DRUGS (PRICES CONTROL) ORDER, 1987

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DRUGS (PRICES CONTROL) ORDER, 1987

[1]1. Published in the Gazette of India. Extraordinany. Pt. II. Sec. 3 (ii). No. 431. dated 26th August. 1987. pp. 19-36. In exercise of the powers conferred by S.3 of the Essential Commodities Act, 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, 1987.

(2) It extends to the whole of India.

(3) It shall come into force on the date [1] of its publication in the Official Gazette.

1. 26th August. 1987.

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

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

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

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

(d) "drug" includes:-

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

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

(iii) bulk drugs and formulations:

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

(f) "formulation" means a medicine processed out of, or containing one or more bulk 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 the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply:

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

(h) "Government" means the Central Government;

(i) "import", with its grammatical variations 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) "celling price" means a price fixed by the Government for formulations specified in Category I or Category II of the Third Schedule In accordance with the provisions of paras. 6 and 7 keeping In view the cost or efficiency, or both, of major manufacturers of such formulations;

(k) "manufacture", in relation to any drugs 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 paid-up share, capital of a company plus free reserve, if any, and surpluses, excluding outside investments which are not readily available for operation of activity;

(n) "non-scheduled bulk drug" means a bulk drug not specified in the First or Second Schedule;

(o) "non-scheduled formulation" means a formulation not specified in the Third Schedule;

(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) "retailer" means a dealer carrying on the drug arrived at or fixed in accordance with the provisions of this Order and includes a ceiling price;

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

(t) "scheduled bulk drug" means a bulk drug specified in the First or Second Schedule;

(u) "scheduled formulation" means a formulation specified in the Third Schedule;

(v) "sale 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:

(w) "schedule" means a schedule appended to this Order;

(x) "wholesaler" means a dealer or his agent or a stockist appointed by a manufacturer or an importer for the sale o f his drugs to a retailer, hospital, dispensary, medical, educational or research institution purchasing bulk quantities ot drugs;

3. Powers to fix the sale price of indigenously manufactured bulk drugs specified in the First or Second Schedule :-

(1) The Government may with a view to regulate the equitable distribution and increasing supply of an indigenously manufactured bulk drug specified in the First or Second Schedule and making it available from different manufacturers at fair prices, after making such inquiry as It deems fit, from time to time by notification in the Official Gazette, a maximum sale price at which such a bulk drug shall be sold : Provided that for the purpose of

enquiry, details in Form I of the Fourth Schedule and such additional details as may be required shall be provided by the manufacturers twice a year, viz. '31st January and 30th June, in a year or as and when required by the Government : Provided further, that where the Government fixes more than one price for bulk drug produced by different manufacturers, on account of different options exercised by manufacturers of such bulk drug under sub-paragraph (2), Government may also fix a weighted average price for such bulk drug which shall be considered in fixation of prices of formulations containing such bulk drug.

(2) While fixing the price of bulk drug under sub-paragraph (1) the Government may take into consideration a post-tax return of 14 per cent. on net worth or return of 22 per cent. on capital employed or in respect of new plant an internal rate of return of 12 per cent. based on long-term marginal costing depending upon the option for any of the specified rates of return that may be exercised by manufacturer of bulk drug : Provided that the option with regard to the rate of return once exercised by a manufacturer shall be final and for any change In the said rate of return prior approval of the Government shall be necessary :

(3) No person shall sell a bulk drug at a price exceeding the sale price fixed under sub-paragraph (1) plus local taxes, if any, payable: Provided that until the price of a bulk drug is 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 a bulk drug shall not sell such bulk drug at a price exceeding the price which prevailed as aforesaid. If any manufacturer commences production of bulk drug specified in the First or Second Schedule, he shall within 15 days of commencement of production, submit the details in Form-1 along with such additional details as the Government may require him to submit and the Government may after receipt of the details and after making such inquiry as It deems fit, notify the price of a bulk drug produced by such a manufacturer.

4. Procedure to be followed for fixation or revision of bulk drug prices not specified in the First or Second Schedule :-

(1) Every manufacturer, producing a non-scheduled bulk drug shall submit a list of all such bulk drugs currently produced by him within thirty days of the commencement of this Order and indicate the details of cost of such bulk drugs in [1] [Form I-A] of the Fourth Schedule.

(2) Where after the commencement of this Order, any manufacturer commences production of a non-scheduled bulk drug he shall within 14 days of commencement of production, furnish to Government the details in [Form i-A) of the Fourth Schedule along with such additional details as the Government may require and Indicate the price at which he proposes to sell the drug.

(3) Any manufacturer of a non-scheduled bulk drug desiring to revise the price, may, if necessary, adjust the sale price of the said bulk drug to the changes in cost and revise the price after submitting to the Government the details of cost in [Form I-A] : Provided that, for the purpose of this paragraph, the Government, may after making such inquiry as it may deem necessary, in public interest, fix or revise the price of any non-scheduled bulk drug and the manufacturer or importer of such bulk drug shall implement the price so fixed or revised within fifteen days of receipt of the order.

1. Subs. by S.O. 273 (E), dated 22nd March, 1988 (w.e.f. 22nd March, 1988).

5. Power to direct manufacturers of bulk drugs to sell bulk drugs to manufacturers of formulations :-

(1) The Government may, from time to time, by general or special order, direct any manufacturer of any bulk drug to sell such bulk drug to such manufacturers of formulations as may be specified in such order : Provided that while making any such order, the Government shall have regard to allow any of the following factors, namely :

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

(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.

6. Calculation of retall price of formulations :-

The retail price of the formulation shall be calculated in accordance with the following formula, namely: R.P.= (M.C.+C.C.+P.M.+P.C.)x(l+MAPE/100)+E.D. where-"R.P." means retail price, "M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf, "C.C." means conversion cost worked out in accordance with established procedures of costing and may be fixed as a norm from time to time by notification in the Official Gazette in this behalf, "P.M." means cost of the packing material used in the packing of concerned formulation and includes process loss, a norm fixed from time to time by notification in the Official Gazette in this behalf, "P.C." means packing charges worked out in accordance with established procedures of costing and may be fixed as a norm from time to time by notification in the Official Gazette in this behalf, "MAPE" means Maximum Allowable Post-Manufacturing Expenses including trade margin referred to in para. 7, "E.D." means excise duty : Provided that in the case of an imported feormulation, the landed cost shall form the basis for

fixing its price alongwith such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed 50 per cent. of the landed cost.

Explanation.-For the purposes of above proviso, "landed cost" shall mean the cost of import of drug inclusive of customs duty and clearing charges.

7. MAPE :-
MAPE referred to in para. 6 means the maximum allowable post-manufacturing expenses including trade margin and shall not exceed-

(a) seventy-five per cent. in the case of formulations specified in Category I of the Third Schedule ;

(b) one hundred per cent. in e case of formulations specified in Category II of the said Schedule.

Explanation.-

(a) For the purpose of this paragraph "post-manufacturing expenses" means all costs incurred by a manufacturer from the stage of ex-factory cost of retailing and includes trade margin.

(b) For the purpose of categorisation of a formulation it shall be deemed as-

(i) Category I formulation, if it contains any bulk drug either individually or in combination, specified for Category I formulations:

(ii) Category II formulation, if it contains any bulk drug either individually or in combination, specified for Category II formulations: Provided that, in case the formulation contains bulk drugs specified in both Categories I and II, it shall be deemed as a Category I formulation.

8. Power of Government to fix ceiling prices of formulations specified in Category I of the Third Schedule :-

(1) The Government may. from time to time, by notification in the Official Gazette, fix the ceiling price of a formulation specified in Category I of the Third Schedule in accordance with provisions of paras. 6 and 7 and such price shall operate as the ceiling sale price for every manufacturer or such formulations.

(2) The Government may, of its own motion or on application made to it in this behalf by a manufacturer in Form 2 or Form 3, as the case may be, after calling for such information as it may consider necessary, by notification in the Official Gazette, fix a revised-ceiling price for a formulation.

9. Power of Government to fix retall prices of formulations spec- ified in Third Schedule :-

(1) The Government may. from time to time, by order, fix the retail price of a formulation specified in the Third Schedule in accordance with the provisions of paras. 6 and 7.

(2) Where the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilises such bulk drug in his formulations specified in the Third Schedule he shall, within thirty days of such fixation or revision, make an application to the Government in Form 2 and the 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 2 or Form 3, 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 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) Without prejudice to the provisions of preceding sub- paragraphs,-

(a) the Government may, if it considers necessary or expedient so to do, by notification in the Official Gazette, fix or revise a ceiling price for any formulation specified in 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) with a view to enabling the manufacturers of similar formulations in pack sizes other than those for which ceiling prices referred to in the above sub-paragraph have been notified, to market. such formulation packs at worked-out prices, the Government may, by notification in the Official Gazette, fix norms from time to time and such manufacturers shall work out the price for their respective formulation packs in accordance with such norms and market such formulation packs after thirty days of intimation to the Government in this behalf: Provided that the Government may, if it considers necessary by order, revise the price so intimated by the manufacturer and upon such revision, such manufacturer shall not sell such formulation at price exceeding the price so revised. The manufacturer received Exs. L and M. The two documents were an imposition of prices under para 13 (now para. 9) together with an explanation for some features that had guided the exercise carried out. The crucial question is

whether Exs. L and M are violative of the land. The Court held that Exs. L and M are not legislation, but an executive order purporting to be upon legislation. Agreeing with the views contained in Cyanamid case it was further held that Exs. L and M cannot be sustained. [1]

1. Sandoz (India) Ltd. u. Union of India, 1988 E.F.R. 82 at pp. 84, 85, 91 (Bom.).

10. General provisions regarding prices of formulations :-

(1) No manufacturer or importer shall market a new formulation or a new pack, or a new dosage form of his existing formulation specified in Category I or Category II 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 formulation specified in Category I or Category II 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 formulation referred to in sub-paragraph (1) or sub-paragraph (2), shall make an application to the Government in Form 2 or Form 3, 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 (1) at a price not exceeding the price claimed by him in his application after intimating the Government accordingly : Provided further that the Government may, if it considers necessary, by order, revise the price as declared by the manufacturer or importer, as the case may be, and upon such revision, the manufacturers or importer shall not sell such formulation at a price exceeding the price so revised.

11. Information to be furnished by the manufacturers and im- porters of non-scheduled formulations :-

(1) Every manufacturer or importer of non-scheduled formulations shall, within thirty days of the commencement of this order, submit to Government a separate price list of such formulations in Form 5.

(2) Any manufacturer or importer who desires to market a new pack or revise the prices of an existing pack, of a non-scheduled formulation, may do so after furnishing the details of the proposed retail price and cost data in [1] [Form 2-A] or Form 3, as the case may be.

(3) Every manufacturer or importer of a non-scheduled formulation shall furnish to the Government in January and June every year, the details of new packs introduced and revision of retail prices of the said non-scheduled formulations effected during the said period in Form 4 and shall furnish such additional information as may be called for, by the Government in this behalf : Provided that, for the purpose of this paragraph, the Government may, after making such Inquiry as it may deem necessary, in public interest, fix or revise a retail price for any non-scheduled formulation and the manufacturer or importer of such formulation shall implement the price so fixed within fifteen days of receipt of the order.

1. Subs. by S.O. 273 (E), dated 22nd March, 1988 (w.e.f. 22nd March, 1988).

12. Power to revise prices of bulk drugs and formulations :-
Not withstanding anything contained in this Order :

(a) the Government may, after obtaining such information as may be considered 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, after calling for such information by order fix or revise the retall price of any formulation including a non-scheduled formulation:

(c) the Government may, if it considers necessary so to do in public Interest, by order Include any bulk drug or formulation In Sch. I, Sch. II or Sch. Ill, as the case may be, and fixor revise the price of such a bulk drug or a formulation in accordance with the provisions of paras. 3, 6 and 7, as the case may be.

13. Fixation of price under certain circumstances :-
Where any manufacturer, importer of a 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.

14. Power to recover dues accrued under the Drugs (Prices Con- trol) Order, 1979, Into the Drug Prices Equalisation Account :-

(1) Notwithstanding anything contained in this Order, the Government may, by notice require the manufacturer, importer or distributor, as the case may be, to deposit the amount which has accrued on account of the actions under the Drugs (Prices Control) Order, 1979 , on or before the commencement of this Order, into the Drugs Prices Equalisation Account and the manufacturer, importer or distributor, as the case may be, shall deposit the said amount Into the said account within such time as the Government may specify in the said notice.

(2) The existing amount, if any, in the Drugs Prices Equalisation Account on or before the date of commencement of this Order, and the amount deposited under sub-paragraph (1) shall be used for the purposes stipulated in the Drugs (Prices Control) Order, 1979 .

15. Power to recover dues :-
Notwithstanding anything contained in this Order, the Government may, if it considers necessary, by notice, require the manufacturers, importers or distributors, as the case may be, to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government as per the provisions of this Order.

16. Furnishing of price list bymanufacturer or importer to Gov- ernment :-

(1)Every manufacturer or importer of a bulk drug intended for sale shall, within thirty days from the commencement of this Order and thereafter every year within one month of introduction of Annual Finance Bill in Parliament, submit a price-list in Form 5 to the Government.

(2) Every manufacturer, importer or distributor of a formulation intended for sale shall within thirty days from the commencement of this Order and thereafter, every year, within one month of introduction of the Finance Bill in Parliament, shall, furnish .a price-list to the dealers, State Drugs Controllers and the Government in [1] [Form 5, In the case.of scheduled formulations, and In Form 5-A, in the case of non-scheduled formulations]: 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 byway of addition, deletion or alteration in that list, in which case a supplementary price-list including such additions, deletions or alterations shall be furnished.

(3) Every manufacturer or importer shall give effect to the policy of a bulk drug or formulation, as the case may be, as fixed 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 and issue a supplementary price list in this regard to the dealers, State Drug Controllers and the Government and indicate necessary reference to such price fixation.

(4) Every dealer shall display the price-list on 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.

1. Subs. by S.O. 230 (E), dated 1st April, 1991 (w.e.f. 1st April, 1991).

17. Retall 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 container of the formulation and 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, in the case of scheduled formulations and the words "maximum retail price" preceding it and the words "inclusive of all taxes" succeeding it, in the case of non-scheduled formulations: Provided that in the case of a container consisting of smaller saleable packs the retail price of such smaller pack shall also be displayed on the label of each smaller pack and such price shall not be more than the pro-rata price of the main pack rounded off to nearest paise.

18. Control of sale prices of bulk drugs and formulations :-
No person shall- sell any bulk drug or formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container of pack thereof, whichever is less, plus all local taxes, if any, payable in the case of scheduled formulations and maximum retail price inclusive of all taxes in the case of non-scheduled formulations.] This revision case Is filed against the judgment of the Sessions Judge, Srikakulam in STC No. 3/87, dated the 9th September, 1988 convicting the petitioner for the violation of the provisions of para. 21 (now 18) of the Drugs (Prices Control) Order, 1979 read with Section 7 of the Essential Commodities Act, 1955 , and sentencing him to undergo R.I. for three months and to pay fine of Rs. 100 and in default to suffer S.I. for 15 days. The High Court observed that it is not just and proper to remand the case to the Court below for fresh disposal according to law, because, the offence took place on 10th May, 1983 and more than 5 years have elapsed and the sentence of imprisonment is for shorter period and the fine is a small amount. The conviction and sentence were however set aside, and the revision allowed. It was observed that the fine amount, if paid be refunded to the petitioner herein. [1]

1. Ch.Surya Raou. State, 1989 E.F.R. 493 at pp. 493, 497 (A.P.).

19. Sale of split quantities of formulations :-
No dealer shall sell loose quantity of any formulation drawn from a bottle containing not less than 100 units of such formulation at a price which exceeds the pro-rata price of the formulation plus 5 per cent. thereof.

20. Manufacturer, distributor and dealer not to refuse sale of drug :-
Subject to the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940), and rules made thereunder-

(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.

21. Prices to the traders :-

(1) A manufacturer, distributor or wholesaler shall sell a formulation to a retaller unless otherwise permitted under the provisions of this Order or any order made thereunder, at a price equal to the retail price (excluding excise duty, if any) minus 16% thereof In the case of price controlled drug.

(2) Notwithstanding anything contained in sub-paragraph (1), 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]

1. Ramanujan v.State of Kerala. 1988 (l) Ker.L.T. 254 at pp. 255-256: 1988 E.F.R. 204 at p. 207 (Ker.).

22. Maintenance of records and production thereof for inspec- tion :-

(1) Every manufacturer and importer shall maintain In such form as may be specified by the Government, records relating to the saies turnoever of individual bulk drugs, manufactured or imported by him, as the case may be, 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 the Government shall have the power to call for such records or to inspect such records at the premises of the manufacturer or importer.

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

23. 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, by 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, alongwith the containers, packages, or coverings in which the drug is found, in respect of which the suspects that any provisions 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, or is about to be contravened.

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

24. Power of review :-
Any person aggrieved by any notification issued or order made under paras. 3,4,8,9, 10, 11. 12 or 13 may apply to the Government for a review of the notification or order within 15 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 : Provided that pending a decision by the Government on the application submitted under the above paragraph no manufacturer importer or distributor, as the case may be, shall sell a bulk drug or formulation, as the case may be, at a price exceeding the price fixed by the Government, of which a review has been applied for.

25. Power to issue guidelines and directions :-

(1) The Govern- ment, may for the purpose of implementing various paragraphs of this Order, authorise any official, by a general or special order, to Inspect the premises of any manufacturer, importer, distributor or dealer and such person shall allow such authorised officer and make available all relevant information required for such purpose.

(2) The Government may, from time to time, issue such guidelines and directions, consistent with the provisions of this Order to any manufacturer or importer, as may be necessary, to carry out the provision of this Order and such manufacturer or importer shall comply with such guidelines and directions.

26. Penalties :-
Any contravention of any of the provisions of this Order shall be punished in accordance with the provisions of the Essential Commodities Act, 1955 (10 of 1955).

27. Interpretation of categorisation :-
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.

28. 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 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.

1 [(e) production of bulk drugs from basic stage by process developed through indigenous research and developments.

1. Ins. by S.O. 82 (E), dated 18th January, 1989 (w.e.f. 19th January, 1989).

29. 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 paras. 24, 25, 27 and 28 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 Government, or

(b) such State Government or such officer or authority subordinate to the State Government, as may be specified In the direction.

30. Repeal and saving :-

(1) The Drugs (Prices Control) Order, 1979, is hereby repealed.

(2) Notwithstanding such repeal, anything done or any action taken, including any notification or order made, direction given, notice Issued or exemption granted under the Drugs (Prices Control) Order, 1979 , shall, in so far as it is not inconsistent with the provisions of this Order, be deemed to have been done, taken, made, given, Issued or granted, as the case may be, within the corresponding provisions of this Order.

SCHEDULE 1
BULK DRUGS

List of bulk drugs (including salts, esters and derivatives, if any) required for the following National Health Programmes used in Category I formulations appearing in Third Schedule. I. National T.B. Bradication Programme. 1. Streptomycin. 2. Isoniazid. 3. Thiacetazone. 4. Ethambutol. 5. Sodium PAS 6. Pyrazinamide. 7. 1[***] II. National Leprosy Eradication Programme. 1. Dapsone. 2. Clofazamine. 3. 2[* * *] III. National Trachoma Control Programme and National Programme for Control of Blindness. 1. Tetracycline Hydrochloride. 2. 3[* * *] 4[2] Pilocarpine 5[3] Hydrocortisone 4[4] lodoxouridine 6. 6[* * *] 4[5] Acetazolamide. 4[6] Atropine. 4[7] Homatropin 6[* * *] 7[IV] National Malaria Bradication Programme : 1. Chloroquine. 2. Amodiaquine. 3. Quinine. 4. Primetheamine. 5. Sulfamethopyrezine. 6. 8[* * *] 7[[V] National Filaria Bradication Programme : 1. Diethyl Carbamazine.

SCHEDULE 2
BULK DRUGS

List of bulk drugs (Including salts, esters and derivatives, If any) used in Category II formulations appearing In Third Schedule. 1. Aspirin 2. Oxycillin 3. Ampicillin. 4. 1[* * *] 5. Aluminiu Hydroxide. 6. 2[* * *] 7. Aminophylline. 8. Baralgan Kutoe. 25 9. 3[* * *] 10. \Benzathine Benzylpenicillin. 11. \Betamethasone. 12. \Chlorpheniramine. 13. \Cyprehoptadine. 14. \Carbamazopine. 15. \Chloroquine. 16. \Cephalexin. 17. \Chloramphenicol. 18. \Cloxacillin. 19. \Cetrimide. 20. \Cemetidine. 21. \2[* * *] 22. \3[* * *] 23. \Calcium Pantothenate. 24. \Chlorhexidine. 25. \Dextropropoxyphene. 26. \Dexamethasone. 27. \1[* * *] 28. \2[* * *] 29. \Diloxanide. 30. \Doxycyollne. 31. \Digoxin. 32. \Dihydralazine. 33. Dipyridamole. 34. \2[* * *] 35. \Dichloro Meta Xylenol. 36. Diphenoxylate. 37. 1[* * *] 38. \1[* * *] 14 39. \Erythromycin. 40. \1[* * *] 41. \1[* * *] 42. \Ergometrine. 43. \Ephedrine. 44. \Framycetin. 45. \Folic Acid. 46. \Frusemide. 47. \2[* * *] 48. \Furazolidone. 49. \Gentamycin. 50. \Griseofulvin. 51. \1[* * *] 52. \2[* * *] 53. \HydroxycobalamIn/Cyanocobalamin 54. \1[* * *] 55. \Hydralazine. 56. \Hydrochlorothiazld 57. \Hydrocortisone. 58. \1[* * *] 59. \Ibuprofen. 60. \Iodochlorohydroxyquinoline. 61. \Iron Doxtran. 62. \1[* * *] 63. \Isosorbide Dinitrate. 64. \Insulin. 65 \2[* * *] 66. \Ketoprofen. 67. \Lidocaine /Xylocaine. 68. \Levamisole. 69. \Loperamide. 70. \2[* * *] 71. \Metamizol (Analgin). 72. \Mebhydrollne. 73. \Metronidazole. 74. \Muthyl Dopa. 75. \Metoclopramide. 76. \2[* * *] 77. \Methyl Salicylate. 78. \Nalidixio Acid. 79. \3[* * *] 80. \4[* * *] 81. \Oxytetracycline. 82. \Oxethazine. 15 83. Oxytocin. 84. 1[* * *] 85. Pentazocine. 86. 1[* * *] 87. 1[* * *] 88. Pheniramine. 89. Prednisolone. 90. 2[* * *] 91. Phenobarbitone. 92. Phenytoin. 93. Piperazine. 94. Py rental. 95. Penicillins. 96. Phenoxymethylpenicillin. 97. Procaine Benzylpenicillin. 98. 2[* * *] 99. 1[* * *] 100. 1[* * *] 101. 1[* * *] 102. Parachloro Meta Xylenol. 103. Promethazine. 104. 1[* * *] 105. Reserpine. 106. Ranitidine. 107. Salazosulfapyridine. 108. Sulphadimidine. 109. Sulphacetamie. 110. Sulphadiazine. 111. Sulphamel.hizole. 112. Sulphamethoxazole. 113. Sulphaphenazole. 114. 1[* * *] 115. Sulphadoxine. 116. 1[* * *] 117. Spironolactone. 118. 1[* * *] 119. Salbutamol. 120. 1[* * *] 121. 1[* * *] 122. Tetracy dine. 123. Trimethoprini. 124. Triamterene. 125. 2[* * *] 126. 2[* * *] 127. Turbutaline. 16 128. Theophylline. 129. Valporic Acid. 130. Verapamil. 131. Vitamin A. 132. Vitamin B1. 133. Vitamin B2. 134. Vitamin B6. 135. Vitamin C. 136. Vitamin D. 137. Vitamin E. 138. 1[* * *] 139. Xanthinol. 140. Paracetamol. 141. Refampicin. 142. Timololl. 143. Isoxsuprine 144. Metoprolol 145. Neomycin 146. Sulphamoxole] 147. Chlorpromazine 148. Thioridazine 149. Trifluperazine 150. Amitryptyline 151. Imipramine 152, Trimipramine 153. Triprolidine 154. Polymixin B. Sulphate 155. Glipizide 156. Pyrithyidione 157. Zinc Bacitracin 158. Mitomycin 159. Tolnafatate 160. Fluocinolone Acetonide 161. Carbemicillin Sodium 162. Oxyfidrine HCI. 163. Hysoline N-Butyl Bromide 164. Triamclnolone 165. Naproxen 166. Pyrithioxine 167. L-Dospa] 168. Diclofinac Acidi 5[NOTE : All Vitamins as bulk drugs except Vitamin A and Vitamin C are exempt from price control as required under para. 3.]

SCHEDULE 3
Category-I and Category II

1. Category-I Formulations All formulations based on the bulk drugs specified under the First Schedule either individually or in combination with other bulk drugs. 2. Category-II Formulations All formulations based on bulk drugs specified In the Second Schedule either individually or in combination with other drugs except the following: (i) Single ingredient formulations based on

the bulk drugs specified in the Second Schedule and sold under generic name. [(ii) All single ingredient Vitamin formulations containing individual vitamins specified In the Second Schedule sold either in brand name or in generic name, except the single ingredient Vitamin formulations based on the bulk drugs. Vitamin A and Vitamin C sold in brand name.]

SCHEDULE 4

4

FORM 1 (To be submitted in duplicate) [See paras. 2 (e),3 and 4] Form of Application for Fixation or Revision of Prise of Bulk Drugs 1 Name of bulk drug 2 Name of the manufacture 3 Address of the Registred Head Office of the manufacture 4 Address of the facture 5 Licensed of the factory (a) Industrial Licence\\SSI Registration No (b) Date of issue of the Licence/Date of registration (c) Production capacity : Licensed : Tonnes/Kgs./Liter/etc. 6 Installed capacity (a) No. of Shifts : One/Two/Three (b) No. of operating days per year (c) Max. production per shift : Tonnes/Kgs./Liter/etc. (d) Date of commissioning (e) Installed capacities per annum. 7. Date of commencement of commercial production 8. Actual production achieved during the last accounting year (preferably month-wise) and also monthly production during the current year.. .Tonnes/Kgs/Litres/etc. 9. Brief note on the manufacturing process adopted by you Indicatin all stages Including recovery of by-products. If any, solvents, etc. and stage-wise overall yields for each drug. 10. Average hourly rate of production for each of the bulk drug since commencement of commercial production. 11. Maximum hourly rate of production achievable. 12. Estimated production of the bulk drug during the next three years. 13. If the production is proposed to be captively consumed for manufacture of the formulation, please furnish the quantity to be so consumed out of the production given against SI. No. 8 and 12. 14. Capital employed for the manufacture of the bulk drug (s) : (a) Net fixed assets (after depreciation).... (b) Working capital..... (c) Total... (in the case of multi-purpose plant the capital employed as above and the share to be allocated to the bulk drug/intermediate under consideration to be given). 15. Please state how the above capital employed is financed by net worth and borrowings. 16. Please state the average rate of interest paid by you on your borrowings, supported by figures. 17. Please furnish latest c.i.f., price of the bulk drug. If the same had been imported or Is being imported by you or by any other agency known to you. 18. Please furnish the cost of production of the bulk drug as per proforma (attached) duly certified by a Practising Cost Accountant/Chartered Accountant. 19. Please furnish No. of persons employed/to be employed, grade-wise, and their average monthly emoluments including contribution on account of provident fund, etc. 20. Please furnish the total amount of expenses under each of the element of other conversion costs, viz. stores, factory and administration overheads and depreciation and the basis adopted for allocation to the production question. 21. If this item is manufactured, to be manufactured in a multi- product plant, the method adopted for allocations to Individual drugs of common expenses, viz., process hours, equipment hours, etc. may be furnished. 22. Please furnish the amounts of loans, average rate of interest as per lates audited balance-sheet. 23. Please also furnish the followings : (a) The types of packing materials used and their average rates. (b) Calculations of profit margins-Basis. (c) Photo copies of invoices of raw materials having substantial consumptions and also for power, fuel oil, etc. (d) Details of fixed assets, method of depreciation, rate of depreciation along with working capital required for the product. (3) Please furnish a copy of audited balance-sheet and profit and loss account for the last three years. \Proforma (See item No. 18) I. Name of bulk drug. II. (a.) Production In Tonnes/Kgs./LItres/etc. \(b) Sales in Tonnes/Kgs./LItres/etc. \ \(c) Despatches In Tonnes/Kgs./Litres/etc. III. Period for which the cost data is given :

_____ Particulars \ Norms of \Units \ Actual \Rate \Amount \Per unit \ \ consumption as \ consumpt- \Qty. of pro- \ \ \ \ per project \ ion during \ duction/ report of know how or suppliers gua ran t e ed norms of the n o r m s developed by you as standards.

_____ 1. Raw materials: (a) Imported. 1. 2. 3. (b Indigenous 1. 2. 3. Total raw material cost-Loss recoveries of solvents Net raw material cost 2. Utilities: (a) Power. (b) Water. (c) Fuel Oil. (d) Other services (to be specified). 3. Conversion cost: (a.) Salaries and wages. (b) Operating supplies or consumable stores. (c) Repairs and maintenance. (d) Other factory overheads. (e) Administration overheads. (fl Depreciation. 4. Total cost of production. 5. Interest on borrowings. 6. Minimum bonus. Total 7. Packings: (a) Materials. (b) Other expenses. 8. Selling expenses. 9. Transport charges. 10. Transit insurance charges. 11. Total cost of sales. 12. Profit margin (basis of calculation to be given). 13. Selling price (11+12). 14. Existing price or notional price or declared price. FORM 1A (Information to be submitted in respect of price of non-scheduld bulk drug under para. 4 to be submitted in duplicate) 1. Name of the bulk drug. 2. Name of the manufacturer. 3. Address of the Rrgistered/ Head Office of the manufacturer. 4. Address of the Factory. 5. Licensed capacity. (a} Industrial Licence/SSI Registration No. (b) Date of Issue of the Licence/Date of Registration. (c) Production capacity Licensed Tonnes/Kgs/Litres etc. 6. Installed capacity per annum. 7. Date of commencement of commercial production. 8. Actual production achieved during the last accounting Year/current Year, Tonnes/Kgs/Litres etc. 9. Brief note on the manufacturing process. 10. Estimated production of the bulk drug during the next three years. 11. If the production is proposed to be captively consumed for manufacture of the formulation, please furnish the quantity to be so consumed out of the production given against S1. No. 8 and S1. No. 10. 12. Please furnish latest c.i.f. price of the bulk drug If the same had been imported or Is being imported by you or any other agency known to you. 13. Please furnish the cost of production of the bulk drug as per Annexure. FORM 2 (Form of Application for Approval or Revision of Price of Formulations-to be submitted in seven copies.) 1. Name of manufacturer. 2. Address of the registered Head Office 3. Address Of the factory. 4. Name of the foumulation. 5. Category of formulation to which it belongs as per Third Schedule of Drugs (Prices Con- trol) Order, 1987 6. Composition as per lable claim and approved by Drug Control Authorities. 7. Industrial Licence Small Scale Industries Unit Registration No. and Date (copy to be enclosed). 8 Drug Control Authority Permis- sion No. and Date (Copy to be en- closed). 9. TVpe of formulation and average Plain tablets/Coated tablets/ mul- weight of 100 tablets/sizes of tilayered/sustained release/ capsule In case of tablets/cap- Soft/Hard/ Pointed/Cap- sules. sules/Without /wlth/sealing \ \ \ \ \ \ band/sterile/non-sterile/Liquid/ \ \ \ \ \ \ Powder/Ointment/Cream/etc. 10. Type of packing Aluminium/Paper/Cellophane/Str \ \ \ \ \ \ i-ps/Bllster/Vials/Ampoules/Whl \ \ \ \ \ \ te/colour/Bottles/TIns/Jars/wIth \ \ \ \ \ \ /wlthout/dropper/Cutting \ \ \ \ \ \ blades/catch cover/etc. 11. Size of packs 10's/IOO's/etc. I ml./2 ml/IO \ \ \ \ \ \ ml/etc. 5 gms/IO gms/etc. 12. No. of packs sold during the last accounting year and details of other packs of the same formu- lation with their retail prices 13. Value of sales effected during the last accounting year includ- ing duty of excise and its per- centage to total sales of formulations excluding duty of excise [(II) and (12) above ap- plicable in case of revision ap- plication only] 14. Break-up of retail price Existing price (if any) copy of ap- \ \ \ \ \ \roval letter to be now claimed en- \ \ \ \ \ \Rs./pack Rs./pack \a) Material Cost (M.C. as per \b) Conversion Cost (C.C. as \er norms) \c) Packing material Costs \P.M. as per SI. No. 16 or \s per norms) \d) Packing charges (P.C. as \er norms) \e) Ex-factory cost (a to d) \(f) MAPE -% on (e) above \(g) Excise duty \h) Retail Price (R.P.) (e+frg) 15. Material Cost: \a) Batch Size \os/Litres/Kgs/etc. \b) No. of packs actually \btained from the batch \ize as in (a) above. \c) No. of packs that can be \theoretically obtained from \the batch size as in (a) \above. \(d) Materials' cost for the batch \size as in (a) above:

_____ SI. Name of Units Previous Curren Theoretical Actual Total Cost for No. the Rate/Unit Rate/Unit Qty. Requ- Over- Qty. the batch Material If any(Date) (Date) ired per ages required (5x8) \ \ \ \Rs. \ \Rs. batch \ \ Rs.

_____ (1) (2) \ (3) \(4) \ \ (5) (6) \ (7) (8) \(9) _____ IMPORTED 1. 2. 3. etc. INDIGENOUS 1. 2. 3. etc. _____ Total: _____ Add :Process Loss as per Norms..... %_____ Total material cost _____ Material Cost : Total Material Cost per pack..... \ \Theoretical No. of packs 16. Packing Material Cost : Packs of _____ Batch size : _____ Tabs/Gms/etc. each

_____ SI. Name of the Unit Rate per Unit Quantity Value of packing No. Packing Material \ \ Rs. required per materials per _____ batch Nos/ batch (Rs.) \Previous Present Kgs/etc. _____ (1) (2) (3) \(4) \ \(5) (6) (7) _____

_____ Total Add: Process loss as per Norms.....%: Total Packing material cost \ \ \ \ \Total packing Material cost Packing material per pack \ \ \ \ \No. of pack as per batch size [FORM 2A (information to be submitted in respect of prices oj non-scheduled formulation under para. 11-to be submitted in duplicate). 1. Name of the manufacturer. 2. Address of the Registered/Head Office of the Manufacturer. 3. Name of the formulation. 4. Composition as per label claim and approval by Drug Control Authorities. 5. Types of packing. 6. Size of Packs. 7. Break-up of Retail. Price: Existing Now claimed \ \ \ \ \ \price Rs. pack \ \ \ \ \ \(If any) \ \ \ \ \ \ \ \ \date (a) Material Cost. (b) Conversion Cost. (c) Packing material cost. (d) Packing charges. (e) Ex-factory cost (a) to (d). (f) MAPE.....% on (e) above. (g) Excise Duty. (h) Local

taxes, if any. \(e+/+g+h). 8. Rates of active ingredients. The Information furnished in this form is to be certified by authorised signatory of the company and a Chartered/Cost Accountant.] FORM 3 [See paras. 2 (3), 8, 9, 10, and III (To be Submitted in Seven Copies) Form o application to be submitted for price approval of formulation imported in finished form. 1. Name of the company 2. Address of the Registered Head Office/Factory, if any. 3. Reference to permission, if any, given by drug control authori- ties for import of the item. 4. Name of the imported formula- tion therapeutic group. 5. Types of formulation : Cap- sule/Tablet, etc. 6. Composition of the formulation. 7. Type of Packs : Strip/vial/am- poule, etc. 8. Pack size: 10's etc./10 ml. etc./5 gms. etc. 9. Country from which imported and date of import. 10. Quantity/No, of packs imported Total Rs. Per Pack Rs. with batch/Lot No. 11. C.1.F. value in foreign currency (Not to include bank commis- sion, interest, etc.) 12. C.I.F. value in Rs. actually paid (Not to include bank commis- sion, interest, etc.) 13. Duty of customs. If any, actually paid. 14. Clearing Charges (with details) actually incurred. 15. Landed Cost (12+13+14). 16. Packing Material, I any, as per norms applicable In case of re- packing. 17. Packing Charges, if any, as per norms. 18. Landed cost (including repack- ing cost, if any (15 to 17). 19. Margin 50% 20. Duty of Excise, if any. 21. Retail Price claimed (18 to 20). 22. (a) Existing Retall Price, If any (Copy of approval letter to be enclosed). (b) No. of Packs sold during the last aiccounting year, if any. (c) Value of sales excluding duty o excise effected during the last accounting year. If any. FORM 4 {See paras. 2 (3) and 11 (3)] Unformation to be Furnished by Manufacturer or Importer of Marketing. non-scheduled Formulations-to be submitted in duplicate) 1. Name of the manufacturer or the importer 2. Address of Registered/Head Of- fice 3. Address of factory. 4. Details of non-scheduled for- \mulations : (a) Name of the formulation (b) Composition. (c) Pack Size. (d) Current retail price. (e) Retail Prices charged before and after the commencement of DPCO, 1987 (Retail prices/Date of revision) : (f) Sales turnover during the last two accounting years : (g) Percentage of (J) to total sales of formulations during the last accounting year. (h) Rate(s) of concerned bulk drug(s) : (i) Previous year. (ii) Current year. (i) Basis of price revision, if any, during the year : 5. Total sales turnover during the last two accounting years : (a) Scheduled formulations (Categor I and II separately). (b) Non-scheduled formulations. (c) All formulations. FORM 5 [See paras. 2 (e) and 16] (Form of Price List) 1. Name and address of the manufacturer/importer/distributor. 2. Name and address of the marketing company, if any.

_____ Sl. Name of Compo-
Specification Duty of Excise Price to be Retail Effective No. the Bulk sition as of the pack if any retailed price Batch Drug/For- approved
_____ _____ (inclusive (inclusive mulation by State Type* Size** Rate Amount of Excise of Excise and its Drugs Rs.
Rs. Duty) Duty) Form Controller Rs. Rs.

_____ 1 2 \ \3 \4 \5 \ 6 \ \7 \8 \ \9 \
\10 _____ A. BULK DRUGS. B.
FORMULATIONS: d) Own Formulations. da Purchased Formulations. *Strip, Bottle, etc. **10s/100s Tabs., I ml., I gm. etc.

_____ [FORM 5A {See paras. 2 (e) an
16 (2)) (Form of Price List) 1. Name and address of the manufacturer/importer/distributor : 2. Name and address of the marketing company, if any. _____ Sl. Name of Compo-
Specification Duty of Excise Maximum Effective No. the Bulk sition as of the pack if any retail Batch Drug/For- approved _____
_____ price No/Date mulation by State Type* Size** Rate Amount Inclusiv of and its Drugs Rs. Rs. Ammount all taxes Form
Controller Rs. _____ 1 2 \ \3 \4 \5 \ 6 \ \7 \8 \ \9 \
_____ A. BULK DRUG B. FORMULATIONS d) Own
Formulations. (ii} Purchased Formulations. * Strip, Bottle etc. ** 10's/100's/ Tabs., I ml, I gm. etc. FORM 6 [See paras. 2 (e) and 22 (Yearly Information)) Name of the Manufacturer. Address of the Registered/Head Office/Factory. Accounting period for which in- formatio is given. Turnover of bulk drugs.

_____ Name of the Bulk Drugs
Quantity \ \Sale value (Excluding duty \ \ \ \ \ \ \ \ \ \ \ \of excise. If any) \ \ _____ \
_____ \ \ \ \Consumed Sold \ \ \ \Kg./Ltrs. etc. Sold Kg/Urs./etc. Consumed Sold \ \ \ \ \ \ \ \ \Rs. \ Rs.
_____ (i) Drugs listed in First
Schedule (a.) Imported: 1. 2. 3. etc. (b) Indigenous: 1. 2. 3. etc. (ii) Drugs listed in Second Schedule. (a.) Imported: 1. 2. 3. etc. (b) Indegenous: 1. 2. 3. etc. (iii) Other bulk drugs : 1. 2. 3.

_____ TOTAL
_____ 5. Turnover of formulations
_____ Name Pack Size No. of Packs
Sale Value \ \ \ \ \ \ \ \excluding of Excise dut \ \ \ \ \ \ \ \ \Rs.
_____ (i) Own Formulations: (a)
Category I 1. 2. 3. etc. (b) Category II 1. 2. 3. etc. (c) Non-scheduled 1. 2. 3. etc. Sub Total (ii) Purchased Formulations: (A) Imported: (a) Category I: 1. 2. 3. etc. (b) Category II: 1. 2. 3. etc. (cj Non-scheduled 1. 2. 3. etc. Sub Total (B) Indigenous: (Category-wise with name of the manufacturer) Sub Total (iii) Export Sales:

_____ Total
_____ 6. Allocation of sales and
expenses as shown in the audited Profit and Loss Account. (In Rupees)

_____
Sl. \Parti- \Total \ \Allocation \ \Own \ \Allocation to For \mulations \Other \ \Basis of No. \culars \as per \to bulk \ \Manu- \ \Purchased \export \ \Activities \Allocation \audited \drugs \ \ \ \ \facture \ \ \Sales \ \ \(it any) \ \profit \ \ \Im- \Indi- \ \Sub total \ \ \and loss \ \ \ported genous \(5 to 8) \ \ \account \ \ \ \ \ \

_____
1 \2 \ \3 \ \4 \5 \ \6 \ \7 \8 \ \9 \ \10 \ \114

_____
A. INCOME 1. Sales Income (excluding duty oi excise and other taxes) 2. Cash Subsidy (if any) 3. Other Income Total (I to 3) B. EXPENSES 4. \Raw Materials 5. \Packing Materials 6. \Power and Fuel 7. \Salaries and wages 8. \Stores and Spares 9. \Repairs and maintenance 10. \Insurance 11. \Depreciation 12. \Royalty 13. \Interest 14. \Head Office Expenses 15. \Dealer's Commission and Discount 16. \Research and Development Expenses 17. \Other Expenses

_____
Total (4 to 17)

_____
C. PROFIT BEFORE TAX (AB) D. PROFIT BEFORE TAX (As a % age of Sale Income) C/A x 100

_____

SCHEDULE 5

5

(ScePara. 12) (Statement Showing Maximum pre-tax return on Sales turnover of Manufacturers by Importers of Formulations) Category A: Large units with turnover exceeding Rs. 6 crores per annum- (a) having no basic drug-manufacturing activity nor any research activity. 8% (b) having basic drug-manufacturing activity at 5% or more of turnover but not 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 units 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 activity. 12% (b) having basic drug-manufacturing activity at 5% or more of turnover. 13%