेष्टनों को न्यायालय में पेश किए जाने के लिए और ऐसे पेश किए जाने तक उनकी सुरक्षित अभिरक्षा के लिए, सभी आवश्यक उपाय करेगा ;

(ग) किसी ऐसी औषधि के क्रय विक्रय से संबंधित, जिसकी बाबत उसे यह संदेह है कि इस आदेश के किसी उपबंधित का उल्लंघन किया गया है, किया जा रहा है या किया जाने वाला है, किसी दस्तावेज, जैसे, केश मेमो या उधार मेमो पुस्तकें लेखा पुस्तकें और अन्य अभिलेख अभिगृहीत कर सकेगा ।

(2) तलाशी और अभिग्रहण से संबंधित दण्ड प्रक्रिया संहिता, 1973 (1974 का 2) की धारा 100 के उप-बंध, यथासंभव, इस आदेश के अधीन तलाशी और अभिग्रहण को लागू होंगे ।

27. पुनरीक्षण की शक्ति :—पैरा 3, 4, 5, 6, 7, 9, 12, 13, 14, 15 या 16 के अधीन किसी अधिसूचना या आदेश से व्यथित कोई व्यक्ति ऐसी अधिसूचना या आदेश के पुनरीक्षण के लिए सरकार को राजपत्र में ऐसी अधिसूचना के प्रकाशन की तारीख से या, यथास्थिति, उसके द्वारा ऐसा आदेश प्राप्त करने की तारीख से 15 दिन के भीतर आवेदन कर सकेगा और सरकार ऐसे आवेदन पर ऐसा आदेश कर सकेगा जैसा वह आवश्यक समझे ।

28. निदेश जारी करने की शक्ति :—सरकार, किसी विनिर्माता या आयातकर्ता को इस आदेश के उपबंधों से सुसंगत ऐसे निदेश समय-समय पर जारी कर सकेगी जो वह इस आदेश के उप-बंधों के अनुपालन के लिए आवश्यक समझे और ऐसा विनिर्माता या आयातकर्ता ऐसे निदेशों का पालन करेगा ।

29. शास्तियां :—इस आदेश के उपबंधों में से किसी भी उपबंध का उल्लंघन, आवश्यक वस्तु अधिनियम, 1955 (1955 का 10) के उपबन्धों के अनुसार दण्डनीय होगा ।

30. निर्वचन :—यदि किसी विनिर्मिति को तृतीय अनुसूची के प्रवर्गों में से किसी प्रवर्ग में रखने के बारे में कोई प्रश्न उत्पन्न होता है तो ऐसा प्रश्न सरकार द्वारा विनिश्चित किया जाएगा ।

31. छूट देने की शक्ति :—1 सरकार, उपपैरा (2) में उल्लिखित बातों को ध्यान में रखते हुए, और ऐसी शर्तों के यदि कोई हों, अधीन रहते हुए जो वह राजपत्र में आदेश द्वारा विनिर्दिष्ट करे, किसी औषधि विनिर्माता एकक या ऐसे किसी एकक वर्ग को, इस आदेश के सभी या किसी उपबंध के प्रवर्तन से छूट दे सकेगी और यथाशक्य ऐसे आदेश का प्रतिसंहरण या उपांतरण भी कर सकेगी ।

(2) सरकार, उपपैरा (1) के अधीन छूट देते समय, औषधि विनिर्माता एकक या किसी एकक वर्ग से संबंधित निम्नलिखित बातों में से सभी या किसी का ध्यान रखेगी, अर्थात :—

(क) नियोजित कर्मकारों की संख्या ;

(ख) विनिहित पूंजी की रकम ;

(ग) विनिर्मित उत्पादों की रेंज और किस्म;

(घ) विक्रय आवर्त ।

32. शक्तियों का प्रत्यायोजन :—सरकार, राजपत्र में अधिसूचना द्वारा यह निदेश दे सकेगी कि इस आदेश द्वारा प्रदत्त शक्तियों में से पैरा 27,28, 30 और 31 में अन्तर्विष्ट शक्तियों को छोड़कर, सभी या उनमें से किसी का प्रयोग, ऐसे निर्बंधनों, अपवादों और शर्तों के, यदि कोई हों, अधीन रहते हुए, जो निदेश में विनिर्दिष्ट किए जाएं, निम्नलिखित द्वारा भी किया जाएगा, अर्थात :—

(क) केन्द्रीय सरकार के अधीनस्थ ऐसे अधिकारी या प्राधिकारी द्वारा; अथवा

(ख) ऐसी राज्य सरकार या राज्य सरकार के अधीनस्थ ऐसे अधिकारी या प्राधिकारी द्वारा जो निदेश में विनिर्दिष्ट किया जाए ।

33. निरसन :—इस आदेश के प्रारम्भ से, औषधि (मूल्य नियंत्रण) आदेश 1970 प्रवृत्त नहीं रहेगा किन्तु ऐसी बातों के बारे में वह प्रवृत्त बना रहेगा जो ऐसे प्रवृत्त न रहने के पूर्व की गई है या जिनके किए जाने में लोप हुआ है ।

[सं० 5(3)/78—औषध-II]
एम० एम० पंडित, उप-सचिव,

प्रथम अनुसूची

[पैरा 3, 4, 6 (1), 7 (1) देखिए]

प्रपुंज औषधि

तृतीय अनुसूची में उल्लिखित प्रवर्ग 1 और 2 की विनिर्मितियों में प्रयोग की जाने वाली प्रपुंज औषधियों (जिनके अन्तर्गत लवण, संजात और एस्टर, यदि कोई हों, भी हैं)

I. प्रवर्ग : विनिर्मितियों में प्रयुक्त प्रपुंज औषधियां

क्रम सं०	प्रपुंज औषधि का नाम
1.	इन्सुलिन
2.	आयडो क्लोरो हाइड्रोक्वीनलिन
3	आयसोनिकोटीनिक आम्ल हाइड्राजाइड
4.	पास आम्ल
5.	पास सोडियम
6.	पोटैसियम पैंसिलीन जी
7.	सैमोडियम पैंसिलीन जी
8.	प्रोसीन पैंसिलीन
9.	पैंसिलन पोटैसियम (फेनोक्जी मिथाइल पैंसिलिन)
10.	स्ट्रेप्टोमाइसीन सल्फेट
11.	थियासेटाजोन
12.	डैप्सोन
13	एस्पिरिन
14.	पैथाडिन
15.	बेन्जाथिन पैंसिलीन
16.	कैल्सियम पास
17.	परटूसिस टोक्साइड
18.	डिप्थारिया टोक्साइड
19.	टेटनस टोक्साइड
20.	डिगोजिन
21.	हाइड्रोक्लोथियाजाइड
22.	डि-आयोडोहाइड्रोजीक्विनोलिन
23.	मार्फाइन सल्फेट

II. प्रवर्ग विनिर्मितियों में प्रयुक्त प्रज्ञ औषधियां

1. एमोडियाक्विन
2. क्लोरामफेनिकोल
3. क्लोरोक्विन
4. प्रेडनिसोलोन,
5. टेट्रासाइक्लिन
6. टालबुटामाइड
7. सल्फा डायमिडाइन
8. डिथाइल कार्बामजाइन साइट्रेट
9. एनल्जिन
10. फेनोबार्बिटोन
11. फेथालाइल सल्फाथायाजोल
12. कैल्सियम बी० पास
13. पिपराजाइन
14. फ्यूसेमाइड
15. आक्जीटेट्रासाइक्लिन
16. प्राइमाक्विन
17. ग्लीसरील ट्रिनाइट्रेट
18. क्विनाइन
19. पाइरोलिडिन मिथाइल टेट्रासाइक्लीन
20. डाइमेथाइल क्लोरो टेट्रासाइक्लिन

द्वितीय अनुसूची

[(पैरा 3, 4, 6(1), 7(i) देखिए]

तृतीय अनुसूची में उल्लिखित प्रवर्ग 3 के विनिर्मितियों में प्रयोग की जाने वाली प्रपुंज औषधियों (जिसके अंतर्गत लवण, संजात और एस्टर यदि कोई हों, भी हैं) की सूची

साधारण और स्थानिक निश्चेतक

1. बेंजोकाइन
2. क्लोरोफार्म
3. कोकीन
4. ईथर
5. इथाइल क्लोराइट
6. हालोथेन
7. ट्रि क्लोरोइथिलीन
8. प्रोकेन
9. कजाइलोकेन (लिग्नोकेन)
10. मार्फेन

11 थायोबेन्टोन सोडियम
12 केटामिन

II. पीड़ा नाशी और ज्वर नाशी

1 एमिडोपाइरीन
2 बरालगन केटोन
3 कोडीन
4 डेक्टोप्रोबोजाइपेन
5 फेन्टानिल साइट्रेट
6 मिथाइल सेलिकेनेट
7 ओसोडिन
8 पैरासिटामाल
9 पेन्टाजोकेन
10 फेनासेटीन
11 प्रोपोक्जी फेनाजोन
12 फेनीलिसो प्रोपाइल पैराजोनोल

III. कृमिनाशी

1 बेफेनियम
2 डिथाइजामिन आयोडिन
3 पाइरिविनियम
4 टैट्रामिसोल
5 थायबेन्डाजोल
6 पाइरान्टेल

IV. एन्ट्रीएमियोबिक

1 क्लोकीक्विनोलिन
2 क्लोबेन्जोक्सलिडिन
3 बिस्मथ ग्लाइकोलीलरसेनिलेट
4 डिहाइड्रोइमिटिन
5 डाइलोक्सामाइड
6 इमिटिन
7 फ्यूराजोलिडान
8 क्लोरोफेनोक्जामाइड
9 मेट्रोनिडाजोल
10 फानकोन

V. दमारोधी और आंत्रिक प्रतिरोधक (एन्टी सेप्टिक)

1 इफेड्रीन
2 प्स्टो डेकेड्रीन
3 सालबुटामाल
4 एमिनोफिलीन
5 थियोफिलीन
6 पापावेरीन
7 अजमलीसिन

VI. प्रतिजीवी (एन्टीबायटिक)

1 एम्फोटेरिसिन
2 बेसिट्रासिन
3 कार्बेनिसिलीन
4 कलाकेसिलिन
5 सेफालजीन
6 साइक्लोसेरिन
7 सेफालोरिडीन
8 डाक्सोसीलिन
9 फ्रामेस्टिन
10 जेन्टामाइसिन
11 ग्रामिसिडीन
12 ग्रीसेवफुलविन
13 कानामाइसिन
14 लिंको माइसिन
15 मैथिसिलन
16 निस्टाटिन
17 नीवोमाइसिन
18 ओक्जा सिलिन
19 ग्रोलियोन्डोमाइसिन
20 पैरान्थोमाइसिन
21 पोलीमिक्सिन
22 रिफाम्पिसिन
23 स्पीरामाइसन
24 विवोमाइसिन
25 लीवेसाइक्लीन
26 कोलीस्टीन
27 टाइरोथ्रीसिन
28 एम्पीसिलिन
29 एरिथ्रोमाइसिन

VII, कैंसर-रोधी औषधियां :

1 ला-स्पागिनेज
2 बसल्फान
3 क्लोरम्बुसिल
4 साइक्लोफास्फोमाइड
5 सेरुबिडिन (डाउनोरोबिसिन)
6 5 फ्लुरो यूरेसिल
7 मरकाप्टो प्यूरिन
8 थायोटेपा (एन एन ट्रिथाइनेथिपो-फासफोरामाइड
9 मिटोमाइसिन
10 एडबिवाबाइसिन
11 ब्लेयोमाइसिन
12 एजथियो प्राइम
13 मेल्फलान
14 विनब्लास्टिन
15 विक्रास्टिन

VIII. प्रतिस्कन्दक

1 वारफेरिन (3—(एल्फा-एसीटोनिल बेंजाइल)-4 हाइड्रोक्सी कोमेरिन)
2 हेपारिन
3 इथाइल बिस्कूमसिटेट
4 फनिरिडाइन
5 फेफड़े के ऊतक से पृथक किया गया या व्युत्पन्न हेपारिनाइड पदार्थ

IX. आक्षेप रोधी

1 ईथोसक्सीमाइड
2 डिफेनिल हाइडान्टोइन
3 प्रीमिडोन

X. मधुमेह रोधी

1 कार्बुटामाइड
2 क्लोरप्रोपामाइड
3 ग्लेबइक्लेमाइड
4 मिलफिजाइड
5 मटफार्मेन
6 फेनमार्मेन

XII. प्रतिहिस्टामिन :

1 एन्टाजोलिन
2 ब्रुसिलिजीन

3 साइक्लाइजिन
4 कार्बिनोक्जामाइन
5 क्लोरोसाइक्लिजाइन
6 क्लोरोफेनिरामाइन
7 क्लेमिसोल
8 डिमेनहाइड्रिनेट
9 डियेफिन्डोन
10 डिफेनहाइड्रामिन
11 दिफेनिल-पैरालिन
12 डिफेनिल विपेराडिन-प्रोपेन
13 हाइड्रोक्सिजिन
14 मेपिरामिन
15 मेथडिलाजिन
16 मेथापाइरिलेन
17 मेक्लोजिन
18 फेनिरामिन
19 ट्रेलोपिरामिन
20 प्रोमेथाजिन
21 मन० फिनान-एन-बेंजोन.-4-एमिनो-1-निथाइल पिपरामाइड
22 [illegible] फेनाल, बेंजील- एमिने
23 आइसोथियो पेण्डिल
24 फेनिण्डामिन
25 ट्राइईप्रोलिडिन
26 ट्रिप्यूनामिन
27 थेनालिडिन
28 ट्रिमेप्राजिन
29 साइप्रोहेप्टाडिन
30 डेक्साक्लोरोफेनिरामिन
31 वार्मीपियम (सावेन्टाल)

XII. कुष्ठ रोधी औषधियां :
क्लोफजिमिन

XIII. मलेरिया रोधी औषधियां
1 मेपाक्रीन
2 पीरिमेथामिन

XIV. आमवात रोधी :
1 इब्रूप्रोफेन
2 इण्डोमेथासिन
3 आक्सी-फिनाल बुटाजोन
4 फैनाल-बुटाजोन
5 सोडियम सेलिमिलेट

XV. प्रतिरोधी (एंटीमेंटिक)
1 क्लोरोक्जीनेनोल्म
2 क्लोरोक्रीसोल्म
3 हेक्सील रिसोरिनाल
4 थियोमोट
5 हाइड्रोजन पेरोक्साइड
6 आयोडिन
7 सैट्रीमाइड
8 क्लोरहैक्सिडिन

XVI. प्रतिउद्वेष्टी :
1 एट्रोपिन मिथाइलनाइट्रेट
2 हयाइन मोर्फिन
3 बेलाडोना अल्कालाइड
4 हाइमीन

XVII. यक्ष्मा रोधी :
1 ईथाम्बुटाल
2 इथियोनामाइड
3 पैराजिनामाइड
4 मार्फाजाइनामाइड
5 प्रोथियोना माइड

XVIII. हृदवाहिका :
(i) अतिरिक्त दाब रोधी :
1 रावेल्फिया आल्कलाइड्स
2 गुआनेथिडिन सल्फेट
3 मिथाइल डोपा
4 पेन्टोलिनियम टार्टरेट
5 डिहाइड्रोआर्गोक्रिस्टोन
6 फ्लोप्सोमाइड
7 क्लोनिडिन
8 डिहाइड्रालाजिन

(ii) पैरीफेरल वासोडायलेटर और कोरोनरी वासोडायलेटर :
1 हिस्टामाइन
2 आइसोएक्सुप्रीन
3 नीलीड्रिन
4 पेन्टा इरोथ्रीटाल टेट्रानाइट्रेट
5 प्रेनिलामिन
6 सोर्बाइड नाइट्रेट
7 डिपेरिडायाल
8 अमील नाइट्रेट
9 मेनीटाल हेक्सानाइट्रेट

(iii) हृदय ग्लाइकोसाइड्स :
1 डिजीटाविसन
2 लेनाटोसाइड्स
3 ओनाबाइन

(iv) अन्य :
1 निक्थेमाइड
2 क्लोफिब्रेट
3 जान्थिनाल निकोटिनेट
4 कार्वाकोल (40)
5 प्रोप्रानालोल
6 क्विनिडाइन
7 प्रोमेनामाइड
8 मेथाकोलीन

XIX. कोर्टिकास्टरायड्स
1 डेक्सामेथासोन
2 बेटानेथासोन
3 ट्रियामेमिनोलोन
4 प्रिडोनिसोन
5 हाइड्रोकोर्टिसोन
6 कोर्टिसोन
7 ए सी टी एच (कोर्टिकोट्रोपिन)

XX. ड्यूरोटिक्स
1 बेंजेथायाजाइड
2 बेंड्रोफ्लुआजाइड

3 क्लोरोथालिडेन
4 पोलाथायाजाइड
5 स्पीरानोलेक्टोन
6 ट्रिएम्बरेन
7 मर्मेलाइल एसिड
8 एसेटाज़ोला माइड
9 इथोजोला माइड
10 क्लोरोथियाजाइड
11 माइक्लोपैथ्या जाइड
12 हाइड्रो फ्यूमेथिया जाइड
13 इथेक्रीनिक एसिड

XXI. कैल्सियम थिरेपी में प्रयोग की जाने वाली औषधियां :

1 कैल्सियम ग्लूकोनेट
2 कैल्सियम लेवलिनेट
3 कैल्सियम लैक्बेट
4 कैल्सियम लैक्टोबायनेट

XXII. हेमाटिनिक्स :

1 फेरल ग्लूकोनेट
2 फेरस फूमारेट
3 केरस सल्फेट
4 आइरन डेक्ट्रान कम्पनेक्स
5 लिवर इक्स्ट्रैक्ट
6 फेरिक अमोनियम साइट्रेट
7 आइरन–सार्बिटाल कम्पनेक्स

XXIII. खाए जाने वाले गर्भ निरोधक :

1 ओस्ट्राडियोल
2 लीनेस्ट्रेनोल
3 ईथीस्टेरोन
4 मेस्ट्रानाल
5 नार–एस्थिट्रोन
6 डायमेथिस्ट्रोन
7 नारकेस्ट्रल
8 मेजेस्ट्राल
9 इथिनोडायल
10 नोरोथीनोड्राल

XXIV. नेत्र विज्ञान सम्बन्धी विनिर्मितियां :

1 सल्फासेटामाइड
2 बोरिक एसिड
3 एट्रोपिन
4 पिलोकार्पिन
5 फिनाइलोकाइन
6 होमाट्रोपिन
7 फिसोस्टिगमिन सेलिसिलेट

XXV. आक्सीटोकिक :

1 एर्गाट अल्कलाइड्स
2 आक्सीटोसिन

XXVI. प्लाज्मा प्रभासोज और संचरण घोल :

1 डेक्सट्रान
2 पालीविनायल पाइरोलिडीन
3 डेक्सट्रोज एनहाइड्रोज
4 सोडियम क्लोराइड
5 सोडियम लैक्टेट
6 पोटेसियम क्लोराइड

XXVII. सेरा और टीके :

1 (एन्टीरैबिक वैसिन) प्रत्यलर्क टीके
2 पीला ज्वर के टीके
3 कालरा के टीके
4 टेटनस एन्टीटाक्सिन
5 डिप्थेरिया एन्टीटाक्सिन
6 गैसगेंजरेन एन्टीटाक्सिन
7 एन्टीरैबिक सीरम
8 एण्टीवेनाम सीरम
9 बी० सी०जी० वैसिन
10 मियादी बुखार का टीका
11 पोली माइक्लिटिक्स वैसीन (ओरल)
12 टी ए बी वैसीन

XXVIII. मूत्रीय :

1 नाइट्रोफ्यूरान्टाइन
2 नालिडिक्सिक एसिड
3 मेथनिमाइन

XXIX. विटामिन :

1 विटामिन-ए
2 विटामिन-बी $_1$
3 विटामिन-बी $_2$
4 विटामिन-बी $_6$
5 विटामिन-बी 12 (साइनो और हाइड्रोक्सी)
6 विटामिन सी
7 विटामिन डी $_3$
8 विटामिन-के
9 विटामिन बी
10 विटामिन ई
11 नयासिना और निसिनामाइड
12 पैन्थेनॉल एवं पेन्टोन्थेनेट्स
13 फ्लोइक एसिड

XXX. प्रतिअम्ल

1 एल्युमिनियम हाइड्रोक्साइड
2 मैग्नीशियम कार्बोनेट
3 मैग्नेसियम ट्रिसेलिकिट
4 मैग्नेसियम हाइड्रोक्साइड
5 सोडियम बाइकार्बोनेट
6 कैल्सियम कार्बोनेट

XXXI. प्रवाटिका रोधी :

1 डिफेनोकनीलेट
2 सल्फागुआनिडिन
3 कावलिन
4 पेक्टिन

XXXII. गठिया रोधी औषधियां :

1 एलोपुरिनाल
2 प्रोबेनेसिड

XXXIII. निःसंक्रामक :

क्रेसोल्स

XXXIV. कासरोधी और कफोत्सारक :

1 क्लोफेडिनाल
2 डेक्ट्रोमेथोरफान

3 गुयाकोल ग्लाइकोरेल ईथर
4 नोस्कापिन
5 ऑक्सेलाडिन
6 पिपरोजेथेट
7 फोलकोडिन
8 मेथाल

XXXV. स्थानिक पीड़ानाशक पदार्थों से भिन्न दंत्य उत्पाद

1 सोडियम फ्लोराइड
2 स्टैनस फ्लोराइड

XXXVI. त्वचा संबंधी विनिर्मितियां जिनके अन्तर्गत प्रतिरोधी सल्फोनामाइड और कॉर्टिकोस्टराइड्स न हों :

1 सल्फर सबलाइड
2 मेथाक्सेलेन
3 इच्थामोल
4 अमोनिएटेड मर्करी
5 रिसोसिनोल
6 चेरीसारबिन
7 डिथ्रनोल
8 सेलिसाइक्लिक एसिड
9 बेंजाइक एसिड
10 जिंक आक्साइड
11 बेंजाइल बेंजोएट
12 गामा बेंजेनहेक्साक्लोराइड
13 कालामिन
14 क्लोरफेनिसन

XXXVII. परानुकम्पीसम

1 मेथाकोलिन
2 कार्बाकोल
3 नियोस्टिगमाइन
4 साइसोस्टामिन
5 एसेटेल कोलिन क्लोराइड
6 पीरिडोस्टिगामिन

XXXVIII. अन्य संक्रमण-रोधी

1 ट्राइमेथोप्रिन
2 सल्फामेथोक्जाल
3 सल्फामोक्सोल
4 सल्फाडिमेथोक्सिन
5 सल्फाफेनाजोल
6 सल्फापेथोक्सी पीरिडाजिन
7 सल्फासोमिडिन
8 सल्फाडायाजिन
9 सल्फाकुराजोल
10 सक्सिनाइल सल्फाथायाजोल
11 टोलनाफ्टेट

तृतीय अनुसूची

[पैरा 2(ञ), 11, 12, 13, 14, 15, 18, 21 और 30 देखिए]

विनिर्मितियां

प्रवर्ग I विनिर्मितियां

1. एस्प्रिन टेबलेट
2. डिजाक्सिन टेबलेट
3. डी डी एस टेबलेट
4. टी पी टी टीके
5 इन्सुलिन इंजेक्शन (सभी किस्म के)
6 हाइड्रो क्लोरोथाइजाइड टेबलेट
7 आयडो-क्लोरो-हाइड्रोक्सी, क्विनोलिन टेबलेट और डि-आयडो हाइड्रा आक्सी क्विनोलिन टेबलेट
8 आई एन एच टेबलेट
9 आई एन एच प्लस थायासेराजान टेबलेट
10 मार्फिन सल्फेट इंजेक्शन
11 पेंसिलिन इंजेक्शन इसके अन्तर्गत प्रोसिन पेंसिलिन-जी एवं बेंजिथिन पेंसिलिन (सभी प्रबलता वाले) भी हैं।
12 पास और उसके लवण, दाने और टेबलेट
13 फेनोक्सीमेथिल पेंसिलीन टेबलेट
14 स्ट्रेप्टामाइसिन इंजेक्शन सभी शक्तिवाले प्लस पेंसिलीन का काम्बिनेशन
15 पेथिडिन इंजेक्शन

प्रवर्ग II विनिर्मितियां

1 एनेल्जिन टेबलेट
2 एमोडियाक्विन टेबलेट
3 क्लोरम्फेनिकोल ओरल विनिर्मितियां जिसके अन्तर्गत क्लोरम्फेनिकोल पाल्मिटेट, सस्पेंसन और सीरप तथा क्लोरम्फेनिकोल इंजेक्शन योग्य सोडियम सक्सिनेट भी सम्मिलित है।
4 स्ट्रेप्टोमाइसिन यूक्त क्लोरामफेनिकोल
5 क्लोरोक्विन साल्ट
6 प्राइमाक्विन टेबलेट
7 कैल्शियम बेंजोल पारा टेबलेट
8 डियाइल कार्बोमाज इन साइट्रेट टेबलेट
9 फर्मेसाइड टेबलेट, इंजेक्शन
10 ग्लाइकोरल, ट्रिनाइट्रेट टेबलेट
11 फेथालिल सल्फाथायाजोल टेबलेट
12 प्रेडनिसोलोन टेबलेट और इंजेक्शन
13 फेनोबार्बिटोन टेबलेट्स
14 पिपराजाइन और इसके लवण, टेबलेट, सीरप
15 सल्फाडिमिडिन टेबलेट
16 टेट्रासाइक्लिन, कैप्सूल, टेबलेट, सीरप, इंजेक्शन ; आंख का मलहम (इसके अन्तर्गत आक्सीडिमिथाइल-क्लोरो एवं पीरोलिडिन मिथायल टेट्रासाइक्लिन भी सम्मिलित हैं)
17 टोलबुटामाइड
18 टेटनस टाक्साइड इंजेक्शन
19 डिप्थेरिया टेटनस टाक्साइड इंजेक्शन
20 क्वीनाइन साल्ट, टेबलेट और इंजेक्शन

प्रवर्ग III विनिर्मितियां

प्रवर्ग I और प्रवर्ग II में सम्मिलित की गई विनिर्मितियों से भिन्न निम्नलिखित प्रवर्गों में आने वाली औषधियों पर आधारित विनिर्मितियां

1 एनस्थेटिक, सामान्य और स्थानिक
2 एनल्जेसिक्स एवं एन्टीपैरेटिक्स
3 एन्थेलिमिनिक्स
4 एन्टीएमोएबिक्स
5 प्रतिश्वासरोधी औषधियां और आंत्रिक पूतिरोधी
6 प्रतिजीवी इसके अन्तर्गत अर्धकृत्रिम प्रतिजीवी भी हैं
7 कैंसररोधी औषधियां
8 स्कंधनरोधी
9 आक्षेपरोधी
10 मधुमेहरोधी
11 प्रतिहिस्टामिन
12 कुष्ठरोधी औषधियां

13. मलेरिया रोधी औषधियां
14. आमवातरोधी और एन्टीगाउट औषधियां
15. प्रतिरोधी
16. आक्षेपरोधी
17. यक्ष्मारोधी औषधियां
18. हृदयवाहिका औषधियां
19. कार्टिकोस्टेराइड्स
20. डयूरेटिक्स
21. कैल्सियम थिरेपी में प्रयोग की जाने वाली औषधियां
22. हेमेटिनिक्स
23. ओरल कन्ट्रासेप्टिव
24. नेत्रविज्ञान संबंधी विनिर्मितियां
25. आक्सीटोसिक्स
26. प्लास्मा इक्सपेन्डर्स और ट्रांसफ्यूजन सल्यूशन
27. सैरा और टीके
28. विटामिन
29. मूत्रीय औषधियां
30. प्रत्यम्ल (एन्टासाइड्स)
31. डायरिया-रोधी
32. निःसंक्रामक
33. कासरोधी और कफोत्सारक
34. स्थानिक संज्ञाहरण पदार्थों से भिन्न दन्त उत्पाद
35. त्वचा संबंधी विनिर्मितियां जिनमें प्रतिरोधी सल्फोनामाइड और कार्टिकोस्टराइड्स न हों
36. ओटिक विनिर्मितियां जो प्रतिरोधियों पर आधारित न हों
37. पैराअनुकम्पीसम
38. अन्य संक्रमण रोधी

चौथी अनुसूची

प्ररूप

प्ररूप-1 (दो प्रतियों में दिया जाए)

[पैरा 2(ङ) 3(4) 5 और 8(1) देखिए]

प्रपुंज औषधियों की कीमत नियत करने या पुनरीक्षित करने के लिए आवेदन का प्ररूप

1. प्रपुंज औषधि का नाम
2. विनिर्माता का नाम
3. विनिर्माता के रजिस्ट्रीकृत/प्रधान कार्यालय का पता
4. कारखाने का पता :
   (क) औद्योगिक अनुज्ञप्ति/एस एस आई रजिस्ट्रीकरण संख्यांक
5. अनुज्ञप्त क्षमता
   (ख) अनुज्ञप्ति जारी करने की/रजिस्ट्रीकरण की तारीख
   (ग) उत्पादन क्षमता :
   अनुज्ञप्त : टन/किलोग्राम/लिटर आदि
6. प्रतिष्ठापित क्षमता :
   (क) पारियों की संख्या ; एक/दो/तीन
   (ख) प्रतिवर्ष कार्य दिनों की संख्या
   (ग) प्रति पारी अधिकतम उत्पादन : टन/किलो/लिटर आदि
   (घ) कार्याधिकार प्रदान किए जाने की तारीख
   (ङ) प्रतिवर्ष प्रतिष्ठापित क्षमता
7. वाणिज्यिक उत्पादन आरम्भ होने की तारीख :
8. अन्तिम लेखा वर्ष के दौरान वस्तुतः हुआ उत्पादन (अधिमानतः मास दर मास) और चालू वर्ष के दौरान मासिक उत्पादन भी—टन/किलो/लिटर आदि
9. आप द्वारा अपनाई गई विनिर्माण प्रक्रिया का संक्षिप्त टिप्पण जिसमें सभी प्रक्रम, जिनके अन्तर्गत उप उत्पाद, यदि कोई हों, विलायकों आदि की प्राप्ति भी है, और प्रत्येक औषधि के लिए प्रक्रमवार पूर्ण उत्पादन उपदर्शित किया जाए ।
10. वाणिज्यक उत्पादन आरम्भ होने से प्रत्येक प्रपुंज औषधि के प्रति घंटे औसत उत्पादन की दर ।
11. प्रति घंटे अधिकतम उत्पादन-दर जो प्राप्त करनी है ।
12. अगले तीन वर्षों के दौरान प्रपुंज औषधि का अनुमानित उत्पादन ।
13. यदि विनिर्मितियां के विनिर्माण के लिए उत्पादन का उपभोग भीतर ही करने का प्रस्ताव है तो कृपया क्रम सं० 8 और क्रम सं० 12 के सामने दिए गए उत्पादन में से इस प्रकार उपभोग की जाने वाली मात्रा का उल्लेख करें ।
14. प्रपुंज औषधियों के विनिर्माण के लिए नियोजित पूंजी :
   (क) शुद्ध नियत आस्तियां (अवक्षयण के पश्चात्) =
   (ख) काम-काज पूंजी =
   (ग) योग =

   (बहुउद्देश्यीय संयंत्रों की दशा में, उपरोक्त रीति में नियोजित पूंजी और विचाराधीन प्रपुंज औषधि । मध्यवर्ती के लिए आवंटित की जाने वाली रकम का उल्लेख करें)
15. कृपया बताएं कि किस प्रकार उक्त नियोजित पूंजी को निवल संपत्ति और उधारों द्वारा वित्तपोषित किया जाएगा ।
16. कृपया बताएं कि उधारों पर आप द्वारा संदत्त औसत ब्याज की दर क्या है, समर्थन में अंक भी दें ।
17. कृपया प्रपुंज औषधि का लागत, बीमा और भाड़ा सहित कीमत प्रस्तुत करें, यदि ऐसी औषधि आप द्वारा या आपकी जानकार किसी अभिकरण द्वारा निर्यात की गई है या निर्यात की जा रही है ।
18. कृपया संलग्न प्ररूप में, प्रपुंज औषधि के उत्पादन की लागत व्यवसायरत लागत । चार्टर्ड एकाउन्टेंट द्वारा सम्यक्तः प्रमाणित रूप में प्रस्तुत करें ।

टिप्पण :

(1) उत्पादन को प्रमाणित करने वाला कोई अवरोध स्पष्टरूप से क्रम सं० 8 के सामने उपदर्शित किया जाएगा ।

(2) यदि एक से अधिक उत्पादों के लिए एक ही संयंत्र की सुविधाएं ली गई हैं तो क्रम सं० 6 के अनुसार उत्पादवार जानकारी दी जा सकती है ।

(3) कृपया पिछले तीन वर्ष के लेखा परीक्षित तुलन पत्रों और लाभ तथा हानि की प्रतियां प्रस्तुत करें ।

प्ररूप

(मद 18 देखिए)

1 प्रपुंज औषधि का नाम

2. (क) उत्पादन—टन/किलो/लिटर/आदि में

(ख) विक्रय—टन/किलो/लिटर/आदि में

(ग) प्रेषण—टन/किलो/लिटर/आदि में

3 अवधि जिसकी बाबत लागत लेखा दिया गया :

विशिष्टियां	जानकारी संबंधी परियोजना रिपोर्ट के आधार पर प्रतिमान या प्रदायकर्ता द्वारा प्रत्याभूति प्रतिमान या मानक के रूप में आपके द्वारा विकलित प्रतिमान				
एकक	अवधि के दौरान वास्तविक उपयोग	दर	रकम	उत्पादन प्रति एकक	
				मात्रा	लागत रु०
1. कच्ची सामग्री					
(क) आयातित					
1.					
2.					
3.					
(ख) देशी					
1.					
2.					
3.					
प्राप्त विनायक निकाल कर कुल कच्ची सामग्री की लागत शुद्ध कच्ची सामग्री की लागत					
2 उपयोगी चीजें					
(क) विद्युत					
(ख) जल					
(ग) ईंधन तेल					
(घ) अन्य सेवाएं (विनिर्दिष्ट की जाएं)					
3 संपरिवर्तन लागत :					
(क) वेतन और मजदूरी					
(ख) प्रचालन प्रदाय या उपभोज्य वस्तुएं					
(ग) मरम्मत और अनुरक्षण					
(घ) अन्य कारखाना उपरिव्यय					
(ङ) प्रशासनिक उपरिव्यय					
(च) अवक्षयण					
4. उत्पादन की कुल लागत					
5. उधारों पर ब्याज					
6 न्यूनतम बोनस					
योग					
7. पैकिंग					
(क) सामग्री					
(ख) अन्य व्यय					
8. विक्रय व्यय					
9 परिवहन प्रभार					
10 परिवहन बीमा प्रभार					
11. कुल विक्रय लागत					
12 लाभ का मार्जिन (संगणना का आधार दिया जाए)					
13 विक्रय कीमत (11+12)					
14 विद्यमान कीमत या अभिकल्पित कीमत या घोषित कीमत					

टिप्पण :

(1) व्यय की वे मदें, जिनकी लागत में अवक्रमण करना है :

(क) कानूनी न्यूनतम से अधिक बोनस
(ख) डूबत ऋण और व्यवस्थाएं
(ग) अनुदान और खैरात
(घ) आस्तियों के विक्रय में हानि/लाभ
(ङ) दलाली और कमीशन
(च) व्यय जिन्हें आय-कर प्राधिकारियों ने मान्यता नहीं दी है (वेतन/परिलब्धियां, विज्ञापन आदि)
(छ) पूर्व वर्षों से सम्बद्ध समायोजन ।

(2) आयातित कच्ची सामग्री की दशा में कृपया पृथक रूप से लागत बीमा भाड़ा कीमत, सीमा शुल्क और अन्य प्रभार भी हैं, जिनका योग, क्रम सं० 1क के सामने दी गई अवक्रमित लागत के बराबर है ।

(3) भीतरी उपयोग के लिए विनिर्मित मध्यवर्तियों की लागत, कारखाने की उत्पादन लागत, जिसके अन्तर्गत प्रशासनिक उपरिव्यय भी हैं, के आधार पर होनी चाहिए और क्रम सं० 1(ख) के सामने पृथकतः दर्शित की जानी चाहिए । उसी प्ररूप में पृथक रूप से एक लागत-पत्र उपाबद्ध किया जाना चाहिए ।

(4) जनन की जाने वाली उपयोगी चीजों जैसे विद्युत, भाप आदि की लागत पृथक रूप से दी जाएगी । साथ में क्रय कर के उपयोग की गई उपयोगी चीजों की दर और लागत के विवरणों सहित क्रम सं० 2 के प्रतिनिर्देश में उनके जनन पर उपगत अन्य व्यय ।

(5) कारखाना उपरिव्यय, प्रशासनिक उपरिव्यय और विक्रय व्ययों के संबंध में उल्लेख, क्रम सं० 3(घ), (ङ) और क्रम सं० 8 के सामने किया जाना चाहिए ।

(6) आपके वित्तीय लेखा में अपनाया गया अवक्षयण का आधार क्रम सं० 3(च) के सामने दें ।

(7) कृपया क्रम सं० 14 के सामने यह उपदर्शित करें कि विद्यमान अभिकल्पित, घोषित या अनुमोदित कीमत है ।

लागत लेखापाल/चार्टर्ड एकाउन्टेंट द्वारा प्रमाणित किया जाए ।

प्ररूप 2 (अनुसूची I और II के अन्तर्गत आने वाली औषधियों के सभी आयातकर्ता प्रत्येक आयातित परिणाम के लिए इसे दो प्रतियों में प्रस्तुत करें ।)

[पैरा 2(ङ) और (6) देखिए]

प्रपुंज औषधि के प्रत्येक आयात के पश्चात प्रत्येक आयातकर्ता द्वारा प्रस्तुत किए जाने वाले आवेदन का प्ररूप ।

1. कम्पनी का नाम
2 रजिस्ट्रीकृत प्रधान कार्यालय/कारखाने का, यदि कोई है, पता
3 प्रपुंज औषधि के आयात के लिए सक्षम प्राधिकारियों द्वारा दी गई अनुज्ञा का संदर्भ
4 औषधि का नाम
5. औषधि की विशिष्टता
6. वह देश जहां से आयात की गई

7. आयातित माल की इकाई/किलो/लिटर/आदि

8. विदेशी मुद्रा में परिवहन, बीमा, भाड़ा मूल्य

	योग रु.	प्रति एकक रु०
(क) वस्तुतः संदत्त परिवहन बीमा भाड़ा मूल्य (रुपयों में) (इसके अन्तर्गत, बैंक कमीशन, ब्याज आदि नहीं हैं)		
(ख) वस्तुतः संदत्त सीमा-शुल्क		
(ग) वस्तुतः उपगत निकासी प्रभार, विस्तार सहित।		
(घ) अवतरण लागत (क+ख+ग)		
(ङ) उन व्यक्तियों की दशा में जो केवल विक्रय के लिए आयात करते हैं, आयातकर्ता का लाभ।		
(च) प्रस्तावित विक्रय कीमत/अभिकल्पित कीमत		
(छ) विद्यमान विक्रय कीमत/अभिकल्पित कीमत, यदि कोई है		

टिप्पण : यहां दिए गए आंकड़े आवश्यकतः लागत लेखापाल/चार्टर्ड एकाउन्टेंट द्वारा प्रमाणित किए जाएंगे।

प्ररूप 3 [पैरा 2(3), 12, 13 और 14]

(विनिर्माताओं की कीमत का अनुमोदन या पुनरीक्षण चाहने वाले विनिर्माताओं के लिए आवेदन का प्ररूप—यह सात प्रतियों में प्रस्तुत किया जायगा)

1. विनिर्माता का नाम
2. रजिस्ट्रीकृत/प्रधान कार्यालय का पता
3. कारखाने का पता
4. विनिर्मिति का नाम
5. विनिर्मित का प्रवर्ग और औषधि (कीमत नियंत्रण) आदेश, 1979 की अनुसूची 3 के अनुसार उसका चिकित्सीय समूह।
6. औषधि नियंत्रण प्राधिकारियों द्वारा यथा अनुमोदित मिश्रण
7. औद्योगिक अनुज्ञप्ति/लघु उद्योग एकक का रजिस्ट्री सं० और तारीख
8. औषधि नियंत्रण प्राधिकारियों की अनुज्ञा और तारीख
9. विनिर्मिति की किस्म :

सादी टेबलेट/लेपित टेबलेट/नरम/कठोर/मुद्रित/कैप्सूल/सीलिंग वैक्स/सहित/रहित/रोगाणुरहित/गैर रोगाणुरहित/द्रव/चूर्ण/मलहम/क्रीम आदि।

10. पैकिंग की किस्म

अल्मोनियम/कागज/सेलोफेन/पट्टियां/बायल/एम्पुल/बोतल/टिन/जार/ड्रापर/सहित/रहित/काटने की ब्लेड/कैच ओवर आदि।

11. पैकेज का आकार :

10 वाला/100 वाला/आदि/1 मि०लि०/2 मि०लि०/10 मि०लि०/आदि/5 ग्राम/10 ग्राम/आदि।

12. पूर्व लेखा वर्ष के दौरान विक्रीत पैकेटों की संख्या

13. पूर्व लेखा वर्ष के दौरान किए गए विक्रय का मूल्य उत्पाद निकाल कर और उत्पाद निकाल कर विनिर्मितियों के कुल विक्रय के साथ उसका प्रतिशत (ऊपर 12 और 13 केवल पुनरीक्षण आवेदन की दशा में ही लागू होंगे)।

14. फुटकर मूल्य का कोटा विद्यमान (यदि कोई है) अब दावा किया गया है।

	रु०	रु०
	..... को	पैकेज
(अनुमोदित पैक)		
(क) सामग्री लागत (क्रम सं० 15 (घ) के अनुसार सं०ला०)		
(ख) संपरिवर्तन लागत (प्रतिमान के अनुसार सं०ला०)		
(ग) पैकिंग सामग्री की लागत (पै०सा०) (प्रतिमान के अनुसार क्रम सं० 16 के अनुसार)		

15. सामग्री लागत :

(क) बैच आकार

संख्या टिलर किलो आदि

(ख) ऊपर (क) के अनुसार बैच आकार में वस्तुतः प्राप्त पैकेजों की संख्या

(ग) ऊपर (क) के अनुसार बैच आकार में सिद्धांतः प्राप्त हो सकने वाले पैकेजों की संख्या

(घ) ऊपर (क) में के बैच आकार के लिए सामग्री की लागत :

क्रम सं०	सामग्री का नाम	एकक	पूर्व दर एकक, यदि कोई है (तारीख) रु०	चालू दर एकक (तारीख)	प्रति बैच अपेक्षित सैद्धांतिक मात्रा	अधिक्य उपरिभार, यदि कोई हो	अपेक्षित कुल मात्रा	बैच की लागत (5×8) रु०
1	2	3	4	5	6	7	8	9
आयातित								
1								
2								
3 आदि								
देशी								
1								
2								
3 आदि								
जोड़								

जोड़े : प्रतिमान के अनुसार प्रसंस्करण क्षति ..... प्रतिशत

कुल सामग्री लागत

प्रति बैच सामग्री लागत

कुल सामग्री लागत

सैद्धांतिक पैकेज संख्या

प्ररूप 4 (सात प्रतियों में प्रस्तुत किया जाए)

[पैरा 2(ग) 12, 13 और 14]

तैयार रूप में आयातित विनिर्मितियों की कीमत अनुमोदित करने के लिए दिए जाने वाले आवेदन का प्ररुप

1. कम्पनी का नाम
2. रजिस्ट्रीकृत प्रधान कार्यालय/कारखाने का पता यदि कोई है
3. इस मद के आयात के लिए प्राधिकारियों द्वारा दी गई अनुमति का निदेश, यदि कोई है
4. आयातित विनिर्मिति का नाम
5. विनिर्मिति की किस्म
   कैप्सूल/टेबलेट आदि
6. विनिर्मितियों का मिश्रण
7. पैकों की किस्म
   पट्टियां/वायल/एम्पुल/आदि
8. पैकेज का आकार
   10 वाला/आदि/10 मि०ली०/आदि 5/ग्राम/आदि
9. वे देश जहां से आयात किया गया है और आयात की तारीख
10. आयातित माल/पैकों की संख्या — योग — प्रति पैकेज रु०
11. विदेशी मुद्रा में लागत बीमा भाड़ा मूल्य
    (इसमें बैंक कमीशन, ब्याज आदि सम्मिलित नहीं है)
12. वस्तुतः संदत्त लागत बीमा भाड़ा मूल्य (रुपयों में)
    (इसमें बैंक कमीशन, ब्याज आदि सम्मिलित नहीं है)
13. वस्तुतः संदत्त सीमा-शुल्क, यदि कोई है।
14. वस्तुतः उपगत निकासी प्रभार (ब्यौरे सहित)
15. अवतरण लागत (12+13+14)
16. पैकिंग सामग्री, यदि कोई है, प्रतिमान के अनुसार — पुनः पैकिंग की दशा में लागू होगा
17. पैकिंग प्रभार, यदि कोई है, प्रतिमान के अनुसार
18. अवतरण लागत, जिसके अन्तर्गत पुनः पैकिंग लागत, यदि कोई है, भी है (15 से 17)
19. क्रम सं० 18 के ..... प्रतिशत की दर से वर्धित कीमत का दावा
20. उत्पाद शुल्क, यदि कोई है
21. दावाकृत फुटकर कीमत (18 से 20) .....
    .....
22. (क) विद्यमान फुटकर कीमत, यदि कोई है
    (ख) पूर्व लेखा वर्ष के दौरान विक्रीत पैकों की संख्या, यदि कोई है
    (ग) विक्रयों का मूल्य, पूर्व वर्ष में लगाए गए उत्पाद शुल्क यदि कोई है, को अपवर्जित करके

टिप्पण : यहां दिए गए आंकड़ें व्यवसायरत लागत लेखापाल/चार्टर्ड एकाउण्टेंट द्वारा प्रमाणित किए जाएंगे।

16. पैकेजिंग सामग्री लागत :

क्रम सं०	पैकेजिंग सामग्री	एकक	प्रति एकक दर रु०		बैच आकार पैकेज प्रत्येक ग्राम /आदि टेबलेट के——— प्रति बैच के लिए अपेक्षित मात्रा संख्या किलो आदि	प्रति बैच पैकेजिंग सामग्री का मूल्य रु०
			पूर्व (तारीख)	वर्तमान (तारीख)		
1	2	3	4		5	6

जोड़

जोड़ : प्रतिमान के अनुसार प्रसंस्करण क्षति

ऊपर का

कुल पैकिंग सामग्री लागत

प्रति पैकेज पैकिंग सामग्री लागत

कुल पैकिंग सामग्री लागत

बैच आकार पैकेजों की सं०

टिप्पण : इस प्रारूप के आंकड़े व्यवसायरत लागत लेखापाल चार्टर्ड एकाउण्टेण्ट द्वारा प्रमाणित किए जाएंगे ।

(घ) पैकिंग प्रभार (प० ए०) (प्रतिमान के अनुसार)

(ङ) कारखाने के द्वार पर लागत

(क से घ)

(च) ऊपर (ङ) का दर वर्धित कीमत (व० की) का प्रतिशत.....

(छ) उत्पाद-शुल्क

(ज) फुटकर कीमत

(फु० की०) (ङ+च+छ)

प्ररूप 5

[पैरा 2 (ग) और 17 देखिए]

(कीमत सूची का प्ररूप)

क्रम सं०	विनिर्मिति का नाम और उसका प्ररूप	विनिर्मिति (मुख्य संघटक दिए जाएं)	पैकों की विशिष्टियां		उत्पाद-शुल्क		फुटकर विक्रेता के लिए कीमत (उत्पाद शुल्क सहित) रु०	फुटकर कीमत (उत्पाद शुल्क सहित) रु०
			किस्म (पट्टियां/ बोतल/आदि)	आकार (10 वाली/ 100 वाली/ आदि मि० लि०/ आदि 1 मि० ग्रा० / आदि)	दर प्रतिशत	रकम रु०		
1	2	3	4	5	6	7	8	9

टिप्पण : इस प्ररूप के अनुसार सभी मदों के लिए, जिसके अन्तर्गत अनियंत्रित औषधियां भी हैं, जानकारी अनुसूची 1 में विनिर्दिष्ट रूप में प्रवर्गानुसार दी जाएगी ।

प्ररूप 6

वार्षिक जानकारी

[पैरा 2 (ङ) और 25 देखिए]

1. विनिर्माता का नाम
2. रजिस्ट्रीकृत प्रधान कार्यालय/कारखाने का पता
3. लेखा वर्ष जिसकी जानकारी दी गई है
4. प्रपुंज औषधि का आवर्त :—

प्रपुंज औषधि का नाम	मात्रा उपयुक्त	विक्रीत	विक्रय मूल्य (उत्पाद-शुल्क यदि कोई है, छोड़कर)
			खपत की गई रु०	विक्रीत रु०
(i) अनुसूची 1 में सूचीबद्ध औषधियां	किलो/लिटर/ आदि	किलो/लिटर/ आदि		
(क) आयातित				
1.				
2.				
3. आदि				
(ख) देशी				
1.				
2.				
3. आदि				
(ii) अनुसूची 11 में सूचीबद्ध औषधियां				
(क) आयातित				
1.				
2.				
3. आदि				
(ख) देशी				
1.				
2.				
3. आदि				
(iii) अन्य प्रपुंज औषधियां				
1.				
2.				
3.				
योग				

विनिर्मितियों का आवर्त

क्रम सं०	नाम	पैकों का आकार	पैकों की संख्या	उत्पाद शुल्क छोड़कर विक्रय मूल्य रु०
क. निजी विनिर्मितियां				
(i) प्रवर्ग 1				
1.				
2.				
3. आदि				
(ii) प्रवर्ग 2				
1.				
2.				
3. आदि				
(iii) प्रवर्ग 3				
1.				
2.				
3. आदि				
(iv) अन्य				
1.				
2.				
3. आदि				
ख. उपयोग ( )				
क्रय की गई विनिर्मितियां				
(क) आयातित				
(i) प्रवर्ग 1				
1.				
2.				
3. आदि				
(ii) प्रवर्ग 2				
1.				
2.				
3. आदि				
(iii) प्रवर्ग 3				
1.				
2..				
3. आदि				
(4) अन्य				
1.				
2.				
3. आदि				
उपयोग (ख क)				
ख) देसी :				
बताए गए रूप में प्रवर्गानुसार				
(ग) उपयोग (ख ख)				
निर्यात विक्रय				
कुल जोड़ (क ख ग)				

लेखा परीक्षित लाभ और हानि लेखे में यथादर्शित विक्रय और व्ययों का आबंटन

(रुपयों में)

क्र० सं०	विशिष्टियां	लेखा परीक्षित लाभ और हानि			निम्नलिखित को आबंटन					
		लेखा के अनुसार योग	प्रपुंज औषधि	निजी विनिर्माता	आयातित	निर्यात	देशी क्रय	(5 से 8) का उपयोग	अन्य क्रिया-कलाप (यदि कोई हो ( )	आबंटन का आधार
1	2	3	4	5	6	7	8	9	10	11
क. आय										
	1. विक्रय आय (उत्पाद शुल्क तथा अन्य करों को छोड़कर)									
	2. नकद सहायकी (यदि कोई है)									
	3. अन्य आय योग (1 से 3 तक का)									
ख. व्यय										
	4. खपत की गई कच्ची सामग्री									
	5. पैकिंग सामग्री									
	6. पावर और ईंधन									
	7. वेतन और मजदूरी									
	8. सामान और पुर्जे									
	9. मरम्मत और रखरखाव									
	10. बीमा									
	11. अवक्षयण									
	12. स्वामित्व									
	13. ब्याज									
	14. प्रधान कार्यालय व्यय									
	15. व्यवहारी का कमीशन और छूट									
	16. अनुसंधान और विकास व्यय									
	17. अन्य व्यय									
	(4 से 17 का) जोड़									
ग.	कर पूर्व लाभ (क-ख)									
घ.	विक्रय आवर्त के प्रतिशत के रूप में कर पूर्व लाभ (क------100 (क-1									

टिप्पण (1) आबंटन का आधार युक्ति युक्त होना चाहिए और संगत रूप से अपनाया जाना चाहिए ।

(2) क्रम सं० 1 के सामने स्तम्भ 4 से 9 के नीचे के अंक उस प्ररूप में क्रमशः क्रम सं० 4 और 5 के नीचे के अंकों के अनुरूप हों।

(3) यह प्ररूप कम्पनी के लेखापरीक्षक द्वारा प्रमाणित किया जाना चाहिए ।

पांचवीं अनुसूची

(पैरा 15 देखिए)

विनिर्माताओं या विनिर्मितियों के आयातकर्त्ताओं के विक्रय आवर्त का कर पूर्व अधिकतम प्रत्यागम दर्शित करने वाला विवरण

	विक्रय आवर्त पर कर पूर्व अधिकतम प्रत्यागम
प्रवर्ग 'क'—बड़े एकक जिनका प्रतिवर्ष आवर्त 6 करोड़ रुपए से अधिक है	
(क) जिनमें आधारी औषधि का विनिर्माण कार्य या कोई अनुसंधान कार्य नहीं होता है।	8 प्रतिशत
(ख) जिनमें प्रत्यागत के 5 प्रतिशत या अधिक तक का आधारी औषधि का विनिर्माण कार्य होता है किन्तु कोई अनुसंधान कार्य नहीं होता है।	9 प्रतिशत
(ग) जिनमें प्रत्यागम के 5 प्रतिशत या अधिक तक का आधारी औषधि का विनिर्माण कार्य होता है और नई औषधियों के संबंध में, अनुमोदित अनुसंधान और विकास कार्य होता है	10 प्रतिशत
प्रवर्ग 'ख'—मध्यम श्रेणी एकक जिनका प्रत्यागम 1 करोड़ रुपए से 6 करोड़ रुपए तक प्रतिवर्ष है	
(क) जिनमें आधारी औषधि का विनिर्माण कार्य या कोई अनुसंधान कार्य नहीं होता है	9 प्रतिशत
(ख) जिनमें प्रत्यागम के 5 प्रतिशत या अधिक तक का आधारी औषधि का विनिर्माण कार्य होता है किन्तु कोई अनुसंधान कार्य नहीं होता है	11 प्रतिशत
(ग) जिनमें प्रत्यागमन के 5 प्रतिशत या अधिक तक का आधारी औषधि का विनिर्माण कार्य होता है और नई औषधियों के संबंध में, अनुमोदित अनुसंधान और विकास कार्य होता है	13 प्रतिशत
प्रवर्ग 'ग'—अन्य एकक जिनका प्रत्यागम 1 करोड़ रुपए प्रति वर्ष से कम है	
(क) जिनमें केवल विनिर्मितियां तैयार करने की क्षमता है	12 प्रतिशत
(ख) जिनमें प्रत्यागम के 5 प्रतिशत या अधिक तक आधारी औषधि का विनिर्माण कार्य होता है	13 प्रतिशत

[सं 5(3)/78-औषधि-II]

एम० एम० पंडित उप सचिव

MINISTRY OF PETROLEUM CHEMICALS AND FERTILIZERS

(Department of Chemicals and Fertilizers)

ORDER

New Delhi, the 31st March, 1979

S.O. 190(E).—In exercise of the powers conferred by Section 3 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby makes the following Order, namely :—

1. Short title, extent and commencement—(1) This Order may be called the Drugs (Prices Control) Order, 1979.

(2) It extends to the whole of India.

(3) It shall come into force on the date of its publication in the Official Gazette.

2. Definitions—In this Order, unless the context otherwise requires —

(a) "bulk drug" means any substance including pharmaceutical, chemical, biological or plant product or medicinal gas conforming to pharmacopoeial or other standards accepted under the Drugs and Cosmetics Act, 1940 (23 of 1940), which is used as such, or as an ingredient in any formulation;

(b) "dealer" means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and whether or not in conjunction with any other business and includes an agent of a dealer ;

(c) "distributor" means a distributor of drugs or his agent or a stockist appointed by a manufacturer or an importer for stocking his drugs for resale to a dealer ;

(d) "drug" includes :—

(i) a medicine for internal or external use of human beings or animals and all substances intended to be used for, or in, the diagnosis treatment, mitigation or prevention of disease in human beings or animals ;

(ii) such substances, intended to affect the structure or any function of the human or animal body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Government by notification in the Official Gazette ; and

(iii) bulk drugs and formulations ;

(e) "Form" means a Form specified in the Fourth Schedule ;

(f) "formulation" means a medicine processed out of, or containing one or more bulk drugs or drugs, with or without the use of any pharmaceutical aids for internal or external use for, or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but shall not include :—

(i) any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicine ;

(ii) any medicine included in the Homoeopathic system of medicine ;

(iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply ;

(g) "free reserve" means a reserve created by appropriation of profits, but does not include reserves provided for contingent liability, disputed claims, goodwill, revaluation and other similar reserves ;

(h) "Government" means the Central Government ;

(i) "import", with its grammatical variation and cognate expressions, means bringing into India from a place outside India; and "importer", in relation to any goods at any time between their importation and consumption, includes any owner or any person holding himself out to be the importer ;

(j) "leader price" means a price fixed by the Government for formulations specified in Category I, Category II or Category III of the Third Schedule, in accordance with the provisions of paragraphs 10 and 11 keeping in view the cost or efficiency, or both, of major manufacturers of such formulations;

(k) "manufacture", in relation to any drug, includes any process or part of a process for making, altering, finishing, packing, labelling, breaking-up or otherwise treating or adapting any drug with a view to its sale and distribution but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business, and "to manufacture" shall be construed accordingly ;

(l) "manufacturer" means any person who manufactures a drug ;

(m) "net-worth" means the share capital of a company plus free reserve, if any ;

(n) "new bulk drug" means a bulk drug manufactured, within the country, for the first time after the commencement of this Order ;

(o) "pooled price", in relation to a bulk drug, means the price fixed under paragraph 7 ;

(p) "pre-tax return" means profits before payment of income-tax and surtax and includes such other expenses as do not form part of the cost of formulation ;

(q) "price list" means a price list referred to in this Order and include a supplementary price list ;

(r) "retail price" means the retail price of a drug arrived at or fixed in accordance with the provisions of this Order and includes a leader price ;

(s) "retailer" means a dealer carrying on the retail business of sale of drugs to customers ;

(t) "retention price", in relation to a bulk drug, means the price fixed under paragraphs 4 and 7 for individual manufacturers, or importers, or distributors, of such bulk drugs ;

(u) "sales turn-over" means the product of units of formulations sold by a manufacturer or an importer, as the case may be, in an accounting year multiplied by retail price inclusive of sales tax, if any, paid on direct sales by the manuafcturer or importer but does not include excise duty and local taxes, if any ;

(v) "Schedule" means a Schedule appended to this Order ;

(w) "wholesaler" means a wholesaler of drugs or his agent, or a stockist appointed by a manufacturer or an importer for the sale of his drugs to a retailer.

3. Power to fix the maximum sale price of indigenously manufactured bulk drugs specified in First Schedule or Second Schedule.—(1) The Government may, with a view to regulating the equitable distribution of an indigenously manufactured bulk drug specified in the First Schedule or the Second Schedule and making it available at a fair price and subject to the provisions contained in sub-paragraph (2) and after making such inquiry as it deems fit, fix, from time to time, by notification in the Official Gazette, the maximum price at which such bulk drug shall be sold.

(2) While fixing the price of a bulk drug under sub-paragraph (1), the Government may take into account the average cost of production of such bulk drug manuafctured by an efficient manufacturer and allow a reasonable return on net-worth.

Explanation.—In this sub-paragraph, the expression "efficient manufacturer" means a manufacturer :—

(i) whose production of such bulk drug in relation to the total production of such bulk drug in the country is large or

(ii) who employs efficient technology in the production of such bulk drug.

(3) No person shall sell a bulk drug at a price exceeding the price notified under sub-paragraph (1), plus local taxes, if any, payable :

Provided that until the price of a bulk drug is so notified, the price of such bulk drug shall be the price which prevailed immediately before the commencement of this Order and the manufacturer of such bulk drug shall not sell such bulk drug at a price exceeding the price which prevailed as aforesaid.

(4) (a) Where (after the commencement of this Order) any manufacturer commences production of a bulk drug specified in the First Schedule or the Second Schedule, the price of which has already been notified by the Government, he may sell the bulk drug at a price not exceeding the price so notified.

(b) Where the price of a bulk drug has not been notified by the Government, the manufacturer shall, within fourteen days of the commencement of the production of such bulk drug, make an application to the Government in Form 1 and intimate Government the price at which he intends to sell the bulk drug and the Government may, after making such inquiry as it deems fit, by order, fix a provisional price at which such bulk drug shall be sold.

(c) The manufacturer referred to in this sub-paragraph shall, within six months of the commencement of such production, make a further application to the Government in Form 1 and the Government may, after making such inquiry as it deems fit, by notification in the Official Gazette, fix the price of such bulk drug.

4. Power to fix retention price and common sale price.—Notwithstanding anything contained in paragraph 3, the Government may, if it considers necessary or expedient so to do for increasing the production of an indigenously manufactured bulk drug specified in the First Schedule or the Second Schedule, by order, fix :—

(a) a retention price of such bulk drug ;

(b) a common sale price for such bulk drug, taking into account the weighted average of the retention price fixed under clause (a).

5. Power to fix maximum sale price of new bulk drug.—(a) Every manufacturer of new bulk drug shall, within fourteen days of the commencement of production of such new bulk drug, make an application to the Government in Form 1, and the Government may, after making such inquiry as it deems fit, decide to include such new bulk drug in this Order and by order, fix a provisional price at which such new bulk drug shall be sold.

(2) (a) In every case where a provisional price has been fixed for a new bulk drug, every manufacturer of such new bulk drug shall on completion of six months of production of such new bulk drug, make a further application to the Government in Form 1.

(b) On receipt of an application under clause (a), the Government may, after making such inquiry as it deems fit, by notification in the Official Gazette, fix the price of such bulk drug.

(c) The price fixed under clause (b) shall be the maximum selling price of such new bulk drug and no person (including a person manufacturing such bulk drug thereafter) shall sell such new bulk drug at a price exceeding the price so notified.

6. Power to fix the maximum sale price of imported bulk drug specified in First or Second Schedule.—(1) Every importer of a bulk drug specified in the First Schedule or the Second Schedule shall, within fourteen days of the import of such bulk drug, make an application to the Government in Form 2.

(2) (a) The Government may, after taking into consideration the information furnished in Form 2, by order, fix the price of such drug.

(b) The price fixed under clause (a) shall be the maximum sale price of such bulk drug and no person shall sell such bulk drug at a price exceeding the price so fixed.

7. Power to fix retention price and pooled price for the sale of bulk drugs specified in First Schedule or Second Schedule indigenously manufactured as well as imported.—(1) Where a bulk drug specified in the First Schedule or the Second Schedule is manufactured indigenously and is also imported, the Government may, having regard to the sale prices prevailing from time to time in respect of indigenously manufactured bulk drugs and those of imported bulk drugs, by order, fix, with such adjustments as the Government may consider necessary,—

(a) retention prices for individual manufacturers, importers, or distributors of such bulk drugs ;

(b) a pooled price for the sale of such bulk drugs.

(2) Where a manufacturer of formulations utilises in his formulations any bulk drug, either from his own production or procured by him from any other source, the price of such bulk drug being lower than the price allowed to him in the price of his formulations, the Government may require such manufacturer—

(a) to deposit into the Drug Prices Equalisation Account referred to in paragraph 17 the excess amount to be determined by the Government ; or

(b) to sell the formulations at such prices as may be fixed by the Government.

8. Prices of bulk drugs produced through indigenous research and development.—(1) With a view to providing encouragement to the manufacturers of new bulk drugs, produced through original research and developmental efforts in the country and have not been produced elsewhere, the provisions of this Order shall not apply to such bulk drugs for a period of five years from the date of commencement of production of such new bulk drugs :

Provided that every manufacturer of such new bulk drug shall, within fourteen days of the commencement of production of such new bulk drug, make an application to the Government in Form 1 with a certificate from the Department of Science and Technology authenticating his claim of having produced it as an entirely new bulk drug and also furnish to the Government the name of the said new bulk drug, the price at which it may be margeted by him or used by him for captive consumption and such other additional information as may be required by the Government.

Provided further that the price furnished to the Government in respect of the said new bulk drug shall not be increased without the prior approval of the Government.

(2) After the expiry of the period of five years referred to in sub-paragraph (1), the provisions of this Order shall apply to the new bulk drug referred to in that sub-paragraph..

9. Power to direct manufacturers of bulk drugs to sell bulk drugs to manufacturers of formulations.—(1) The Government may, from time to time, by general or special order, direct any manufacturer of any bulk drug to sell such bulk drug to such manufacturers of formulations as may be specified in such order :

Provided that while making any such order, the Government shall have regard to all or any of the following factors, namely :

(a) the requirements for captive consumption of such manufacturer ;

(b the requirements of other manufacturers of formulations ;

(c) the planned growth of the pharmaceutical industry in conformity with the policy of the Government from time to time.

(2) For the purpose of making any order under sub-paragraph (1), the Government may call for such information from manufacturers, importers or distributors, of bulk drugs as it may consider necessary and such manufacturers, importers or distributors shall be bound to furnish such information within such time as may be specified by the Government.

10. Calculation of retail price of formulations .—The retail price of a formulation shall be calculated in accordance with the following formula, namely :

$$R.P. = (M.C. + C.C. + P.M. + P.C.) \times \left[1 + \frac{MU}{100}\right] + E.D.$$

Where——

"R. P." means retail price.

"MC" means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, and process loss thereon in accordance with such norms as may be specified by the Government from time to time by notification in the Official Gazette in this behalf.

"C.C." means conversion cost worked out in accordance with such norms as may be specified by the Government from time to time by notification in the Official Gazette in this behalf.

"P.M." means the cost of packing material including process loss thereon worked out in accordance with such norms as may be specified by the Government from time to time by notification in the Official Gazette in this behalf.

"P.C." means packing charges worked out in accordance with such norms as may be specified by the Government from time to time by notification in the Official Gazette in this behalf.

"M.U." means mark-up referred to in paragraph 11.

"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 as the Government may allow from time to time.

Provided further that where an imported formulation is repacked, its landed cost plus the cost of packing materials and packing charges as worked out in accordance with such norms as may be specified by the Government from time to time, by notification in the Official Gazette, shall from the basis for fixing its price.

Explanation.—For the purposes of this paragraph, "landed cost" shall mean the cost of import of drug inclusive of customs duty and clearing charges.

11. Mark-up.—Mark-up referred to in paragraph 10 includes the distribution cost, outward freight, promotional expenses, manufacturer's margin and the trade commission and shall not exceed—

(a) forty per cent in the case of formulations specified in Category I of the Third Schedule :

(b) fifty-five per cent in the case of formulations specified in Category II of the said Schedule ;

(c) one hundred per cent in the case of formulations specified in Category III of the said Schedule.

12. Power of Government to fix leader prices of formulations specified in Categories I and II of the Third Schedule—(1) The Government may, from time to time, by notification in the Official Gazette, fix the leader price of a formulation specified in Category I or Category II of the Third Schedule and such leader price shall operate as the ceiling sale price for every manufacturer of such formulations.

(2) Notwithstanding anything contained in sub-paragraph (1) where the selling price of a formulation of a manufacturer on the date of commencement of this Order is less than the leader price fixed under sub-paragraph (1), such manufacturer shall not except with the prior approval of the Government increase the selling price of his formulation.

(3) The Government may, of its own motion or on application made to it in this behalf by a manufacturer in Form 3 or Form 4 as the case may be, after calling for such information as it may consider necessary, by order, fix a revised leader price for a formulation.

13. Power of Government to fix retail price of formulations specified in Category III of Third Schedule.—(1) The Government may, from time to time, by order, fix the retail price of a formulation specified in Category III of the Third Schedule in accordance with the provisions of paragraphs 10 and 11.

(2) Where the Government fixes or revises the price of any bulk drug under the provisions of this order and a manufacturer utilises such bulk drug in his formulations specified in Category III of the Third Schedule he shall, within thirty days of such fixation or revision, make an application to the Government in Form 3 or Form 4, as the case may be and Government may, if it considers necessary, fix or revise the price of such formulation.

(3) The retail price of a formulation once fixed by the Government under sub-paragraph (1) shall not be increased by any manufacturer except with the prior approval of the Government.

(4) Any manufacturer, who desires revision of the retail price of a formulation fixed under sub-paragraph (1), shall make an application to the Government in Form 3 or Form 4, as the case may be, and the Government may, after calling for such information as it may consider necessary, by order, fix a revised price for such formulation.

(5) Notwithstanding anything contained in the foregoing sub-paragraphs, the retail price of a formulation, specified in Category II of the Third Schedule, of a manufacturer shall, until the retail price thereof is fixed under the provisions of this Order, be the price which prevailed immediately before the commencement of this Order and the manufacturer of such formulation shall not sell such formulation at a price exceeding the price which prevailed as aforesaid.

(6) (a) Without prejudice to the provisions of the preceding sub-paragraphs the Government may, if it considers necessary or expedient so to do, by notification in the official Gazette, fix a leader price for any formulations specified in Category III of the Third Schedule and any manufacturer of such formulation may sell such formulation at a price not exceeding the price so notified and intimate the Government accordingly.

(b) The privisions of sub-Paragraph (2) shall not apply to such manufacturer

14. General provisions regarding prices of formulations .—(1) No Manufacturer or importer shall market a new formulation or a new pack, or a new dosage form of his existing formulation specified in Category I or Category II or Category III of the Third Schedule without obtaining the prior aproval of its price from the Government.

(2) No person shall sell or dispose of any imported formulations specified in Category I or Category II or Category III of the Third Schedule without obtaining the prior approval of its price from the Government.

(3) Any manufacturer or importer, who desires to obtain the approval of the Government in respect of the price for any formulations referred to in sub-paragraph (1) or Sub-Paragraph (2), shall make an application to the Government in Form 3 or Form 4, as the case may be, and the Government may, within a period of four months of the receipt of an application accord its approval, subject to such modifications, as it may consider necessary :

Provided that where approval is not accorded with the said period of four months, the manufacturer or importer, as the case may be, may market the new formulation or new pack or new dosage form referred to in sub-paragraph (1) at the price declared by him in his application, issue the price list forthwith and intimate the Government accordingly.

Provided further that the Government may, if it considers necessary, by order, revise the price so declared by the manufacturer or importer, as the case may be, and upon such region, the manufacturer or importer shall not sell such formulation at a price exceeding the price so revised.

15. Power to revise prices of formulations .—Notwithstanding anything contained in this Order :—

(a) The Government may, after obtaining such information as it may consider necessary from a manufacturer or an importer, fix or revise the retail price of one or more formulations marketed by such manufacturer or importer, including a formulation not specified in any of the categories of the Third Schedule, in such manner as the pre-tax return on the sales turnover of such manufacturer or importer does not exceed the maximum pre-tax return specified in the Fifth Schedule ;

(b) the Government may, if it considers necessary so to do in public interest, by order, revise the retail price of any formulation specified in any of the categories of the Third Schedule.

16. Fixation of price under certain circumstances .—Where any manufacturer, importer, or distributor of any bulk drug or formulation fails to furnish information as required under this order within the time specified therein, the Government may, on the basis of such information as may be available with it, by order, fix a price in respect of such bulk drug or formulation, as the case may be.

17. Drug Prices Equalisation Account .—(1) The Government shall maintain an Account to be known as the Drugs Prices Equalisation Account to which shall be credited—

(a) by the manufacturer, importer or distributor, as the case may be—

(i) the amout determined under sub-paragraph (2) of paragraph 7 ;

(ii) the excess of the common selling price or, as the case may be, pooled price over his retention price ; and

(b) such other sums of money as the Central Government may, after due appropriation made by Parliament by law in this behalf, grant from time to time.

(2) The amount credited under sub-paragraph (1) shall be spent only :—

(a) for paying to the manufacturer, importer or distributor, as the case may be, the short-fall between his retention price and the common selling price or, as the case may be, the pooled price for the purpose of increasing the production, or securing the equitable distribution and availability at fair prices, of drugs ;

(b) for expenses incurred by the Government in discharging the functions under this paragraph.

(3) Every manufacturer, importer or distributor may, if he has any claim under clause (a) of sub-paragraph (2), make an application to the Government and the Government may, in settling the claim, require the manufacturer, importer or distributor, as the case may be, to furnish such details as may be specified by it in this behalf.

(4) The Government shall maintain account of all moneys credited to, and expended from out of, the Drug Prices Equalisation Account and such other reports and returns as it may consider necessary relating to the said account.

18. Certain provisions of this Order to apply to formulations not included in Category I, Category II or Category III of Third Schedule.—The provision of this Order, other than those contained in paragraphs 10 to 14 (both inclusive), shall apply to any formulation not specified in Category I, Category II or Category III of the Third Schedule.

19. Furnishing of price list by manufacturer or importer to dealers.—(1) Every manufacturer or importer of a formulation intended for the sale shall furnish to the dealers, State Drug Controllers and the Government, a price list showing the price at which the formulation is sold to a retailer (inclusive of excise duty) and the retail price of such formulation and the list shall be furnished to the dealers, in Form 5, not later than thirty days from the commencement of this Order :—

Provided that where a manufacturer or an importer furnishes such a price list, it shall not be obligatory for such manufacturer or importer to furnish a fresh price list at the time of every subsequent sale to the dealer unless there is any change by way of addition, deletion or alteration in that list, in which case a supplementary price list including such additions, deletions or alterations shall be furnished.

(2) Every manufacturer or importer shall give effect to the change in prices as approved by the Government from time to time, within fifteen days from the receipt by such manufacturer or importer of the communication in this behalf from the Government.

(3) Every dealer shall display the price list at a conspicuous part of the premises where he carries on business, in a manner so as to be easily accessible to any person wishing to consult the same.

20. Retail price to be displayed on label of container.—Every manufacturer, importer or distributor of a formulation intended for sale shall display in indelible print mark on the label of the container of the formulation or the minimum pack thereof offered for retail sale, the maximum retail price of that formulation with the words "retail price not to exceed" preceding it, and "local taxes extra" succeeding it.

21. Control of sale prices of formulations specified in Third Schedule.—No retailer shall sell any formulation specified in any of the categories in the Third Schedule to any person at a price exceeding the price specified in the current price list or the price indicated on the label ot the container or pack thereof, whichever is less, plus the local taxes, if any, payable.

Explanation.—For the purposes of this paragraph, "local taxes" include sales tax and octroi actually paid by the retailer under any law in force in a particular area.

22. Sale of split quantities of formulations.—No dealer shall sell loose quantity of any formulation drawn from a bottle pack of such formulation at a price which exceeds the pro-rata price of the formulation plus 5 per cent thereof :

Provided that nothing in this behalf shall apply to any formulation compounded at the premises of the dealer.

23. Manufacturer, distributor and dealer not to refuse sale of drug.—Subject to the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) :—

(a) no manufacturer or distributor shall withhold from sale or refuse to sell to a dealer any drug without good and sufficient reasons ;

(b) no dealer shall withhold from sale or refuse to sell and drug available with him to a customer wanting to purchase such drug.

24. Price to the wholesaler and retailer.—(1) No manufacturer, importer or distributor shall sell a formulation to a wholesaler unless otherwise permitted under the provisions of this Order or any other order made thereunder, at a price higher than :—

(a) the retail price minus 14 per cent thereof, in the case of ethical drugs, and

(b) the retail price minus 12 per cent thereof, in the case of non-ethical drugs.

(2) No manufacturer, importer, distributor or wholesaler shall sell a formulation to a retailer unless otherwise permitted under the provisions of this Order or any order made thereunder, at a price higher than :—

(a) the retail price minus 12 per cent thereof, in the case of ethical drugs, and

(b) the retail price minus 10 per cent thereof, in the case of non-ethical drugs.

Explanation.—For the purposes of this paragraph, —

(i) "ethical drugs" shall include all drugs specified in Schedule C, entries Nos. 1, 2, 3, 7, 8 and 9 of Schedule C(1), Schedule F, Schedule G, Schedule H and Schedule J, appended to the Drugs and Cosmetics Rules, 1945, made under the Drugs and Cosmetics Act, 1940 (23 of 1940) ; and

(ii) "non-ethical drugs" shall mean all drugs other than ethical drugs.

(3) Notwithstanding anything contained in sub-paragraphs (1) and (2), the Government may, by a general or special order, fix, in public interest, the price to the wholesaler or retailer in respect of any formulation the price of which has been fixed or revised under this Order.

25. Maintenance of records and production thereof for inspection.—(1) Every manufacturer shall maintain in such form as may be specified by the Government, records relating to the sales turnover of individual bulk manufactured by him and the sales turnover of formulations packwise, and also such other records as may be directed from time to time by the Government and such records shall be open for inspection by the Government.

(2) Every manufacturer shall, within six months of the close of the accounting year, submit to the Government information for that year in Form 6.

(3) Every dealer or manufacturer shall maintain the cash memo or credit memo, books of account and records of purchase and sale of drugs and shall make available the said records for inspection by the Government.

26. Power of entry, search and seizure.—(1) Any gazetted officer of the Central Government or of a State Government authorised by a general or special order by the Central Government or, as the case may be, the State Government in this behalf may, with a view to securing compliance with this Order or to satisfy himself that the provisions of this Order have been complied with—

(a) enter and search any place ;

(b) seize any drug, along with the containers, packages, or coverings in which the drug is found, in respect of which he suspects that any provision of this Order has been, is being, or is about to be, contravened, and thereafter take all measures, necessary for securing production of the drug, containers, packages or coverings, so seized, in a court of law and for their safe custody pending such production ;

(c) seize any document, such as, cash memo or credit memo books, books of account and records of purchase and sale of the drugs in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened.

(2) The provision of section 100 of the Code of Criminal Procedure, 1973 (2 of 1974), relating to search and seizure shall, so far as may be, apply to searches and seizures under this Order.

27. Power to review.—Any person aggrieved by any notification or order under paragraphs 3, 4, 5, 6, 7, 9, 12, 13, 14, 15 or 16 may apply to the Government for a review of the notification or order within fifteen days of the date of publication of the notification in the Official Gazette, or, as the case may be, the receipt of the order by him, and the Government may make such order on the application as it may consider necessary.

28. Power to issue directions.—The Government may, from time to time, issue such directions, consistent with the provisions of this Order to any manufacturers or importer, as may be necessary to carry out the provisions of this Order and such manufacturer or importer shall comply with such directions.

29. Penalties.—Any contravention of any of the provisions of this Order shall be punishable in accordance with the provisions of the Essential Commodities Act, 1955 (10 of 1955).

30. Interpretation.—If any question arises as to the placing of a formulation in any of the categories of the Third Schedule, such question shall be decided by the Government.

31. Power to exempt.—(1) The Government may, having regard to the factors mentioned in sub-paragraph (2) and subject to such conditions, if any, as it may specify, by Order in the Official Gazette, exempt any drug manufacturing unit or a class of such units from the operation of all or any of the provisions of this Order and may, as often as may be, revoke or modify such Order.

(2) While granting exemption under sub-paragraph (1), the Government shall have regard to all or any of the following factors relating to the drug manufacturing unit or a class of such units, namely :—

(a) number of workers employed ;
(b) amount of capital invested ;
(c) range and type of products manufactured ;
(d) sales turnover.

32. Delegation of powers.—The Government may, by notification in the Official Gazette, direct that all or any of the powers conferred upon it by this Order, other than those

contained in pragraphs 27, 28, 30 and 31 shall, subject to such restrictions, exceptions and conditions; if any, as may be specified, in the direction, be exercisable also by—

(a) such officer or authority subordinate to the Central Government ; or

(b) such State Government or such officer or authority subordinate to the State Government.

as may be specified in the direction.

33. Repeal.—As from the commencement of this Order, the Drugs (Prices Control) Order, 1970, shall cease to operate except as respects things done or omitted to be done before such cesser.

[No. 5(3)/78-Drug. II]
M. S. PANDIT, Dy. Secy.

THE FIRST SCHEDULE

[See Paragraph 3, 4, 6(1) 7 (1)]

BULK DRUGS

List of Bulk Drugs (Including salts, derivatives and esters, if any) used in Cat. I & II formulations appearing in Third Schedule

I. Bulk Drugs used in Category I formulations

Sl. No.	Name of the Bulk Drug
1.	Insulin
2.	Iodo-Chlorohydroxyquinoline
3.	Isonicotinic Acid Hydrazide
4.	PAS Acid
5.	PAS Sodium
6.	Potassium Penicillin G.
7.	Sodium Penicillin G.
8.	Procaine Penicillin
9.	Penicillin Potassium V (Phenoxy Methyl Penicillin)
10.	Streptomycin Sulphate
11.	Thiacetazone
12.	Dapsone
13.	Aspirin
14.	Pethidine
15.	Benzathine Penicillin
16.	Calcium PAS
17.	Pertussis Toxoid
18.	Diptheria Toxoid
19.	Tetanus Toxoid
20.	Digoxin
21.	Hydrochlorthiazide
22.	Di-Iodohydroxyquinoline
23.	Morphine Sulphate

II. Bulk Drugs used in Category II Formulations

1. Amodiaquin
2. Chloramphenicol
3. Chloroquin
4. Prednisolone
5. Tetracycline
6. Tolbutamide
7. Sulphadimidine
8. Diethylcarbamazine Citrate
9. Analgin
10. Phenobarbitone
11. Phthalyl Sulphathiazole
12. Calcium B. PAS
13. Piperazine
14. Frusemide
15. Oxytetracycline
16. Primaquin
17. Glyceryl Trinitrate
18. Quinine
19. Pyrolidine Methyl Tetracycline
20. Demethyl Chlorotetracycline

THE SECOND SCHEDULE

[See Paragraph 3, 4, 6(1), 7(1)]

List of Bulk Drugs (including salts, esters and derivatives, if any) used in Category III formulations appearing in Third Schedule

I. Anaesthatics, General and Local :

1. Benzocaine
2. Chloroform
3. Cocaine
4. Ether
5. Ethyl Chloride
6. Halothane
7. Trichloroethylene
8. Procaine
9. Xylocaine (Lignocaine)
10. Marcaine
11. Thiopentone Sodium
12. Ketamine

II. Analagesics and Antipyretics :

1. Amidopyrin
2. Baralgan Ketone
3. Codiene
4. Dextropropoxyphene
5. Fentanyl Citrate
6. Methyl Salicylate
7. Osadrine
8. Paracetamol
9. Pentazocaine
10. Phenacetein
11. Propoxy Phenazone
12. Phenylisopropylpyrazolone

III. Anthelmintics :

1. Bephenium hydroxy nephthoate
2. Dithiazamin Iodide
3. Pyrivinium
4. Tetramisol
5. Thiabendazole
6. Pyrantel

IV. Antiameobics :

1. Broxyquinoline
2. Brobenzoxalidine
3. Bismuth Glycollylarsanilate
4. Dehydroemetine.
5. Diloxamide
6. Emetine
7. Furazolidone
8. Chlorophenoxamide (Clefamide)
9. Metronidazole
10. Phanquone

V. Anti-asthmatic and Enteric Antiseptics :

1. Ephedrine
2. Pseudo-Ephedrine
3. Salbutamol

4. Aminophylline
5. Theophylline
6. Papaverine
7. Ajmalicin

VI. **Antibiotics :**

1. Amphotericin
2. Bacitracin
3. Carbenicillin
4. Cloxacillin
5. Cephalexin
7. Cephaloridine
6. Cycloserine
8. Doxycycline
9. Framycetin
10. Gentamycin
11. Gramicidin
12. Griseofulvin
13. Kanamycin
14. Lincomycin
15. Methicillin
16. Nystatin
17. Neomycin
18. Oxacillin
19. Oleandomycin
20. Paranmomycin
21. Polymixin
22. Rifampicin
23. Spiramycin
24. Viomycin
25. Lymecycline
26. Colistin
27. Tyrothricin
28. Ampicillin
29. Erythromycin

VII. **Anti-Cancer Drugs :**

1. L-Asparaginase
2. Busulphan
3. Chlorambucil
4. Cyclophosphamide
5. Cerubidin (Daunorubicin)
6. 5 Flurouracil]
7. 6-Mercaptopurine
8. Thiotepa (NNN-Trienthylenethiophosphoramide)
9. Mitomycin
10. Adviamycin
11. Bleomycin
12. Azathioprime
13. Melphalan
14. Vinblastin
15. Vincrastine

VIII. **Anticoagulants :**

1. Warfarin 3—£—Acetonylbenzyl)-4-hydroxycoumarin).
2. Heparin
3. Ethyl Biscoumacetate.
4. Pheniyridione
5. Heparinoid substance isolated or derived from Lung Tissue.

IX. **Anticovulsants :—**

1. Ethosuximide
2. Diphenyl Hydantoin
3. Primidone

X. **Antidiabetics :**

1. Carbutamide
2. Chlorpropamide
3. Glybenclamide
4. Glipizide
5. Metformin
6. Phenformin

XI. **Antihistaminics :**

1. Antazoline
2. Bucilizine
3. Cyclizine
4. Carbinoxamine
5. Chlorocyclizine
6. Chlorpheniramine
7. Clemisole
8. Dimenhydrinate
9. Dimethindone
10. Diphenhydramine
11. Diphenyl Pyraline
12. Diphenyl-Piperadine-Propane
13. Hydroxyzine
14. Mepyramine
15. Methdilazine
16. Methapyrilene
17. Meclozine
18. Pheniramine
19. Halopyramine
20. Promethazine
21. N-Phenyl-N-Benzyl-4-Amino-1-Methyl-Piperadine
22. Pyrolidylethyl Phenyl Benzyl-Amine
23. Isothiopendyl
24. Phenindamine
25. Triprolidine
26. Triplenamine
27. Thenalidine
28. Trimeprazine
29. Cyproheptadine
30. Dexachloropheniramine
31. Bamipiem (Soventol)

XII. **Antileprotic Drugs :**

Clofazimine

XIII. **Antimalarial Drugs :**

1. Mepacrine
2. Pyrimethamine

XIV. **Antirheumatic :**

1. Ibuprofen
2. Indomethacin
3. Oxy-Phenylbutazone
4. Phenyl Butazone
5. Sodium Salicylate

XV. **Antiseptics :**

1. Chloroxylenols
2. Chlorocresols
3. Hexyl-Resorcinol
4. Greosote
5. Hydrogen Peroxide
6. Iodine
7. Cetrimide
8. Chlorhexidine

XVI. **Antispasmodics :**

1. Atropine Methylnitrate
2. Ethylmorphine
3. Belladonna Alkaloids
4. Hyoscine

XVII. **Antitubercular :**

1. Ethambutol
2. Ethionamide
3. Pyrazinamide
4. Morphazinamide
5. Prothionamide

XVIII. **Cardiovascular :**

(i) **Antihypertensive :**

1. Rauwelfia Alkaloids
2. Guanethidine Sulphate
3. Methyl Dopa
4. Pentolinium Tartarate
5. Dihydroargocrystine
6. Cloposamide
7. Clonidine
8. Dihydralazine

(ii) **Peripheral Vasodilators and Coronary Vasodilator :**

1. Histamine
2. Isoxsuprine
3. Nylidrine
4. Penta Erythritol Tetranitrate
5. Prenylamine
6. Sorbide Nitrate
7. Dipyridamol
8. Amyl Nitrite
9. Mannitol Hexanitrate

(iii) **Cardiac Glycosides :**

1. Digitoxin
2. Lanatosides
3. Onabaine

(iv) **Others**

1. Nikethamide
2. Clofibrate
3. Xanthinol Nicotinate
4. Carbacol (40)
5. Propranalol
6. Quinidine
7. Procainamide
8. Methacholine

XIX. **Corticosteroids**

1. Dexamethasone
2. Betamethasone
3. Triamcinolone
4. Prednisone
5. Hydrocortisone
6. Cortisone
7. A.C.T.H. (Corticotropin)

XX. **Diuretics :**

1. Benzthiazide
2. Bendrofluazide
3. Chlorthalidene
4. Polythiazide
5. Spiranolactone
6. Triamberene
7. Mersalyl Acid
8. Acetazolamide
9. Ethoxzolamide
10. Chlorothiazide
11. Cyclopent iiazide
12. Hydroflumethiazide
13. Ethacrinic acid.

XXI. **Drugs used for Calcium therapy :**

1. Calcium Gluconate
2. Calcium Levulinate
3. Calcium Lactate
4. Calcium Lactobionate

XXII. **Haematinics :**

1. Ferrous Gluconate
2. Ferrous Fumerate
3. Ferrous Sulphate
4. Iron-Dextran Complex
5. Liver Extract
6. Ferric Ammonium Citrate
7. Iron-Sorbitol Complex

XXIII. **Oral Contraceptives :**

1. Oestradiol
2. Lynestrenol
3. Ethisterone
4. Mestranol
5. Nor-ethisterone
6. Dimethisterone
7. Norgestrel
8. Megestrol
9. Ethynodiol
10. Norothynodral.

XXIV. **Opthalmolgical Preparations :**

1. Sulphacetamide
2. Boric Acid
3. Atropine
4. Pilocarpine
5. Phenylophrine
6. Homatropine
7. Physostigmine Salicylate

XXV. **Oxytocics :**

1. Ergot Alkaloids
2. Oxytocin

XXVI. **Plasma Expanders and Transfusion Solution :**

1. Dextran
2. Polyvinyl Pyrrolidone
3. Dextrose Anhydrous
4. Sodium Chloride
5. Sod. Lactate
6. Pot. Chloride

XXVII. **Sera and Vaccines :**

1. Antirabic Vaccine
2. Yellow Fever Vaccine
3. Cholera Vaccine
4. Tetanus antitoxin
5. Diphtheria antitoxin
6. Gasgangrene antitoxin

7. Antirabic Serum
8. Antivenom Serum
9. B.C.G. Vaccine
10. Typhoid Vaccine
11. Polio myclitics Vaccine (oral)
12. TAB vaccine

XXVIII. **Urinary :**

1. Nitrofurantion.
2. Nalidixic Acid.
3. Methanamine.

XXIX. **Vitamins :**

1. Vitamin —A.
2. Vitamin -B1.
3. Vitamin-B12.
4. Vitamin B6.
5. Vitamin B 2 (Cyano and Hydroxy).
6. Vitamin C.
7. Vitamin D3.
8. Vitamin K.
9. Vitamin P.
10. Vitamin E.
11. Niacin and Niacinamide.
12. Panthenols and Panto-thenates.
13. Folic Acid.

XXX. **Antacids :**

1. Aluminium Hydroxide.
2. Magnesium carbonate.
3. Magnesium Trisilicate.
4. Magnesium Hydroxide.
5. Sodium Bicarbonate.
6. Calcium Carbonate.

XXXI. **Antidiarrhoeals :**

1. Diphenoxylate.
2. Sulphaguanidine.
3. Kaolin.
4. Pectin.

XXXII. **Antigout drugs ::**

1. Allopurinol.
2. Probenecid.

XXXIII. **Disinfectants :**

Cresols.

XXXIV. **Antitussives and Expectorants :**

1. Chlophodional.
2. Dextromethorphan.
3. Guiacol Glyceryl Ether.
4. Noscapine.
5. Oxeladine.
6. Piperazethate.
7. Pholcodeine.
8. Menthol.

XXXV. **Dental products other than those containing local anaesthetics:**

1. Sodium Fluoride.
2. Stannous Fluoride.

XXXVI. **Dermatological preparations not containing antibiotics sulphonamides and corticosteroids :**

1. Sulphur sublimed.
2. Methoxsalen.
3. Ichthammol.
4. Ammoniated mercury.
5. Resorcinol.
6. Chrysarobin.
7. Dithranol.
8. Salicylic acid.
9. Benzoic acid.
10. Zinc oxide.
11. Benzyl benzoate.
12. Gamma benzenehexachloride.
13. Calamine.
14. Chlorphenesin.

XXXVII. **Parasympathomimetics:**

1. Methacholine.
2. Carbachol.
3. Neostigmine.
4. Physostigmine.
5. Acetyl Chloline Chloride.
6. Pyridostigmine.

XXXVIII. **Other Anti-infectives**

1. Trimethoprim.
2. Sulphamthoxazole.
3. Sulphamoxole.
4. Sulphadimethoxin.
5. Sulphaphenozole.
6. Sulphamethoxypyridazine.
7. Sulphasomidine.
8. Sulphadiazine.
9. Sulphafurazole.
10. Succinyl Sulphathiazole.
11. Tolnaftate.

THE THIRD SCHEDULE

(See paragraphs 2(j), 11, 12, 13, 14, 15, 18, 21 and 30)

LIST OF CATEGORY I, CATEGORY II AND CATEGORY III FORMULATIONS

Category-I Formulations

1. Aspirin Tablets.
2. Digoxin Tablets.
3. DDS Tablets.
4. DPT Vaccines.
5. Insulin Injection (all sorts)
6. Hydro-Chlorothiazide Tablets.
7. Iodo-chloro-hydroxy-quinoline tablets and Di-iodo-hydro-oxy-quinoline tablets.
8. INH tablets.
9. INH plus Thiacetazone tablets.
10. Morphine sulphate injection.
11. Penicillin injection including procaine Penicillin G and Benzathine Penicillin (all strengths)
12. PAS and its salts, granules and tablets.
13. Phenoxymethyl penicillin tablets.
14. Streptomycin injection all strengths plus combination with penicillin.
15. Pethidine Injection.

Category-II Formulations

1. Analgin Tablets.
2. Amodiaquin Tablets.
3. Chloramphenicol oral preparations including chloramphenicol palmiate, suspension and Syrup and chloramphenicol Sodium Subcinate injectable.

4. Chloramphenicol in combination with Streptomycin.
5. Chloroquin salts.
6. Primaquin Tablets.
7. Calcium Benzoyl PAS Tablets.
8. Diethyl carbamazsine citrate tablets.
9. Fursemide tablets, injection.
10. Glycaryl Trinitrate tablets.
11. Phthalyl Sulphathiazole Tablets.
12. Prednisolone Tablets and injection.
13. Phenobarbitone Tablets.
14. Piperazine and its salts—tablets, syrup.
15. Sulphadimidine tablets.
16. Tetracyclines, capsules, tablets, syrup, injection, eye ointment (including Oxy-Demethyl-Chloro and Pyrrolidine Methyl Tetracyclines).
17. Tolbutamide tablets.
18. Tetanus Toxoid Injection.
19. Diphtheria tetanus toxoid injection.
20. Quinine Salts, tablets and injection.

Category-III Formulations

Formulations based on drugs falling under the following Categories excluding the formulations included in Categories I and II:

1. Anaesthatics, General and Local.
2. Analagesics and Antipyretics.
3. Antheliminics
4. Antiamoebics.
5. Anti asthmetic drugs and Enteric Antiseptics.
6. Antibiotics including semisynthetic antibiotics.
7. Anticancer Drugs.
8. Anticoagulants.
9. Anticonvulsants.
10. Antidiabatics.
11. Antihistaminics.
12. Antileprotic Drugs.
13. Antimalarial Drugs.
14. Antirhemotic and Antigout drugs.
15. Antiseptics.
16. Antispasmodics.
17. Antitubercular Drugs.
18. Cardiovascular Drugs.
19. Corticosteroids.
20. Diuretics.
21. Drugs used for Calcium therapy.
22. Haematinics.
23. Oral Contraceptives.
24. Opthalmological preparations
25. Oxytocics.
26. Plasma Expanders and Transfusion Solutions.
27. Sera and Vaccines.
28. Vitamins.
29. Urinary drugs.
30. Antacids.
31. Antidiarrhoeals.
32. Disinfectants.
33. Antitussives and Expectorants.
34. Dental products other than those containing local anaesthetics.
35. Dermatological preparations not containing antibiotics sulphonamides and Corticosteroids.
36. Otic preparations not beased on antibiotics.
37. Parasympathomimetics.
38. Other Anti-infectives

THE FOURTH SCHEDULE

FORMS

Form-1 (To be submitted in duplicate)

(See paragraphs 2(e), 3(4), 5 and 8(1),

Form of application for fixation or revision of prices of bulk drugs.

1. Name of the Bulk Drug:
2. Name of the Manufacturer:
3. Address of the Registered/Head Office of the Manufacturer.
4. Address of the Factory:
   (a) Industrial Licence/SSI Registration No.
5. Licensed capacity
   (b) Date of issue of the Licence/ Date of Registration.
   (c) Production capacity: Licensed: Tonnes/Kgs/ Litres/etc.
6. Installed capacity:
   (a) No. of shifts; One/Two/ Three
   (b) No. of operating days per year.
   (c) Mase production per shift: Tonnes/Kgs/Litres/etc.
   (d) Date of commissioning.
   (e) Installed capacities per annum.
7. Date of commencement of commercial production:
8. Actual production achieved during the last accounting year (preferably month-wise) and also monthly production during the current year; Tonnes/Kgs./Litres/etc.
9. Brief note on the manufacturing process adopted by you indicating all stages including recovery of bye-products, if any, solvents etc. and state-wise overall yields for each drug.
10. Average hourly rate of production for each of the bulk drug since commencement of commercial production.
11. Maximum hourly rate of production achievable.
12. Estimated production of the bulk drug during the next three years.
13. If the production is proposed to be captively consumed for manufacture of the formulation, please furnish the quantity to be so consumed out of the production given against Sl. No. 8. and Sl. No. 12.
14. Capital employed for the manufacture of the bulk drug(s):
    (a) Net fixed assets (after depreciation) .....
    (b) Working Capital .....
    (c) Total .....

    (In the case of multi-purpose plant the capital employed as above and the share to be allocated to the bulk drug/intermediate under consideration to be given)
15. Please state how the above capital employed is financed by net worth and borrowings.
16. Please state the average rate of interest paid by you on your borrowings, supported by figures.
17. Please furnish latest c.i.f. price of the bulk drug if the same had been imported or is being imported by you or by any other agency known to you.
18. Please furnish the cost of production of the bulk drug as per Proforma (attached) duly certified by a Practising Cost/ Chartered Accountant.

    Notes :

    (1) Any hold up affecting production to be shown clearly against Serial No. 8.

(2) In case the same plant facilities are used for production of more than one product the information as per Serial No. 6 may be given productwise.

(3) Please furnish a copy each of audited Balance Sheet and Profit and Loss Account for the last three years.

PROFORMA

(See Item 18)

I. Name of the Bulk Drug

II. (a) Production in Tonnes/Kgs/Litres/etc.
(b) Sales in Tonnes/Kgs./Litres etc.
(c) Despatches in Tonnes/Kgs./Litres/etc.

III. Period for which the cost data is given :

Particulars	Norms of consumption as per Project report of know-how or suppliers' guaranteed norms or the norms developed by you as standards	Unit	Actual Consumption during the period	Rate	Amount	Per Unit of production Qty.	Cost Rs.
1. Raw materials :							
(a) **Imported**							
1.							
2.							
3.							
(b) **Indigenous**							
1.							
2.							
3.							
Total raw material cost							
Less Recoveries of Solvents							
Net Raw material cost							
2. **Utilities**							
(a) Power							
(b) Water							
(c) Fuel Oil							
(d) other services (to be specified)							
3. **Conversion cost**							
(a) Salaries and Wages							
(b) Operating supplies or consumable stores.							
(c) Repairs and Maintenance							
(d) Other factory overheads							
(e) Administration overheads.							
(f) Depreciation							
4. Total cost of production							
5. Interest on Borrowings							
6. Minimum Bonus							
Total							
7. Packing :							
(a) Materials							
(b) Other expenses							
8. Selling Expenses							
9. Transport Charges							
10. Transit Insurance Charges							
11. Total cost of sales							
12. Profit margin (Basis of calculations to be given)							
13. Selling Price (11+12)							
14. Existing price or National price or Declared price							

Notes

(i) Items of expenses to be excluded from costs :

(a) Bonus in excess of statutory minimum

(b) Bad Debts & Provisions

(c) Donations and charities

(d) Loss/Gain on sale of assets

(e) Brokerage and commission

(f) Expenses not recognised by Income-Tax authorities (salary/prequisities, advertisements etc.)

(g) Adjustments relating to previous years.

(ii) In the case of imported raw materials please furnish separately the c.i.f. price, duty of customs and other charges totalling to the landed cost adopted against Sl. No. 1(a)

(iii) Cost of intermediates manufactured for captive use should be on the basis of factory cost of production inclusive of administration overheads and shown separately against Sl. No. 1 (b). A separate cost-sheet in the same proforma may please be appended.

(iv) Cost of generated utilities like power, steam, etc. should be separately given furnishing the details of purchased [illegible] consumed, rate and cost with other expenses [illegible] on generation, with ref. to Sl. 2.

(v) Details in respect of factory overheads, administration overheads and selling expenses should be furnished, against Sl. No. 3 (d) (e) and Sl. No. 8

(vi) The basis of depreciation adopted in your financial accounts may please be given, against Sl. No. 3 (f)

(vii) Please indicate whether the existing price is notional, delcared or approved against Sl. No. 14.

TO BE CERTIFIED BY COST ACCOUNTANT/ CHARTERED ACCOUNTANT.

FORM 2

(To be submitted in Duplicate by the importers of drugs appearing in the First and Second Schedules for each imported consignment).

[See Paragraph 2(e) and 6]

1. Name of the Company

2. Address of Registered/Head Office/Factory, if any :

3. Reference to permission given by competent authority for import of the bulk drugs.

4. Name of the drug.

5. Specification of the drug

6. Country from which imported

7. Quantity imported Tonnes/Kgs/Littres/etc.

8. c.i.f. value in foreign currency

	Total Rs.	Per unit Rs.
(a) c.i.f. value actually paid in Rs. (Not to include bank commission, interest, etc.)		
(b) Duty of customs actually paid		
(c) Clearing charges actually incurred with details		
(d) Landed cost (a+b+c)		
(e) Importers margin-in case of those who import for sales only		
(f) Proposed Selling Price/Notional Price		
(g) Existing Selling Price/Notional Price, if any		

NOTE : The figures given here to be certified by a paractising Cost Accountant/Chartered Accountant.

FORM 3

[Paragraph 2(e), 12, 13 and (14)]

(Form of application for manufactures seeking approval or revision of price of formulations to be submitted in seven copies)

1. Name of the Manufacturer
2. Address of Reigistered/Head Office
3. Address of the Facotry
4. Name of the Formulation
5. Categoty of formulation and therapeutic group to which it belongs as per Third Schedule of Drugs (Price Control) Order, 1979.
6. Composition as approved by Drug Control Authorities.
7. Industrial Licence/Small Scale Industrial Unit Registration No. and Date
8. Drug Control Authorities Permission No. and Date
9. Type of formulation
   Plain Tablets/coated tablets/soft/hard/printed/capsules/without/with/sealing band/Saterile/Non-Sterile/Liquids/powder/Ointment/Cream/etc.
10. Type of Packing
    Aluminium/Paper/Cellophane/Strips/Vials/Ampoules/bottles/tins/Jars/With/Without/dropper/Cutting blades/catch cover/etc.
11. Size of Packs
    10's/100's/etc./1 ml/2 ml/10 ml/etc./5 gms/10 gms/etc.
12. No. of Packs sold during the last accounting year
13. Value of sales effected durig the last accounting year excluding duty of excise and its percentage to total sales of formulations excluding duty of excise (12 and 13 above applicable in case of revision application only).
14. Break-up of Retail Price :

	Existing (If any) Rs/Pack approved on ——)	Now claimed Rs./Pack
(a) Material Cost [M. C. as per S. No. 15(a)]		
(b) Conversion Cost (C. C. as per norms)		
(c) Packing Material Costs (P. M.) (As per S. No. 16 as per norms)		
(d) Packing charges (P. U.) (as per norms)		
(e) Ex-factory cost (a to d)		
(f) Mark-up (M. U ——% on (e) above		
(g) Excise Duty		
(h) Retail Price (R.P.) (e+f+g)		

15. Material Cost:
    (a) Batch Size:
    Nos./Litres/Kgs/etc.
    (b) No. of packs actually obtained from the batch size as in (a) above.
    (c) No of Packs that can be theoretically obtained from the batch size as in (a) above.
    (d) Materials' Cost for the batch site as in (a) above:—

Sl. No	Name of materials	Unit	Previous Rate/ unit, if any (Date) Rs.	Current Rate/unit (Date)	Theoretical Qty. required per batch	Over age. if any	Total Qty. required	Cost for the batch (5×8) Rs.
1	2	3	4	5	6	7	8	9
	Imported							
1.								
2.								
3.								
	etc.							
	Indigenous							
1.								
2.								
3.	etc.							

Total:
Add : Process loss as per Norms %.....
Total Material Cost .....
.....
.....
Toatl Material cost
.....
Material Cost per Pack
Theoretical No. of Packs

16. Packing Materials Cost:

Batch Size .....Packs of ....Tabs/gms/etc. each

Sl. No.	Name of packing Materials	Unit	Rater per Unit Rs.		Quantity required per batch Nos./Kgs./ etc.	Value of packing materials per batch Rs.
			Previous (date)	Present (date)		
1	2	3	4	5	6	7
1.						
2.						
3						
etc.						

Total

Add : Process loss as per norms .....% of above

Total packing material cost .....

.....

Packing Material cost per pack Total packing Material cost

.....

No. of Packs as per batch size.

Note:—The figures in this form to be certified by a practising Cost Accountant Chartered Accountant.

FORM 4

(To be submitted in seven copies)

(Paragraphs 2(e), 12, 13 and 14)

Form of application to be submitted for price approval of formulation imported in finished form.

1. Name of the Company
2. Address of the Registered/Head Office/Factory, if any
3. Reference to Permssion, if any, given by drug control authorities for import of the item.
4. Name of the imported formulation.
5. Type of formulation : Capsule/Tablets/etc.
6. Composition of the Formulation
7. Type of Packs: Strip/vial/Ampoule/etc.
8. Pack size: 10's/etc./10ml/etc. 5 gms./etc.
9. Country from which imported and Date of Import
10. Quantity/No. of Packs imported

Total Rs.	Per pack Rs.

11. C.I.F.value in Foreign Currency (Not to include bank commission, interest, etc.)
12. C.I.F. value in Rs. actually paid (Not to include bank commission, interest, etc.)
13. Duty of customs, if any, actually paid
14. Clearing Charges (with details) actually incurred
15. Landed Cost (12+13+14)
16. Packing Material, if any as per forms
17. Packing Charges, if any, as per forms

Applicable in case of re-packing

18. Landed cost (including re-packing cost, if any (15 to 17)
19. Mark-up claimed.....% of S. No. 18
20. Duty of excise, if any
21. Retail Price claimed (18 to 20)
22. (a) Existing Retail price, if any
    (b) No. of Packs sold during the last accounting year, if any.
    (c) Value of sales excluding duty of excise effected during the last accounting year, if any.

Note : Figures given here to be certified by a practising Cost Accountant/Chartered Accountant.

FORM 5

(See paragraphs 2 (e) and (19)

(Form of Price List)

S. No.	Name of the formulation and its form	Composition (main ingredients to be given)	Specification of the pack		Duty of excise		Price to the retailer (inclusive of excise duty) Rs.	Retail Price (inclusive of excise duty) Rs.
			Type (strip/ bottle/etc.)	Size 10/100/ etc./1 ml/ etc./1gm/ etc.	Rate %	Amount Rs.		
1	2	3	4	5	6	7	8	9

Note:—Information as per this Form shall be given Categorywise as specified in the Third Schedule for all the items including the formulations which are not price-controlled.

FORM 6

Yearly Information

(See paragraphs 2(e) and 25)

1. Name of the Manufacturer
2. Address of the Registered/Head office/Factory
3. Accounting period for which information is given
4. Turnover of bulk drugs:—

Name of the bulk drugs	Quantity		Sales Value (excluding duty of excise, if any)	
	Consumed	Sold	Consumed	Sold
	Kg/Ltrs/ etc.	Kg./Ltrs/ etc./	Rs.-	Rs.
(I) Drugs listed in First Schedule				
(a) Imported:				
1.				
2.				
3. etc.				
(b) Indigenous:				
1.				
2.				
3. etc.				
(II) Drugs listed in Second Schedule				
(a) Imported:				
1.				
2.				
3. etc.				
(b) Indigenous:				
1.				
2.				
3. etc.				
(III) Other bulk drugs:				
1.				
2.				
3.				
Total				

5. Turnover of Formulations:—

Sl. No.	Name	Pack Size	No. of packs	Sales Value excluding duty of excise Rs.
A. Own Formulations:				
(i) Category I:				
1.				
2.				
3. etc.				
(ii) Category II:				
1.				
2.				
3. etc.				
(iii) Category III:				
1.				
2.				
3. etc.				
(iv) Others				
1.				
2.				
3. etc.				
B. Sub-Total ( )				
Purchased Formulations:				
(a) Imported:				
(i) Category I:				
1.				
2.				
3. etc.				
(ii) Category II:				
1.				
2.				
3. etc.				
(iii) Category III :				
1.				
2.				
3. etc.				
(iv) Others				
1.				
2.				
3. etc.				
Sub-Total (Ba)				
(b) Indigenous :				
(Category-wise as indicated above).				
Sub total (Bb)				
C. Export Sales				
Total (A+B+C)				

6. Allocation of sales and expenses as shown in the audited Profit and Loss Account:—

(In Rupees)

Sl. No.	Particulars	Total as per audited Profit and Loss Account	Allocation to						Other activities (if any)	Basis of allocation
			Bulk Drugs	Formulations						
				Own manufacture	Imported	Export	Indigenous purchased	Sub-total (5 to 8)		
1	2	3	4	5	6	7	8	9	10	11
A. Income										
1. Sales Income (excluding duty of excise and other taxes)										

1	2	3	4	5	6	7	8	9	10	11
	2. Cash subsidy (if any)									
	3. Other Income									
	Total (1 to 3)									
	B. Expenses									
	4. Raw materials consumed									
	5. Packing materials consumed									
	6. Powers and Fuel									
	7. Salaries and Wages									
	8. Stores and Spares									
	9. Repairs and Maintenance									
	10. Insurance									
	11. Depreciation									
	12. Royalty									
	13. Interest									
	14. Head Office Expenses									
	15. Dealer's Commission and Discount									
	16. Research and Development expenses									
	17. Other Expenses									
	Total (4 to 17)									
	C. Profit before tax (A-B)									
	D. Profit before tax as a %age of sales turnover $\frac{C}{A.1} \times 100$									

Note :— (i) The basis of allocation should be reasonable and followed consistently.

(ii) The figures against Sl. No. 1 under Cols. 4 to 9 should tally with the figures under Sl. Nos. 4 and 5 respectively of this Form.

(iii) This Form should be certified by the Company's Auditors.

THE FIFTH SCHEDULE

(See paragraph 15)

Statement showing maximum pre-tax return on sales turnover of manufacturers or importers of formulations.

	Maximum pre-tax return on sales turnover.
Category 'A'—Large units with turnover exceeding Rs. 6 crores per annum.	
(a) having no basic drug manufacturing activity nor any research activity	8%
(b) having basic drug manufcturing activity at 5% or more of turnover but no research activity	9%
(c) having basic drug manufacturing activity at 5% or more of the turnover and engaged in approved research and development work relating to new drugs	10%
Category 'B'—Medium size unit with turnover between Rs. 1 crore to Rs. 6 crores per annum.	
(a) having no basic drug manufacturing activity nor any research activity	9%
(b) having basic drug manufacturing activity at 5% or more of turnover but no research activity	11%
(c) having basic drug manufacturing activity at 5% or more of turnover and engaged in approved research and development work relating to new drugs	13%
Category 'C'—Other units with turn-over of less than Rs. 1 crore per annum.	
(a) having only formulation capacity	12%
(b) having basic drug manufacturing activity at 5% or more of turnover	13%

[5(3)/78-Drug-II]

M. S. PANDIT, Dy. Secy.

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