DRUGS (PRICES CONTROL) ORDER, 1979

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SCHEDULE 5 :- THE SCHEDULE

DRUGS (PRICES CONTROL) ORDER, 1979

[2]2. Published in the Gazette of India, Pt. II, Sec. 3 (ii), dated 31stMarch. 1979; Now stand repealed by the Drugs (Prices Control) Order, 1987, vide S.O. 794 (E) dated 26th August, 1987 (w.e.f. 26th August, 1987). See Cl. 30 of the said Order of 1987. 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) Older, 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 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 resale to a dealer;

(d) "drugs" includes:

(i) a medicine for internal or eternal use of human beings or animals and all substances intended to housed 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 drug 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 Drugs and Cosmetics Act, 1940 do riot 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, inaccordance 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 alter 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 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 paragraphs 4 and 7 [1] [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 Older,

(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.

1. Ins. by S.O. 504 (E), dated 14th July, 1983 (w.e.f. 16th July, 1983)

3. Power to fix the maximum sale price of indigenously manufactured bulk drugs specified in Fist 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.

(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 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

I 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

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, [1][by order published in the Official Gazette], 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).

[2] [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 she 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.]

1. Subs. for .the words "by order" by S.O. 606 (E), dated 23rd August, 1983 (w.e.f. 24th August, 1983).
2. Ins. by S.O. 504 (E), dated 14th July, 1983 (w.e.f. 16th July, 1983).

5. Power to Fix maximum sale price or 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 From 1.

(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

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 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 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 manufacturer 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 shad, 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 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, [1][published in the Official Gazette] direct any manufacturer of any bulk drug to sell such bulk drug to such manufacturers of formulations [2][and in such quantity] 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.

[3] [(3) Where a general or special Order under sub-paragraph (1) has been issued, no manufacturer of formulations other than as specified in the said Order shall purchase such bulk drug.]

1. Ins. by S.O. 504(E), dated 14th July, 1983 (w.e.f. 16th July, 1983).
2. Ins. by S.O. 606(E), dated 23rd August, 1983 (w.e.f. 24th August, 1983).
3. Ins. by S.O. 504(E), dated 14th July, 1983 (w.e.f. 16th July, 1983)

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.) X [1 + M.U. + E. D.] 100 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 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 form the basis for fixing its price.

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 the Category I or Category II of the Third Schedule and such leader price shall operate as the selling sale price for every manufacturer of such formulations.

1[(2) * * *]

2 [(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.

1. Sub-clause (2) omitted by S.O. 978(E), dated 17th December, 1980 (w.e.f. 20th December, 1980).
2. Renumbered as "sub-clause (3)" by S.O. 978(E).

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 theprovisions 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 the 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 provisions 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 formulatior or a new pack, or a new dosage form of his existing formulation specified in Category or Category II or Category III of theThird 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 CategoryIII 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 of 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 modification, 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 (1) at the price declared by him in his application, issued 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, 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 Price 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 amount 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 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 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 provisions 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 duly) and the retail price' of such formulation and the list shall be furnished to the dealers, in Form 5, nol later than thirty days from the commencement of lhis 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 lime, 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 lable 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 of the container or pack thereof whichever is the less, plus the local taxes, if any payable.

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 gpod 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 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.

(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.

1 [(4) The retail price referred to in sub-paragraphs (1) and (2) shall be exclusive of the local taxes.

1. Ins. by S.O. 599(E), dated 19th August, 1983 (w.e.f. 19th August 1983).

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 lime 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 the 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 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 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, 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 importers, 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 paragraphs 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 cessor.

SCHEDULE 1
Bluk Drugs

List of Bulk Drugs (including salts, derivatives and esters, if any) used in Categories and II Formulations appearing in Third Schedule I. Bulk Durgs used in Category I Formulations Sl. No Sl. No. Name of the Bulk Drug 1. Insulin_____ 2. Indo-Chtoro hydroxyquinoline 3. Insonicotinic Acid Hydrazide 4. P A S Acid 5. P A S Sodium 6. Potassium Penicillin G. 7. Sodium Pencilin G. 8. Procaine Penicillin 9. Pencillin Potassium V (Phenoxy Methyl Penicillin) 10. Streptomycin Sulphate 11. Thiacetazone 12. Dipsone 13. Aspirin 14. Pethidine 15. Benzathing Penicillin 16. Calcium P A S 17. Pertussis Toxoid , 18. Diptheria Toxoid 19. Tetanus Toxoid 20. Digoxin 21. Hydrochlorthlazide 22. Di-Iodohydroxyquinoline [23. Morphine II. Bulk Drugs used in Category II Formulations. 1. Amodiaquin 2. Chloramphenicol 3. Chloroquine 4. Prednisolone 5. Tetracycline 6. Tolbutamide 7. Sulphadimidine 8. Diethylcarbamazine citrate 9. Analgin 10. Phenobarbitone 11. Phthalyl Sulphathiazole 12. Calcium B. P AS 13. Piperazine 14. Frusemide 15. Oxytetracycline 16. Primaquin Sl. No. Name of the Bulk Drug 17. Glyceryl Trinitrate 18. Quinine 19. Pyrolidine Methyl Telracyclinc 20. Demethyl Chlorotetracycline [21. * * *]

SCHEDULE 2

THE SECOND SCHEDULE

[See Paragraphs 3,4,6(1), 7 (1)] List of Bulk Drugs (including salts, esters and derivatives, if any) used in Category IIIFormulations 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. Anlagestics and Antipyretics: 1. Amidopyrin 2. Baralgan Ktone 3. Codiene 4. Dextropropoxyphene 5. Fentanyl Salicylate 6. Methyl Salcylate 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 [7. Mebendazole] Sl. No. Name of the Bulk Drug IV. Antiameobics: 1. Broxyquinoline 2. Brobenzoxal idine 3. Bismuth Glycolly larsanilate 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-Ephedirine 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. Cephaloridine 7. 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. Refampicin 23. Spiramycin Sl. No. Name of the Bulk Drug 24. Viomycin. 25. Lymecycline 26. Colistin 27. Tyrothricin 28. Ampicillin 29. Erythromycin [30. Amoxicillin] [31. Dicloxacillin] 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. Melphatan 14. Vinblastin 15. Vincrastine VIII. Anticagulants: 1. Warfarin 3-œ-Acetonylbenzyl (4-hydroxycoumarin) 2. Heparine 3. Ethyl Biscoumacotate. 4. Pheniyridione 5. Heparinoid substance isolated or derived from Lung Tissue. IX. Anticovulsants: 1. Ethosuximide 2. Diphenyl Hydantoin 3. Primidone [4. Carbamazepine] X. Antidiabetics: 1. Carbutamide 2. Chlorpropamide 3. Glybenclamide 4. Glipizide 5. Metformin Sl. No. Name of the Bulk Drug 6. Phenformin XI. Antistaminics: 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. Hydrozynize 14. Mepyramine 15. Methdilazine 16. Methapyrilene 17. Meclozine 18. Pheniramine 19. Halopyramine 20. Promathazine 21. N-Phynyl-N-Benzyl-4-Amino-l-Methyl-Piperadine 22. Pyro-lidylethyl Phenyl Benzyl-Amine 23. Isothiopendyl 24. Phenindamine 25. Triprolidine 26. Triplenamine 27. Thenalidine 28. Trimeprazine 29. Cyprophepta dine 30. Dexachloropheniramine 31. Bamipiem(Soventol) XII. Antileprotic Drugs: Clofazimine XIII. Antimalarial Drugs: 1. Mepacrine 2. Pyrimenthemine XIV. Antirheumatic: 1. Ibuprofun 2. Indomethacin 3. Oxy-Phenylbutazone 4. Phenyl Butazone 5. Sodium Salicylate Sl. No. Name of the Bulk Drug XV. Antiseptics: 1. Chloroxylenols 2. Chlorocresole 3. Hexyl-Resorcinol 4. Greosote 5. Hydrogen Peroxide 6. Iodine 7. Cetrimide 8. Chlorhexidine XVI. Antispasmodics: 1. AtropineMethyInitrate 2. Ethylmorphine 3. Belladonna Alkaloids 4. Hyoscine [5. Hyoscinamine] XVII. Antitubercular: 2 [1. * * * *] [1. Ethionamide] [2. Pyrazinamide] [3. Morphazinamide]

[4. Prothionamide] [5. Ethambutal] XVIII. Cardiovascular: (i) Antihypertensive: 1. Rauwelfia Alkaloids 2. Guanethidine Sulphate 3. Methyl Dopa 4. Pentolinium Tartarate 5. Dihydroargocrystins 6. Cloposamide 7. Clonidine 8. Dihydralazine (ii) Peripheral Vasodilators and Corponary Vasodilator : 1. Histamine 2. Isoxsuprine 3. Nylidrine 4. Penta Erythritol Tetranitrate 5. Prenylamine 6. Sorbide Nitrate 7. Dipyridamol 8. Amyl Nitrite Sl. No. Name of the Bulk Drug 9. Mannitol Hexanitrate (iii) Cardiac Glycosides: 1. Digitoxin 2. Lanatosides 3. Onabaine (iv) Others 1. Nikethamide 2. Clofibrade 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. Diureties: 1. Benzthiazide 2.. Bendrofluazide 3. Chlorthalidene 4. Polythiazine 5. Spiranolactone 6. Triamberene 7. Mersalyl Acid 8. Acetazolamide 9. Ethoxzolamide 10. Chlorothiazide 11. Cyclopenthiazide 12. Hydroflumethiazide 13. Ethacrinic acid. XXI. Drugs used for Calcium therapy : 1. Calcium Gluconate 2. Calcium Levulinate 3. Calcium Labtate 4. Calcium Lactobionate XXII. Haematinics: 1. Ferrous Gluconate 2. Ferrous Fumerate Sl. No. Name of the Bulk Drug 3. Ferrous Sulphate 4. Iron-Dextran Complex 5. Liver Extract 6. Ferric Ammonium Citrate 7. Iron-Sorbitol Complex XXIII. Oral Contraceptives: 1. Oesteradiol 2. Lynestrenol [3. * * *] 4. Mestranol 5. Nor-ethisterone [6. * * *] 7. Norgestrel [8. * * *] 9. Ethynodiol [10. * * *] XXIV. Opthalmological Preparations: 1. Sulphacetamide 2. Boric Acid 3. Atripone 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 Sl. No. Name of the Bulk Drug 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-B 3. Vitamin-B 4. Vitamin-B 5. Vitamin B (Cyenoand Hydroxy). 6. Vitamin C 7. Vitamin D 8. Vitamin K. 9. Vitamin P. 10. Vitamin E. 11. Niacin and Niacioamide. 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: 1. Cresolds. XXXIV. Antitussives and Expectorants : 1. Chlophodional. 2. Dextromethorphan. Sl. No _____Name of the Bulk Drug_____ 3. Guiacol Glyceryl Ether. 4. Noscapine. 5. Oxeladine. 6. Piperazethate. 7. Pholocodeine. 8. Menthol. XXXV. Dental products other than those containing local anaesthetics : 1. Sodium Flouride. 2. Stannous Flouride. XXXVI. Dermatological preparations not containing antibiotics sulphonamides and corticosteroids: 1. Sulphur sublimed. 2. Methoxsalen. 3. Ichthemmol. 4. Ammoniated mercury. 5. Resorcinol. 6. Chrysarobin. 7. Dithranol. 8. Salicylic acid. 9. Benzoic acid. 10. Zinc oxide. 11. Benzyl benzoate. 12. Gamma Benzenchexachloride. 13. Calamine. 14. Chlorphenesin. XXXVII. Parasympathomimetics: 1. Methacholine. 2. Carbachol. 3. Neostigmine. 4. Physostigmine. 5. Acetyl Chlorine 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. Sl. No. _____Name of the Bulk Drug_____. [12. Meconazole 13. Monosulfaran (Tetmasole). 14. Sulphamethizole] [15. Nitrofurazone] [XXXIX. Central nervous System Stimulants : 1. Caffeine]

SCHEDULE 3

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-1 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-iodohydroxy-quinoline tablets. 8. INH tablets. 9. INH plus Thiacetazone tablets. [10. Morphine injection.] 11. Penicillin injection including procaine Penicillin G and Benzathine Pencillin (all strenghts) 12. PAS and its salts, granules and tablets. 13. Phenoxymethyl pencillin tablets. 14. Streptomycin injection all strengths plus combination with penicillin. 15. Pethidine injection. Category-11 Formulations 1. Analgin tablets. 2. Amodiaquin tablets. [3. Chloramphenicol oral preparations including

chloramphenicol palmiate, and chloramphenicol monosteryl glycolate and suspension and Syrup and chloramphenical Sodium Succinate injectable.] 4. Choloramphenicol 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. Phlhalyl Sulphathiazole tablets. 12. Predniolone 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 Pyrroliore Methyl Tetracyclines). 17. Tolbutamide tablets. 18. Tetanus Toxoid Injection. 19. Diptheria tetanus toxoid injection. 20. Quinine Salts' tablets and injection. [21. * * *] 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. Analagesics and Antipyreties. 3. Anthelimincs 4. Antiamoebics. 5. Anti Asthmetic drugs and Enteric Antiseptics. 6. Antibiotics including seimsynthetic antibiotics. 7. Anticancer Drugs. 8. Anticoagulants. 9. Anticonvulsants. 10. Antidiabatics. 11. Anithistaminics. 12. Antileprotic 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. 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 antibiotic sulphonamides and coiticosteroids 36. Otic preparations not based on antibiotics 37. Parasymphathominetics 38. Other Anti-infectives

SCHEDULE 4
THE FOURTH SCHEDULE

SCHEDULE 5
THE SCHEDULE

\ \ \ \(See Paragraph 15) Statement showing maximum pre-tax return on sales turnover of manufacturers or importers of formulations. Category 'A'-Large Units with" turnover Maximum \ \exceeding Rs. 6 crores per annum pre-tax return on sales \ \turnover
(a) having no basic drug manufacturing activity nor any \research activity 8% (b) having basic drug manufacturing 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. I 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 turnover of less than Rs. 1 crore per \annum. \(a) having only formulation capacity 12% \(b) having basic drugs manufacturing activity at 5% or \ \more of turnover \ 13%