

DRUGS (PRICES CONTROL) ORDER, 1979

INTRODUCTION

The special feature to be noticed in the Drugs (Prices Control) Order of 1979 is that the order has exempted new bulk drugs which are developed through research originally made in India and are not produced anywhere else. With regard to other bulk drugs, every importer has to obtain previous approval from the Government. In the case of all varieties of bulk drugs, whether imported or indigenous, the Government is empowered to fix retention prices

for individual manufacturer and importer at pooled prices for the sale of drugs. This process is likely to safeguard the interests of the indigenous manufacturers.

In fixing the maximum price of the indigenous drugs, the powers of the Government have to be exercised only after a proper inquiry and adopting adequate methods so as to ensure a pragmatic approach. Such a fixation of maximum prices has to be based on the average cost of relatively more efficient manufacturing firms. The Government has been vested with discretion in exceptional cases to fix retention prices for individual manufacturers of bulk drugs and a common sale price based on the weighted average of their retention prices.

Any manufacturer utilizing the bulk drugs mentioned in Category III has to apply for the approval of the Government and abide by the instruction contained in the order for sale of the formulation or in respect of which price has been fixed or revised. Until the prices are fixed by the Government according to the provisions laid down in the Drugs (Price Control) Order of 1970, the existing prices will continue to prevail. Wherever feasible leader prices may be established for this category formulation also on the basis of standard compositions and the manufacturer may adopt these prices at his own option even without specific approval by the Government.

It is to be noted that under the present order, bulk drugs, utilized in the production of price-controlled formulation are subject to price control whereas under the Order of 1970 the firm could declare prices of bulk drugs not categorised as "essential". The approval of Government was required only for increasing the declared prices.

Leader prices of formulation specified in Categories I, II and III have to be fixed by the Government and the price so fixed would operate as ceiling sale price for the manufacturers. But where the selling price happened to be less than the leader price fixed under the present order, the manufacturer will have to obtain prior approval of the Government for increasing the selling price of his formulation. Where prices are higher than the leader prices, the manufacturer has to reduce the sale price to the level of the leader price fixed by the Government. Such lowering of prices would remain frozen unless and until the Government permits an increase in the sale price.

The Government will constitute and operate an account called Drug Prices Equalization Account. This account is constituted by accepting deposits from the manufacturers and importers. The depositors would be compensated therefrom with the difference between the retention price and the pooled price and common selling prices fixed under the present order.

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The three categories of formulations have been brought under price control. A percentage of 40 is allowed on Category I and 55 per cent. on Category II and a 100 per cent. on Category **III** has been fixed under the present order. But before introducing a new formulation or new pack or of a new dosage, every manufacturer or importer shall obtain prior price approval from the Government which is equally applicable in respect of imported formulation. If the necessary approval has not been accorded within the specified period the manufacturer or importer may market the new formulation at his declared price.

The manufacturers and importers should furnish price lists to the dealers, drug controllers and the Government, but fresh price lists at the time of subsequent sales need not be furnished unless there is a change therein. If any change of price is approved by the Government, effect is to be given within fifteen days of its receipt by the manufacturer. Every dealer, manufacturer, importer and distributor is obliged to display the price list at a conspicuous place with the words "Retail price not to exceed.. ... local taxes extra" which includes sales tax and octroi actually paid by the retailer.

The present order directs maintenance of proper records by the manufacturer which should show the proper turnover of the individual bulk manufacture and the sale turnover for formulations pack-wise, which should be open for inspection by the Government. Cash memos, credit memos, books of account by every manufacturer and dealer must be available for inspection. Any contravention is punishable under the provisions of the Essential Commodities Act, 1955.

The Government may revoke or modify any provision of this Order and also may grant exemption to any drug-manufacturing unit from any or all the provisions of this Order.

No doubt the Order of 1979 has imposed some fresh restrictions on the manufacturers, importers, distributors and retailers in their respective fields, but such restrictions are intended ultimately to ensure fair deal for all concerned including the customers.

DRUGS (PRICES CONTROL) ORDER, 1979

S.O. 190 (E), dated the 31st March, 1979.1-In exercise of the powers, conferred by Sec. 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 the order, unless the context otherwise requires,

(f) "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 formulations;

(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 re-sale to a dealer;

NOTE.-Cognate Acts.-A dealer under this Order should refer to the following Acts:

(1) Dangerous Drugs Act (II of 1930).

(2) Drugs and Magic Remedies (Objectional Advertisements) Act (XXI of 1954).

(3) Drugs (Control) Act (XXVI of 1950).

(4) Drugs and Cosmetics Act (XXIII of 1940). (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 (XXIII 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;

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

(U) "leader price" means a price fixed by the Government for formulations specified in Category I, Category IT or Category III of the Third

Schedule, in accordance with the provisions of paras. 10 and 11, keeping _
in view the cost or efficiency, or both, or 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 para. 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 includes 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 paras. 4 and 71 [which shall be the maximum retention price] 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 manufacturer 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 manufactured by an efficient manufacturer and allow a reasonable return on net-worth.

4. Power to fix retention price and common sale price.-Notwithstanding anything contained in para. 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 Cl. (a) :

[Provided that the Government may, having regard to the following factors, namely: .

- (a) the production and requirements of such drug in the country;
- (b) the need to afford protection to the production of such bulk drug by the individual manufacturer;
- (c) the planned growth of such drug and the Government policy in force from time to time;

by order, published in the official Gazette, fix the retention price as the common sale price, that is to say, the sale price, in respect of such bulk drug manufactured by such manufacturer, as may be specified in the said Order.]

5. Power to fix maximum sale price of new bulk drug.-(1) 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 I, 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 I.

(b) On receipt of an application under Cl. (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 Cl. (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, taking into consideration the information furnished in Form 2, by order, fix the price of such drug.

(b) The price fixed under Cl. (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 price 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 drug;

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

(2) Where a manufacturer of formulation utilizes in his formulations and 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 Equalization Account referred to in para. 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 manufacture 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 I 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 marketed 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 [published in the official Gazette], 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:

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

where

"**R. P.**" means retail price.

"**M. C.**" means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, 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 para. 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 form the basis for fixing its price.

11. Mark-up.-Mark-up referred to in para. 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 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.-(I) 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 selling price for every manufacturer of such formulations.

(2) 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.-(I) 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 paras. 10 and 11.

(2) Where the Government fixed or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilizes 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 of 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 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 the Government accordingly.

(b) The provisions of sub-paragraph (2) shall not apply to such manufacturer.

14. General provisions regarding prices of formulations. - (I) 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 approval 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 subparagraph (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 within 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 (i) 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.

Comment

Proviso.- The view taken in *Commissioner of Income tax v. P. Krishna, I* however, is that it is not a inflexible rule of construction that a proviso in a statute should always be read as limitation upon the effect of the main enactment. There may be cases where the clear language of the substantive provision as well as the proviso may lead to the conclusion that the proviso is not a qualifying clause but is in itself a substantive provision.²

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 spiffed 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 formula, as the case may be.

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

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

(i) the amount determined under sub-paragraph (2) of para. 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 shortfall 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 Cl. (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 Drugs Prices Equalization 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 provisions of this Order, other than those contained in paras. 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 (I) Every manufacturer or importer of a formulation intended for the sale shall furnish to the dealer³, 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 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 as at a price exceeding the price specified in the current price list or the price indicated on the label of the container or back 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 (XXIII 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 any 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* 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. ,

(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 Sch. C, entries Nos. 1,2, 3,7,8 and 9 of Schs. C. (1), E,G, Hand L, appended to the

Drugs and Cosmetics Rules, 1945, made under the Drugs and Cosmetics Act, 1940 (XXIII 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 pack wise, 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, 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 authorized 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 Sec. 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 para. 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 manufacturer 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 in accordance with the provisions of the Essential Commodities Act, 1955 (X 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 turn over.

32. Delegation of power.-The Government may, by notification in the official Gazette, direct that all or any of the power conferred upon it by this Order, other than those contained in paras. 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. Repeat-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.

DRUGS (PRICES CONTROL) ORDER, 1979

THE FIRST SCHEDULE

[See paras. 3,4,6 (1) and 7 (1)J

Bolks Drugs

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

Sl. No. Name of bulk drug

I. Bulk Drugs used in Category I Formulations:

1. Insulin
2. Iodo Chlorohydroxy quinoline
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. Diphtheria Toxoid
19. Tetanus Toxoid
20. Digoxin
21. Hydrochlorthiazide
22. Di-Iodo-hydroxyquinoline
23. [Morphine]

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. Fruscmide.

- \ 15. Oxytetracycline
 - 16. Primaquim
 - 17. Glyceryl Trinitrate
 - 18. Quinine
 - 19. Phl'Olidine Methyl Tetracycline
 - 20. Demethyl Chlorotetracycline
-

THE SECOND SCHEDULE

[See paras. 3,4,6 (I) and 7 (1)]

List of Bulk Drugs (including sales, esters and derivatives, in Category III formulations appearing in Third Schedule.

I. Anaesthetics, 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. Analgesics and Antipyretics:

- I. Amidopyrin
- 2. Baralgin Ketone
- 3. Codiene
- 4. Dextropropoxyphene 5. Fentanyl Citrate
- 6. Methyl Salicylate
- 7. Osadrine
- 8. Paracetamol
- 9. Pentrazocaine
- 10. Phenacetin
- 11. Propoxy Phenazone
- 12. Phenylisopropylpyrazolone

III. Anthelmintics..

- 1. Bephenium Hydroxy Nephthoate
- 2. Dithiazamin Iodide
- 3. Pyrivinium
- 4. Tetramisol
- 5. Tiabendazole
- 6. Pyrentel
- 7. I[Mebendazole]

IV. Antiameobics..

- 1. Broxyquinoline
- 2. Brobenzoxalidine
- 3. Bismuth Glycolylarsanilate
- 4. Dehydroemetine
- 5. Diloxamide

6. Emetine
7. Furazolidone
8. Chlorophenoxamide (Cefamide)
9. Metronidazole
10. Phanquone

V. Anti-asthmatic and Euteric Antiseptics..

1. Ephedrine
2. Pseudo-Ephedrine
3. Salbutamol
4. Aminophylline
5. Theophylline
6. Papaverine
7. Ajmalicin
8. [Terbutaline]

VI. Antibiotics..

1. Amphotericin
2. Bacitracin
3. Carbenicillin
4. Cloxacillin
5. Cephalexin
6. Cycloserine
7. Cephaloridin
8. Doxycycline
9. Framyoetin
10. Gentamycin
11. Gramicidin
12. Giseofulvin
13. Kanamycin
14. Lincomycin
15. Methioillin
16. Nystatin
17. Neomycin
18. Oxacillin
19. Oleandomycin
20. paranamomycin
21. Polymixin
22. Rifampicin
23. Spiramycin
24. Viomycin
25. Lyme cycline
26. Colistin
27. Tyrothricin
28. ampicillin
29. Erythromycin
30. Amoxycillin

VII. Anti-Cancer Drugs:

1. L-Asparaginase
2. Busulfan
3. Chlorambucil
4. Cyclophosphamide
5. Cerubidin (Daunorubicin)

6. 5-Fluorouracil
7. 5-Mercaptopurine
8. Thiotepa (NNN- Triethylenethiopboramide)
9. Mitomycin
10. Adviamycin
11. Bleomycin
12. Azathioprine
13. Melphalan
14. Vinblastin
15. Vincristine

V III. Anticoagulants:

1. Warfarin 3- ϵ -Acetylbenezyl-4-hydroxycoumarin
1'-2 - Heparin
3. Ethyl Biscoumacetate
4. Pheniridione
5. Heparinoid substance isolated or derived from Lung Tissue.

IX. Anticonvulsants:

- Ethosuximide
- Diphenyl Hydantoin
- Primidone

X. Antidiabetics:

1. Carbutamid
2. Chlorpropamide
3. Glybenclamide 4. Glipizide
5. Metformin.
6. Phenformin

XI. Antihistaminics:

1. Atazoline
2. Bucilizine
3. Cyclizine
4. Carbinoxamine
5. Chlorocyclizine
6. Chlorpheniramine
7. Clemisole
8. Dimenhydrinate
9. Dimethindone
10. Diphenhydramine
11. Diphenyl Pyraline
12. Diphenyl-Piperadine-Propanal
13. Hydroxyzine
14. Mepyramine
15. Methdilazine
16. Methapyrilene
17. Meclozine
18. Pheniramine
19. Halopyramine
20. Promethazine
21. N-Phenyl-N-Benzyl-Amino-l-Methyl-Piperadine
22. Pyrolidylethyl Phenyl Benzyl Amine

23. Isothiopyridyl
24. Phenindamine
25. Triprolidine
26. Triplénamine
27. Thenalidine
28. Trimeprazine
29. Cyproheptadine
30. Dexachloropheniramine
31. Bamipcm (Soventol)

XII. Antileprotic Drug:

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
- 1[5. Hyoscinamine]

XVII. Anti-tubercular:

Ethionamide
Pyrazinamide
Morphazinamide
Prothionamide
Ethambutol

XVIII. Cardiovascular:

Antihypertensive:

1. Rouwelfia Alkaloids
2. Guanethidine Sulphate
3. Methyl Dopa

4. Pentolinium Tartarate
5. Dihydroergocristine
6. Cloposamide
7. Clonidine
- \ 8. Dihydralazine

(ii) Peripheral Vasodilators and Coronary

1. Histamine
2. Isoxsuprine
3. Nyidrine
4. Penta Erythritol
5. Prenylamine
6. Sorbide Nitrate
7. Dipyridamol
8. Amyl Nitrite
9. Mannitol Hexanitate

(iii) Cardiac Glycosides :

1. Digitoxin
2. Lanatosides
3. Onabaine

(iv) Others:

1. Nikethamide
2. Clofibrate
3. Xanthinol Nicotinate
4. Carbacol (40)
5. Propranalol

Vasodilator:

1. Quinidine Procainamide
2. Methacholine *Corticosteroids :*
3. Dexamethasone
4. Betamethasone
5. Triamcinolone
6. Prednisone
7. Hydrocorjisonone
8. Cortison
9. C. T. H. (Corticotropin)

XX. Diuretics:

1. Benzthiazide
2. Bendrofluazide
3. Chlorthalidene
4. Poly thiazide
5. Spiranolactone
6. Triamberene
7. Mersalyl acid

8. Acetazolamide
9. Ethoxzolamide
10. Chlorothiazide
11. Cyclopentiazide
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 Drugs-4
5. Liver Extract
5. Ferric Ammonium Citrate
6. Iron-Sorbitol Complex

XXIII. Oral Contraceptives:

- I. Oestradiol
2. Lynestrenol
3. Mestranol
4. Nore-ethisterone
5. Norgestrel
6. Ethynodiol

XXIV. Ophthalmological Preparations:

1. Sulphacetamide
2. Boric Acid
3. Atropine
4. Pilocarpine
5. Phenylephrine
6. Homatropine
7. Physostigmine Salicylate

XXV. Oxytocics:

1. Ergot Alkaloids
2. Oxytonic

XXVI. Plasma Expanders and Transfusion Solution

1. Dextran
2. Polyvinyl Pyrrolidone 3. Dextrose Anhydrous 4. Sodium Chloride
5. Sod. Lactate
6. Pot. Chloride

"" "

1. Items 3, 6, 8 and 10 omitted by S. O. 6]0 (E), dated 17th August, 1982

XXVII. Sera and Vaccines:

1. Antirabic Vaccine
2. Yellow Fever Vaccine
3. Cholera Vaccine
4. Tetnus Antitoxin
5. Diphtheria Antitoxin
6. Gasgangrene Antitoxin
7. Antirabic Serum
8. Antivenom Serum
9. B. C. G. Vaccinej
10. Typhoid Vaccine
11. Polio Myclitics Vaccine (oral)
12. TAB Vaccine

XXVIII. Urinary:

1. Nitrofurantion
2. Nai.sdxie Acid
3. Methanamine

XXX. Vitamins:

1. Vitamin-A
2. Vitamin-B 11
3. Vitamin-B 12
4. Vitamin-B 6
5. Vitamin-B 12 (Cyano and Hydrox) 6. Vitamin-C
7. Vitamin-D 3
8. Vitamin-K
9. Vitamin-P
10. Vitamin-E
11. Niacin and Niacinamide
12. Panthcnole 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
7. Antidiarrhoeals:
8. Diphenoxylate
9. Sulfhaguanidine
10. Kaolin
11. Pectin

XXXII. Antigout drugs:

1. Allopurinol
2. Probenecid *XXXIII. Disinfectant:* Cresols

XX XIV. Antitussives and Expectorants:

- Chlophodional Dextromethorphan
- Guiacol Glyceryl Ether
- Noscapine
- Oxeladine
- Piperazethate
- Pholcodein
- Menthol

XXXV. Dental products other than those containing local anaesthetics:

1. Sodium Flouride
2. Stannous Flouride

***XXXVI. Dermatological preparations not containing antibiotics, sulphona
mides and cortiosteroids :***

1. Sulphur sublimed
2. Methoxalen
3. Ichthamm'ol
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. Galamine
14. Ghlorphenesin

XXXVII. Parasympathomimetics:

1. Methacholine
2. Carbachol
3. Neostigmine
4. Physosigmine
5. Abetyl Choline Chloride
6. Pyridostigmine

XXXVIII. . Other .{Inti-infectives :

1. . Trimethoprim
2. Sulphamthoxazole

3. Sulphamoxole
4. Sulphadimethoxin
5. Sulphaphenozole
6. Sulphamethoxy-pyridazine 7. Sulphasomidine
8. Sulphadiazine
- 9.. Sulphafurazole
10. Suuccinyl Sulhathiazole 11. Tolnaftate
11. Meconazole
12. Monosulfaram (Tetmasole) 14. Sulphamethizole.]

XXXIX. Central nervous system stimulants:

- 1.Caffine

THE THIRD SCHEDULE

[See paras. 9 (1), 11, 12, 13, 14, 15, 18, 21 and 30]

List of Category I, Cotegory II and Category III Formulations

category I Formulations:

1. Asprin 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 aud Di-iodo-hydro-oxyquinoline tablets
8. INH tablets
9. INH *plus* Thiacetazone tablets
10. Morphine injection]
11. Penicillin injection including Procaine, Penicillin G and Benzathine Penicillin (all strengths)
12. PAS and its salts, granules and tablets
13. Phenoxy-methyl 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
2Chloramphenicol monosteryl glycolate] suspension and syrup and Chloramphenicol Sodium Succinate
injection
4. Chloramphenicol in combination with Streptomycin I
5. Chloroquin salts 1
6. Primaquin tablets
- 7.- Calcium Benzoyl PPS tablets

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1. Diethyl Carbamazsine Citrate tablets

2. Furseimide tablets, injection
3. Glyceryl- Trinitrate tablets
4. Phthalpl Sulphathiazole tablets
5. Prednisone tablets and injection
6. Phenobarbitone tablets
7. Piperazine and its salts-tablets, syrup 15. Sulphadimide tablets
8. Tetracyclines, capsule, tablets; syrup, injection, eye ointment (including Oxy-Demethyl-Choloro and Pyrrolidire Methyl Tetracyclines)
9. Tolbutamide tablets
10. Tetanus Toxoid injection
11. Diphtheria Tetanus Toxoid injection
12. Quinine salts and injection

Category III Formulations:

Formulations based on drugs falling under the following categories excluding the formulations included in categories I and II :

1. Anaesthetics, general and local
2. Analgesics and Antipyretics
3. Anthelmintics
4. Antiamoebics
4. Anti-asthmatic drugs and Enteric antiseptics
5. Antibiotics including Semisynthetic antibiotics
6. Anticancer drugs
8. Anticoagulants
9. Anticonvulsants
10. Antidiabetics
11. Antihistaminics
12. Antibiotic drugs
13. Antimalarial drugs
14. Antirheumatic 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. Ophthalmological 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 based on antibiotics
37. Parasympathomimetics 38. Other anti-infectives

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