DRUGS (PRICES CONTROL) ORDER, 1995

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DRUGS (PRICES CONTROL) ORDER, 1995

S.O. 18 (E), dated 6th January, 1995 1 .-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 and commencement :-

(1) This Order may be called the Drugs (Prices Control) Order, 1995 .

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

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

(a) "bulk drug" means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation;

(b) "capital employed" means net fixed assets plus working capital of amanufacturer in relation to manufacture of bulk drugs;

(c) "ceiling price" means a price fixed by the Government for scheduled formulation in accordance with the provisions of para. 9.

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

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

(f) "drug" includes-

(d) all medicines 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 any disease or disorder in human beings or animals. including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(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;

(g) "Form" means a form specified in the Second Schedule :

(h) "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

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

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

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

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

(j) "Government" means the Central Government;

(k) "import" with its grammatical variation's 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 the importer;

(1) "manufacture" in relation to any drug, includes any process or part of a process for making, altering, finishing, packing, labelling, breaking or otherwise treating or adapting any drugs 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;

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

(n) "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 operational activity :

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

(p) "non-scheduled formulation" means a formulation not containing any bulk drug specified in the First Schedule;

(q) "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;

(r) "price list" means a. price list referred to in paras. 14 and 15 and includes a supplementary price list;

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

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

(u) "scheduled bulk drug" means a bulk drug specified in the First Schedule;

(v) "scheduled formulation" means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs not specified in the First Schedule except single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name;

(w) "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 bulk taxes, if any;

(x) "Schedule" means a Schedule annexed to this Order:

(y) "wholesaler" means a dealer or his agent or a stockist appointed by a manufacturer or an importer for the sale of his drugs to a retailer, hospital, dispensary, medical, educational or research institution purchasing bulk quantities of dru gs.

3. Power to fix the maximum sale prices of bulk drugs specified in the First Schedule :-

(1) The Government may with a view to regulate the equitable distribution and increasing supplies of a bulk drug specified in the First Schedule and making it available at a fair price, from different manufacturers, after making such inquiry as it deems fit, fix from time to time by notification in the Official Gazette, a maximum sale price at which such bulk drug shall' be sold : Provided that for the purpose of enquiry, in addition to the information required to be furnished by the manufacturers under this Order, the manufacturers shall provide any such additional information as may be required by the Government, and shall allow for inspection of their manufacturing premises for verification through on the spot study of manufacturing processes and facilities and records thereof, by the Government.

(2) While fixing the making sale price of a bulk drug under sub- paragraph (3), the Government shall take into consideration a post-tax return of fourteen per cent. on net worth or a return of twenty-two per cent. on capital employed or in respect of a new plant an internal rate of return of twelve 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 the manufacturer of a bulk drug: Provided that where the production is from basic stage, the Government shall take into consideration a post-tax return of eighteen per cent. on net worth or a return of twenty-six per cent. oh capital employed: Provided further that the option with regard to the rate of return once exercised by a manufacturer shall be final and no change of rates shall be made without the prior approval of the Government.

(3) No person shall sell a bulk drug at a price exceeding the maximum sale price fixed under sub-paragraph (1) plus local taxes, if any : Provided that until the price of a bulk drug is fixed, by the Government under sub-paragraph (1), 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 the bulk drug at a price exceeding the price prevailing immediately before the commencement of this Order

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(4) Where, after the commencement of this Order, any manufacturer commences production of any bulk drug specified in the First Schedule, he shall within fifteen days of the commencement of production of such bulk drug, furnish the details to the Government in Form I, and any such additional information as may be required by the Government and the Government may after receipt of the information and after making such inquiry as it may deem fit, may fix maximum sale price of bulk drug by notification in the Official Gazette.

(5) Any manufacturer, who desires revision of the maximum sale price of a bulk drug fixed under sub-paragraph (1) or (4) or as permissible under sub-paragraph (3), as the case may be, shall make an application to the Government in Form I and the Government shall after making such inquiry, as it deems fit within a period of four months from the date of receipt of the complete information fix a revised price for such bulk drug or reject the application for revision for reasons to be recorded in writing.

4. Information to be furnished by the manufacturer in relation to the scheduled bulk drugs :-
Every manufacturer, producing a scheduled bulk drug shall furnish to the Government.-

(a) a list of all scheduled bulk drugs produced by him within thirty days of the commencement of this Order and indicate the details of the cost of each of such bulk drugs in Form. I ;

(b) the details of the cost of each scheduled bulk drug produced by him, including such bulk drug which has been produced after the commencement of this Order, in Form I by the 30th September, every year.

5. Information to be furnished by the manufacturer in relation to the non-scheduled bulk drugs :-
Every manufacturer, producing a non-scheduled bulk drug shall furnish to the Government,-

(a) a list of all such bulk drugs produced by him within thirty days of the commencement of this Order and indicate the details of the cost of each of such bulk drugs in Form II;

(b) the details of the cost of each non-scheduled bulk drug produced by him, including such bulk drug which has been produced after the commencement of this Order, in Form II : Provided that, for 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 [1][give effect to the price so fixed or revised, within fifteen days of receipt of the order and not sell the such non-scheduled bulk drug at a price exceeding the price so fixed or revised thereafter].[1]

1. Subs. by S.O. 642 (E), dated 19th July 1995, published in the Gazette of India, Extraordinary. Part. II. Sec. 3 (ii). dated 19th July. 1995.

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

(1) With a view to achieving adequate production and regulating the equitable distribution, 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 other manufacturers of formulations as may be specified in such order :

(i) the requirement for captive consumption of such manufacturer, and

(ii) the requirement of other manufacturers.

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

7. Calculation of retall price of formulation :-

The retail price of a formulation shall be calculated by the Government in accordance with the following formula, namely,- R.P.=(M.C.+C.C.+P.M.+P.C.)+(1+MAPE/100)+ED. Where- "R.P." means retailprice: "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 producers of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf ; "P.M." means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by notification in the Official Gazette in this behalf: "P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf ; "MAPE"(Maximum Allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for manufacturer and it shall not exceed one hundred per cent. for indigenously manufactured scheduled formulations : "E.D." means excise duty : Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty per cent. of the landed cost.

Explanation.-For the purpose of this proviso, "landed cost" means the cost of import of formulation inclusive of customs duty and clearing charges

8. Power to fix retail price of scheduled formulations :-

(1) The Government may, from time to time. by order, fix the retail price of a scheduled formulation in accordance with the formula laid down in para. 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 scheduled formulations he shall, within thirty days of such fixation or revision, make an 'application to the Government in Form III for price revision of all such formulations 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-paragraphs (1) and (2) 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 From III or From IV, as the case may be. and the Government shall after making such enquiry, as it deems fit within, a period of two months from the date of receipt of the complete information, fix a revised price for such formulation or reject the application for revision for reasons to be recorded in writing.

(5) Notwithstanding anything contained in the foregoing sub- paragraphs the retail price of a scheduled formulation, 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 the formulation at a price exceeding the price prevailing immediately before the commencement of this Order.

(6) No manufacturer or importer shall market a new pack, if not covered under sub-paragraph 3 of para 9, or a new formulation or a new dosage form of his existing scheduled formulation without .obtaining the prior approval of its price from the Government.

(7) No person shall sell or dispose of any imported scheduled formulation without obtaining the prior approval of its price from the Government.

9. Power to fix ceiling price of scheduled formulations :-

(1) Not- withstanding anything contained in this Order, the Government may, from time to time, by notification In the Official Gazette, fix the ceiling price of a scheduled formulation in accordance with the formula laid down in para. 7 keeping in view cost or efficiency, or both, of major manufacturers of such formulation and such price shall operate as the ceiling sale price for all such packs including those sold under

generic name and for every manufacturer of such formulations.

(2) The Government may, either on its own motion or on application made to it in this behalf by a manufacturer in Form III or Form IV, 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 scheduled formulation.

(3) With a view to enabling the manufacturers of similar formulations to sell those formulations in pack size different to the pack size for which ceiling price has been notified under the sub-paragraphs (1). and (2), manufacturers shall work out the price for their respective formulation packs in accordance with such norms, as may be notified by the Government, from time to time, and he shall intimate the price of formulation pack, so worked out, to the Government and such formulation packs shall be released for sale only after the expiry of sixty days after such intimation: Provided that the Government may, if it considers necessary, by order revise the price so intimated by the manufacturer and upon such revision, the manufacturer shall not sell such formulation at a price exceeding the price so revised.

Explanation.-For the purpose of this paragraph the "scheduled formulation" includes single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic na me

10. Power to revise price 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 importer, fix or revise the retail price of one or more formulations marketed by such manufacturer or importer, including a non-scheduled formulation, 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 Third 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 retail 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 in the First Schedule and fix or revise the prices of such a bulk drug and formulations containing such a bulk drug in accordance with the provisions of paragraphs 3, 7, 8, and 9, as the case may be. II. Fixation of price under certain circumstances.-Where any manufacturer or importer of bulk drug or formulation fails to submit the application for price fixation or revision, as the case may be, or 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.

12. Power to recover dues accrued under the Drugs (Prices Con- trol) Order, 1979 and to deposit the same into the Drugs 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 under the provisions of 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 amount deposited under sub-paragraph (1) shall be utilised for,-

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

(b) meeting the expenses. Incurred by the Government in discharging the functions under this paragraph; and

(c) promoting higher education and research in Pharmaceutical Sciences and Technology and for the purposes Incidental thereto.

13. Power to recover overcharged amount :-
Notwithstanding anything contained in this Order, the Government shall by notice, require the manufacturers, importers or distributors, as the case maybe, to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under the provisions of Drugs (Prices Control)Order, 1987 and under the provision of this Order.

14. Carrying into effect the price fixed or revised by the Govern- ment, its display and proof thereof :-

(1) Every manufacturer or importer shall carry into effect the price 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 date of notification in the Official Gazette or receipt of the order of the Government In this behalf by such manufacturer or importer.

(2) 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 retail price of that formulation notified in the Official Gazette or ordered by the Government in this behalf, with the words "retall price not to exceed" preceding it, and "local taxes extra" succeeding it. In the case of 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 retall price of the main pack rounded off to the nearest paisa.

(3) Every manufacturer or importer shall Issue a price list and supplementary price list, if required, in Form V to the dealers. State Drugs Controllers and the Government indicating reference to such price fixation or revision as covered by the order or Gazette notification Issued by the Government from time to time.

(4) Every retaller and dealer shall display the price list and the supplementary price list. If any, as furnished by the manufacturer or importer, 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.

15. Display of prices of non-scheduled formulations and price list thereof :-

(1) Every manufacturer, importer or distributor of a non-scheduled 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 retall sale, the retall price of that formulation with the words [1][retail price not to exceed] preceding it and the words [1] [local taxes extra] succeeding it: Provided that in the case of a container consisting of smaller saleable packs, the retall 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. retall price of the main pack rounded off to the nearest palsa.

(2) Every manufacturer or importer shall issue a price list and supplementary price list, if required of the non-scheduled formulation in Form V to the dealers. State Drugs Controllers and the Government indicating changes from time to time.

(3) Every retailer and dealer shall display the price list and the supplementary price list. If any, as furnished by the manufacturer or importer, 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

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1. Subs. by S.O. 642 (E), dated 19th July, 1995, published in the Gazette of India. Extraordinary, Pt. II. Sec. 3 (ii), dated 19th July, 1995.

16. 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 or pack thereof, whichever is less, plus all local taxes, if any, payable.]

17. Sale of split quantities of formulations :-

No dealer shall sell loose quantity of any formulation at a price which exceeds the pro-rata price of the formulation plus 5 per cent. thereof.

18. Manufacturer, distributor or dealer not to refuse, sale of drug :-

Subject to the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Rules framed 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 intending to purchase such drug. 19. Price of formulations sold to the dealer.-(1) A manufacturer, 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 equal to the retall price, as specified by an order or notified by the Government (excluding excise duty, if any), minus sixteen per cent. thereof in the case of scheduled drugs

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

20. 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 sales turnover of individual bulk drugs manufactured or imported by him, as

(2) Every manufacturer or importer shall, within six months of the close of the accounting year, submit to the Government information in respect of turnover and allocation of Sales and expenses for that year in Form VI.

(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 or any officer authorised in this behalf by the Government.

21. 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, 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, along with the containers, packages or coverings in which the drug is found, in respect or 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, case 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 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

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22. Power to review :-
Any person aggrieved by any notification issued or order made made under paras. 3, 5, 8, 9 or 10 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 the receipt of the order by him, as the case may be, and the Government may make such order on the application as it may deem proper : 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.

23. Power to issue guidelines and directions :-

(1) The Govern- ment may, for the purpose of implementing 'the provisions of this Order, authorise any officer, by a general or special order, to inspect the premises of any manufacturer, importer, distributor or dealer and such manufacturer, importer, distributor or dealer shall allow such authorised officer and make available all relevant information required for the 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 provisions of this Order and such manufacturer or importer shall comply with such guidelines and directions.

24. 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).

25. Power to exempt :-

(1) Government may, having regard to the factors mentioned In sub-paragraph (2) and subject to such conditions as it may specify, by an order in the Official Gazette, exempt any manufacturer from the operation of all or any of the provisions of this Order.

(2) While granting exemption under sub-paragraph (1), the Government shall have regard to all or any of the following factors,-

(a) number of workers employed',

(b) amount of capital invested;

(c) range/group and type of products manufactured;

(d) sales turnover;

(e) production of bulk drugs from basic stage by a process developed through Indigenous research and development, and which is significantly different from known processes and result in cost reduction:

(f) production of a new drug which has not been produced elsewhere, if developed through indigenous research and development.

26. 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. 22, 23 and 25 shall subject to such restrictions, exceptions and conditions as, maybe specified in the direction, be exercisable also by such Officer or authority as may be specified in the notification.

27. Repeal and saving :-

(1) The Drugs (Prices Control) Order, 1987 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, 1987 , 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, under the corresponding provisions of this Order.

SCHEDULE 1
BULK DRUGS

1. \Sulphamethoxazole 2. \Penicllins 3. \Tetracycline 4. \Rifampicin 5. \Streptomycin 6. \Ranitidine 7. \Vitamin C 8. \Betamethasone 9. \Metronidazole 10. \Chloroquine 11. \Insulin 12. \Erythromycin 13. \Vitamin A 14. \Oxytetracycline 15. \Prednisolone 16. \Cephazolin 17. \MethyJdopa 18. \Aspirin 19. \Trimethoxoprim 20. \Cloxacillin 21. \Sulphadimidine 22. \Salbutamol 23. \Famotidine 24. \Ibuprofen 25. \Metamizol (Analgin) 26. \Doxycycline 27. \Ciprofloxacin 28. \Cefotaxime 29. \Dexamethasone 30. \Ephedrine 31. \Vitamin Bl (Thiamine) 32. \Carbamazepine 33. \Vitamin B2 (Riboflavin) 34. \Theophylline 35. \Levodopa 36. \Tolnaftate 37. \Vitamin E 38. \NalidixIcAcid 39. \Griseofalvin 40. \Gentamicin 41. \Dextrorpropoxyphene 42. Halogenated Hydroxyquinojine 43. Pentazocine 44. Captopril 45. Naproxen 46. Pyrental 47. Sulphadoxine 48. Norfloxacin 49. Cefadroxyl 50. Panthonates and Panthenols 51. Furazolidone 52. Pyrithioxine 53. Sulphadiazine 54. Framycetin 55. Verapamil 56. Amikacin Sulphate 57. Glipizide 58. Spironolactone 59. Pentoxyiyiline 60. Amodiaquin 61. Sulphamoxole. 62. Frusemide 63. Pheniramine Maleate 64. Chloroxylenols 65. Becompicillin 66. Lincomycin 67. Chloropropamide 68. Mebhydroline 69. Chloropromazine 70. Methendienone 71. Phenyl Butazone 72. Lynestranol 73. Salazosulphapyrine 74. Diosmine 75. Trimipramine 76. Mefenamic Acid

SCHEDULE 2
FORMS

FORM 1 (To be submitted in duplicate) [See paras. 2, 3 and 4] Form ofinformation/ application for fixation or revision of prices of scheduled bulk drugs. 1. Name of the Bulk Drug. 2. Name of the Manufacturer. 3. Address of the Registered/Head Office of the Manufacturer. 4. Address of the Factory. 5. Capacity under Industrial Licence/ Small Scale Industry / Registration/ Industrial Entrepreneur Memorandum acknowledgment : (a) No. and date of Industrial Licence/ Small Scale Industry Registration/ Industrial Entrepreneur Memorandum acknowledgment ; (b) Production Capacity (Tonnes/ Kgs./ Litres, etc.): 6. Installed Capacity :- (a) Number of shifts per day. (b) Number of operating days per year. (c) Maximum production per shift (Tonne/Kgs./ Litres etc.). (d) Date of commissioning. (e) Annual Installed capacity. 7. Date of commencement of commercial production. 8. Actual production achieved during the last accounting year (preferably month-wise) and also monthly production during the current year (Tonnes/ Kgs./Litres, etc.) 9. Brief note on the manufacturing process adopted by you indicating all stages including recovery of by-products, if any, solvents, etc. and stage-wise overall yield for each bulk drug. 10. Average hourly rate of production for each of the bulk drug since the commencement of the commercial production. 11. Maximum hourly rate of production achieveable. 12. Estimated production of the bulk drug during the next three years. 13. If the production is proposed to be captively consumed for manufacturer of the formulation, please furnish the quantity to be so consumed out of the' production given against Serial No. 8 and Serial No. 12. 14. Capital employed for the manufacture of the bulk drugs) :- (a) Net fixed assets; (b) Working capital; (c) Total. 15. Please state how the above capital employed is financed by net worth and borrowings. (In the case or multi-purpose plant the capital employed/net worth as above and the share to be allocated to the bulk drug/ intermediate under consideration to be given.) 16. Please state average rate of interest paid by you on your borrowings, supported by figures of the amount of loans, average rate of interest etc. as per latest audited Balance Sheet. 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 annexure to this Form duly certified by a Practising Cost Accountant/ Chartered Accountant. 19. Please furnish number 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 or other conversion costs viz. stores, factory and administration overheads and depreciation and the basis adopted for allocation to the product in question. 21. If this item is manufactured/ to be manufactured in a multi-product plant, the method adopted for allocation to Individual drugs for common expenses, viz. process hours, equipment hours, etc. may be furnished. 22. Please also furnish the following :- (a) The types of packing materials used and their average rates: (b) basis and calculations of profit margin; (c) photocopies of Invoices of raw materials having substantial consumption and also for power, fuel oil, etc.: (d) details of the fixed assets, method of depreciation, rate of depreciation along with working capital required for the product: (e) a copy each of audited Balance Sheet and Profit and Loss Account for the last three years and in the case of a company copies of the latest Cost Audit Report and Annual Report. ANNBXURE 1 (See Item No. 18 of the Form I of the First Schedule) 1. Name of the Bulk Drug. II. (a) Production in Tonnes/ Kgs./Litres, etc. (b) Sales in Tonnes/ Kgs./Litres, etc. (c) Despatches in Tonnes/ Kgs./Litres, etc. III. Details of Cost - (a) Period: (b) Cost Data: _____ \ \Norms of Consumption Actual \ \guaranteed by the Consumption \ \ \ \ \ \ (per kg/Litre etc. \ \ \ \ \ \ of the product) Sl. Particulars know-how supplier ..... No. or as per standards Unit Quantity Rate/Unit Amount \ \ \developed (Rs). (Rs.) _____ (1) (2) (3) (4) (5) (6) (7) _____ \1. Raw Materials :- \(a) Imported \1. \2. \3. etc. \(b) Indigenous \1. \2. \3. etc. \Total raw materials cost : \ \Less Recoveries of Solvents : \ \Net Raw Materials Cost : \2. Utilities:- \ \(a) Power \ \(b) Water \ \(c) Fuel \ \(d) Others (to be specified) \ \Total Utilities Cost. \3. Conversion Cost :- \ \(a) Salaries and wages \ \(b) Operating supplies or consumable stores \ \(c) Repairs and Maintenance \ \ (d) Quality Assurance \ \(e) Effluent treatment \ \(f) Other factory overheads \ \(g) Administration overheads \ \(h) Research and Development expenses \ \(i) Depreciation \ \Total Conversion Cost \4. Cost of production (1+2+3). \5. Interest on

borrowings. \6. Minimum Bonus. \7. Total (4+5+6). \8. Packing:- \ \(a) Materials \ \(b) Other expenses. \ \Total Packing Cost. \9. Selling Expenses. \10. Transport Charges. \11. Transit insurance Charges. \12. Non-Recoverable Taxes. \(Please specify and submit details along with supporting documents.) \ \13. Total cost of sales. \14. Profit Margin, (basis of calculations be submitted.) \15. Selling Price (13+14) \16. Price notified by the Government, if any. \(Please give No. and date of Notification) \17. Actual sale price or Notional price,if used captively. FORM 2 (To be submitted in duplicate) [See paras: 2 and 5] \Form of information in respect of price of non-scheduled bulk drugs. \1. Name of the bulk drug. \2. Name of the manufacturer. \3. Address of the Registered/ Head Office of the Manufacturer. \4. Address of the Factory. \5. Capacity under Industrial Licence/Small Scale Industry Reglstration/ Industrial Entrepreneur Memorandum acknowledgment : \ \(a) Number and date of Industrial Licence/Small Scale Industry \Registration/Industrial Entrepreneur Memorandum acknowledgment: \ \ \ \(b) Production Capacity (Tonnes/Kgs./Litres, etc.) \6. Annual Installed Capacity. \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 for next three years. \11. If the production is proposed to be captively consumed for manufacture of formulation, please furnish the quantity to be so consumed out of the production given against S1. Nos. 8 and 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 agency known to you. \13. Please furnish the cost of production of the bulk drug as under :- - \ \I. Name of the Bulk Drug. \ \II. Period. \ \III. Major Raw Materials:- \Name: \Quantity consumed per Kg. of Product:- \Cost per Kg. of Product: \ \ \IV. Total Raw Materials Cost. \ \V. Cos- of Production. \ \VI. Cost of Sales. \ \VII. Profit Margin. \ \VIII. Selling Price (VI+VII). \ \IX. Existing price with effective date. \14. Please furnish a copy each of the audited Balance Sheet, Profit and Loss Account for the last three years and the latest Cost Audit Report and Annual Report.
_____ The information furnished above is correct and true to the best of my knowledge and belief. \ \ \ \ \ \ \ \Authorised Signatory : Place: \ \ Name: Date: \Designation: _____ FORM 3 (To be submitted in seven copies) [See paras. 2, 8, 9 and 10) \Form of Application for approval or revision of price of scheduled formulations. \1. Name of the formulation. \2. Name of the manufacturer. \3. Address of Registered/Head Office/Administrative Office. \4. Address of the Factory : \5. Composition as per label claim and approved by Drug Control Authorities. \6. Drug Control Authority Permission Number and Date (copy to be enclosed). \7. Number and date of Industrial Licence/Small Scale Industry Registration /Industrial Entrepreneur Memorandum acknowledgment (copy to be enclosed). \8. Date of Commencement of Production. \9. Type of formulation:- \ \(i) type plain/coated tablets, multi-layered sustained release/soft/ \hard/ printed/ capsules (without/with/sealing band/sterile/non-sterile \liquid/powder/ointment/cream etc.); \(ii) In case of tablets please furnish average weight of 100 tablets: \(iiii In case of capsules please furnish size of capsules. \10. Type of packing (aluminium/paper/cellophane/strips/blister/ vials/ ampoules/white colour bottles/tins/jars/with/without dropper/cutting blades/ catch cover, etc.]. \11. Size of packs (10's/ 100's/ etc.: lml/2 ml/ 10 ml, etc.: 5 gms 10 gms. etc.]. \12. Number of packs sold during the last accounting year and details of other packs of the same formulation with their retall prices. \13. Break-up of Retail Price :- _____ Details \ Existing Price Now Claimed \ \ \ If Any (Rs./Pack) \ \ \ (Rs./Pack)
_____ \(a) Material Cost las per S. No. 14 (d)] : \(b) Conversion Cost (as per norms) :
_____ * Existing Retail Price Approval letter No. and date-copy to be enclosed.
_____ \(c) Packing Material Costs (Per SI.No. 15 or as per norms): \(d) Packing Charges: \(e) Ex-factory Cost (a) to (d)-. \(f) MAPE 100% on (e) above; \(g) Excise Duty: \(h) Retail Price (R.P.) (e)+(f)+(g) \14. Material Cost: \(a) Batch Size (No./ Litres/ Kgs. etc.) : \(b) No. of packs that can be theoretically obtained from the batch size as in (a) above. \(c) Material Cost for the batch size as in (a) above:
_____ Sl. \Name of \Unit \Theroetical Actual Total \Rate/ Cost for No. \the \ \Quantity \ Overages Quantity Unit the \Material \ \ \(4+5) \ \Batch \ \ \ \ \ \ \ \ \ \ \ (6+7) _____ (1) \(2) \ \(3) \(4) \ \ \(5) \(6) \ \(7) \(8) _____ \Imported 1. \ \ \ \ \ \2. \ \ \ \ \ \3. \ \ \ \ \ \etc. \ \ \ \ \ \Indigenous 1, \ \ \ \ \ \2. \ \ \ \ \ \3. \ \ \ \ \ \etc. \ \ \ \ \ _____ \ \ \ \ \Total.....: \ \ \ \ \Add: Process loss as per norms-% : \ \ \ \ \Total Material cost: \ \ \ \ \ \ \ \ \ \Total Material Cost \Matenal cost per Pack = ---------- \ \ \ \ \Theoritical No.of Packs 15. Packing Material Costs:- Packs of---------- Batch Size"----------Tablets/Gms etc. each
_____ _____ Sl Name of \Unit Rate per Qty. Re- Value of Packing No. the Pack- U n i t quired per material/ Batch \ing Mate- (Rs.) Batch Nos./Kgs. etc. \rial (Rs.) _____ 1 \2 \ \3 \ \4 \ \5 6 _____ \Imported \1. \2. \3. \Indigenous \1. \2. \3. \etc. _____ \ \ \ \ \ \ Total----------: \ \ \ \Add. Process loss as per norms Cost----------%: \ \ \ \ Total Packing Material Cost----------: \ \ \ \ \ Total Packing Material Cost Packing Material Cost per Pack :---------- \ \ \ \ \ No.of Packs as per Batch Size Note: \1. The information furnished in this form is to be certified by the authorised signatory of the company and Cost Accountant/ Chartered Account. \2. In respect of bulk drug and major raw materials the following documents shall be enclosed : \ \(a) A statement indicating the purchases made during the last three months with copies of invoices certified by Cost Accountant/ Chartered Accountant shall be enclosed. \ \(b) Certified copies of recent batch production records or, in case production has not commenced, other documents maintained under Drugs and Cosmetics Act and the Rules made thereunder, in support of the quantities of raw materials claimed. \3. The rates claimed shall be net of modvat, wherever applicable. \4. Basis and calculation of excise duty [SI. No. 13 (g) to be given).
_____ \The information furnished above is correct and true to the best of my knowledge and belief. \ \ \ \ \ \ \ \ \Authorised Signatory: Place: Date: \ \ \ \ \ \ \ \ \ Name: \ \ \ \ \ \ \ \ \Designation: FORM 4 (To be submitted in seven copies) [See paras. 2, 8, 9 and 10] \Form of application for approval or revision of price of scheduled formulations imported in furnished 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 Authorities for import/sale of the item. \4. Name of the imported formulation/therapeutic group. \5. Type of formulation (capsule/tablet/inj. etc.). \6. Composition of the formulation. \7. Type of Packs (strip/vial/ampoule, etc.) \8. Pack size (10's etc./10ml. etc./5gms. etc.) \9. Country from which imported and date of import. \10. Quantity/Number of packs imported with Batch/Lot number. \11. C.I.F. Value in Foreign Currency. (Not to include bank commission, interest, etc.) \ \ \ \ \Total Per Pack \ \ \ \ \(Rs.) (Rs.) \12. C.I.F. Value in Rs, actually paid. (Not to include bank commission, interest etc.) \13. Duty of customs, if any, actually paid. \14. Clearing Charges (with details) actually incurred. \15. Landed cost (12+13+14). \16. Packing Material, if any, as per norms.) (Applicable in case of repacking.) \17. Packing Charges, if any, as per norms. \18. Landed Cost (Including repacking cost, if any), (15+16+17) \19. Margin @50%. \20. Duty of excise, if any. \21. Retail price claimed (18+19+20). \22. Existing retall price, if any: \ \(Copy of approval letter to be enclosed).
_____ The information furnished above is correct and .true to the best of my knowledge and belief. \ \ \ \ \ \ \ \ \Authorised Signatory: Place: Date: \ \ \ \ \ \ \ \ \Name: \ \ \ \ \ \ \ \ \Designation:
_____ FORM 5 (See paras. 2, 14 and 15) Form of Price List \1. Name and address of the manufacturer/ importer/ distributor. \2. Name and address of the marketing

company, if any. \3. Details of Prices,:-

Sl. Name of the Product Composition Specifications of No. \(Bulk Drug/Formulation \approved by Drug. the pack \and its dosage forms) Control Authorities -------Type (*) \ \ \ \ \ \ \ \ \Size (**)

\A. BULK DRUGS \1. \2. \3. etc. \ \ \B. FORMULATIONS \I. Own Production \1. \2. \3. etc. \II. Purchased \1. \2. \3. etc.

Excise \if any \Price to \ \Retail \ \Effective Duty. \ \ \ \be retailed \ \Price \ \ \Batch No. \ \ \ \(Inclusive of \(Inclusive of \and date. \ \ \ \Excise Duty) \Excise Duty) \ Rate \ \Amount \Rs. \ \ \(Rs.) \ \ \(Rs.)

6 7 1 [8] 1[9] 1[10]

\(*) Strip, Bottle etc. \(**) 10's, 100's, lml., lmg. etc. Notes- 1. Information to be given separately for scheduled and non-scheduled Items. 2. In case of purchased formulation, name of the manufacturer shall be indicated. 3. The price list must be signed by the authorised signatory of the manufacturer, importer or distributor. FORM 6 (See paras. 2 and 20(2)) \YEARLY INFORMATION ON TURNOVER AND ALLOCATION OF SALES AND EXPENSES :- \1. Name of the manufacturer. \2. Address of the Registered/Head Office/Factory. \3. Accounting year. \4. Turnover of Bulk Drugs:-

\ \ \ \ Captive \Domestic Sale \EXI \PORTS \ \ \ \ Consumption \ \ \ \ \ \ \ \ SI. \Name \ Unit Produc- Quan- Value \Quan- \ Sale \Quan- \FOB No. \of the \ tion tity Excl. \tity \ Value \tity \Value \Bulk \ \ Quan- \ ED (Rs. \ \ Excl. \ \(Rs. \Drug \ \ tity \ \ Lakhs) \ \ ED (Rs. \ \Lakhs.) \ \ \ \ \ \ \ Lakhs) \ \

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

\I. SCHEDULED BULK DRUGS \ \1. \ \2. \ \3. etc. \II. NON-SCHEDULED BULK DRUGS \ \1. \ \2. \ \3.etc.

\TOTAL

\5. Turnover of \Formulations :- \ \ \ Value of Domestic Sales EXPORTS Sl \ \Description excluding Excise duty and FOB Value TOTAL No. Local Taxes (Rs. Lakhs)(Rs. Lakhs) \ \ \ \ \ (Rs. Lakhs) \ I. SCHEDULED FORMULATIONS 1. Own Produced 2. Purchased \(a) Indigenous \(b) Imported II. NON-SCHEDULED BULK DRUGS 1. Own Produced 2. Purchased (a) Indigenous (b) Imported

TOTAL

6. Allocation of sales and expenses as shown in the Audited Profit and Los Account (in Rupees)

\ \ \ \ \ \ \ \ Allocation to Fom \nulations \ \ \ \ \ \Total \ \Allo- \ \ \ \Purchaised \ \ \ \ \ Basis Sl. \Parti- \as per \cation \Uwn \Indige- \Impor- \Export Total \Other \ of No. \culars \P. and L. \to Bulk \Produ \nous \ \ted \ \Sales \ \ \Acti- Allo- \ \ \Acc- \ \Drugs \ \ced \ \ \ \ \ \ \ \vities, cation \ \ \ount \ \ \ \ \ \ \ \ \ \ \ \If any \

1 \2 \ \3 \ \4 \ \5 \ 6 \ \7 \ \8 \ \9 \10 \ \11

A. INCOME 1. Sales Income (Excl. of Excise duty and other taxes) 2. Cash Subsidy (if any) 3. Other Income (Incl. of import incentives)

TOTAL (1+2+3)

\B. EXPENSES \4. Raw Materials \5. Packing Materials \6. Power and Fuel \7. Salaries and Wages \8. Stores and Spares \9. Repair and maintenance \10. Insurance \11. Royalty \13. Interest \14. Head Office Expenses \15. Dealer's Commission and Discount \16. Research and Development Expenses \17. Other Expenses

\TOTAL (4 to 17)

C. PROFIT BEFORE TAX (A-B) D. PROFIT BEFORE TAX (As a %age of Sales Income) IC X 100/A]

The information furnished above is correct and true to the best of my knowledge and belief. \ \ \ \ \ \ \ \ \Authorised Signatory: Place: Name: Date: Designation:

SCHEDULE 3

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[See para. 10] Specified maximum pre-tax return on sales turnover of manufacturers or 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.....eight per cent. (b) having basic drug manufacturing activity at. five per cent. or more of the turnover but no research activity..... ninie per cent. (c) having basic drug manufacturing activity at five per cent or more of the turnover and engaged on approved research and development work related to new drugs .....ten per cent. Category B : Medium sized units with turnover between Rs. 1 crores to 6 crores per annum : (a.) having no basic drug manufacturing activity nor any research activity.....nine per cent. (b) having basic drug manufacturing activity at five per cent. or more of the turnover but no research activity.....eleven per cent. (c) having basic drug manufacturing activity at five per cent or more of the turnover and engaged in approved research and development work related to new drugs.....thirteen per cent. Category C : Other units with turnover of less than Rs. 1 crores per annum : (a) having only formulation activity.....twelve per cent. (b) having basic drug manufacturing activity at five per cent. or more of the turnover..... thirteen per cent.