The Gazette of India – Extraordinary
PART II – Section 3 – Sub-Section (ii)
Ministry of Chemicals and Fertilizers
Department of Chemicals and Petrochemicals
New Delhi, dated the 6th January, 1995

ORDER

S.O. 18 (E). : In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby makes the following Order, namely:-

1. Short title and commencement :

- This Order may be called the Drugs (Prices Control) Order, 1995
- It shall come into force on the date of its publication in the Official Gazette.

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

- **"bulk drugs"** 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;
- **"capital employed"** means net fixed assets plus working capital of a manufacturer in relation to manufacture of bulk drugs;
- **"ceiling price"** means a price fixed by the Government for Scheduled formulations in accordance with the provisions of paragraph 9;
- **"dealer"** means a person 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 his agent;
- **"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;
- **"drug"** Includes –
    - 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;
    - 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
    - bulk drugs and formulations;
- **"Form"** means a form specified in the Second Schedule;
- **"formulation"** means a medicine processed out of, or containing without the use of any one or more bulk drug or drugs with or pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or and, but shall not include –

    - any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines.
    - any medicine included in the Homeopathic system of medicine; and
    - any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply
- **"free reserve"** means a reserve created by appropriation of profits, but does not include reserves provided for contingent disputed claims, goodwill, revaluation and other similar reserves;
- **"Government"** means the Central Government;
- **"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;
- **"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 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;
- **"manufacturer"** means any person who manufactures a drug;
- **"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;
- **"non-Scheduled bulk drug"** means a bulk drug not specified in the First Schedule;
- **"non-Scheduled formulation"** means a formulation not containing any bulk drug specified in the First Schedule;
- **"pre-tax return"** means profits before payment of lncome-tax and surtax and includes such other expenses as do not form part of the cost of formulation;
- **"price list"** means a price list referred to in paragraphs 14 and 15 and includes a supplementary price list;
- **"retail price"** means the retail price of a drug arrived at or fixed in accordance with the provisions of this Order and includes a ceiling price;
- **"retailer"** means a dealer carrying on the retail business of sale of drugs to customers;
- **"Scheduled bulk drug"** means a bulk drug specified in the First Schedule;
- **"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;
- **"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 retail price inclusive of sales tax, if any, paid or direct sales by the manufacturer or importer but does not include excise duty and local taxes, if any;
- **"Schedule"** means a Schedule annexed to this Order;
- **"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 drugs.

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 avaliable 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 faculties and records thereof, by the Government.

2. While fixing the maximum sale price of a bulk drug under sub-paragraph (1), the Government shall take into consideration a post-tax return of fourteen per cerdit on net worth or a return of twenty-two percent on capital employed or in respect, of a new plant an internal rate of return of twelve percent based on long term marginal costing depending upon the option for any of the specified rates of return that may be excercised 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 percent on net worth or a return of twenty-six percent on 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.

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 the 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 1, and the Government shall after making such enquiry, 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 :

1. a list of all Scheduled bulk drugs produced by him within days of the commencement of this Order and indicate the details of the cost of each of such bulk drug in Form I;
2. 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 :

1. 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;
2. 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 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 not sell the such non-Scheduled bulk drug at a price exceeding the price so fixed or revised, within fifteen days of receipt of the order.

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:

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

   - the requirement for captive consumption of such manufacturer, and;
   - 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 retail 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.) x (1 + MAPE/100) + ED. where

- "R.P." means retail price;
- "M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, 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 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 Aflowable 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 the 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 alongwith such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty percent 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:

- 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 paragraph 7.
- 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.
- The retail price of a formulation once fixed by the Govermnent under (1) and (2) shall not be increased by any manufacturer the prior approval of the Government.
- 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 III or Form IV, as the case maybe, 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.

1. Not with standing 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.
2. 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.

3. 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. Notwithstanding 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 paragraph 7, keeping in view the cost or efficiency, or both, of major manufacturers of such formulations 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 name.

10. Power to revise price of bulk drugs and formulations :

Not withstanding anything contained in this order :

- 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;
- 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;
- 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.

11. Fixation of price under certain circumtances :

Where any manufacturer, importer of a bulk drug or formulation falls 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 Control) Order, 1979 and to deposit the same into the Drugs Prices Equalisation Account :

- Notwithstanding anything contained in this Order, the Government may by notice, require the manufacturer, importer or distributor, as the case maybe, 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.
- 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 utilised for :
    - paying to the manufacturer, importer or distilbutor, 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;
    - meeting the expenses incurred by the Government in discharging the functions under this paragraph; and
    - promoting higher education and research in Pharmaceutical Sciences and Technology and for the purposes incidental thereto.

13. Power to recover Overcharged Amt. :

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 provisions of this Order.

14. Carrying into effect the price fixed or revised by the Government, 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 'retail 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 prorata retail 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 taxation or revision as covered by the order or Gazette notification issued by the Government, from time to time.
4. 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.

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 retail sale, the retail price of that formulation with the words "maximum retail price" preceding it and the words 'inclusive of all taxes' succeeding it:

   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 prorata retail price of the main pack rounded off to the nearest paisa.

2. Every manufacturer or importer shall issue a price list and supplementary price list, if required, of the non-Scheduled formulations 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.

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 excise duty and 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.

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 percent thereof.

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

Subject to the provisions of the Drug and Cosmetics Act, 1940 (23 of 1940) and the Rules framed thereunder –

- no manufacturer or distributor shall withhold from sale or refuse to sell to a dealer any drug without good and sufficient reasons;
- 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 retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen percent thereof in the case of Scheduled drugs.
2. Notwithstanding anything contained in sub-paragraph (1), the Government may be a general or special order fix, in public interest, the price of formulation sold to the wholesaler 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 inspection

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 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 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 Govermnent in this behalf may, with a view to securing compliance with this Order or to satisfy himself that the provision of this Order have been complied with –
    - enter and search any place,
    - seize any drug, alongwith the containers, packages or coverings in which the drug is found, in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened, and thereafter take all measures necessary for securing production of the drug, containers, packages or coverings, so seized, in a court of law and for their safe custody pending such production;
    - seize any document, such as, cash memo or credit memo books, books of account and records of purchase and sale of the drugs in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened.

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

22. Power to review :

Any person aggrieved by any notification issued or order made under paragraphs 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 Government, 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 provision 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 –
    - number of workers employed;
    - amount of capital Invested;
    - range/group and type of products manufactured;
    - sales turnover;
    - 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 results in cost reduction;
    - 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 paragraphs 22, 23, and 25 shall, subject to such restrictions, exceptions and conditions, as may be 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.

sd/-
Vinod Valsh
Joint Secretary to
the Government of India
(No. 5(4)/94-PI-II)

List of Price Controlled Drugs-

THE FIRST SCHEDULE
List of Price Controlled Drugs (DPCO 1995)
BULK DRUGS

1. SULPHAMETHOXAZOLE
2. PENICILLINS
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. METHYLDOPA
18. ASPIRIN
19. TRIMETHOPRIM
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 B1 (THIAMINE)
32. CARBAMAZEPINE
33. VITAMIN B2 (RIBOFLAVIN)
34. THEOPHYLLINE
35. LEVODOPA
36. TOLNAFTATE
37. VITAMIN E
38. NALIDIXIC ACID
39. GRISEOFULVIN
40. GENTAMICIN
41. DEXTROPROPOXYPHENE
42. HALOGENATED HYDROXYQUINOLINE
43. PENTAZOCINE
44. CAPTOPRIL
45. NAPROXEN
46. PYRENTAL
47. SULPHADOXINE
48. NORFLOXACIN
49. CEFADROXYL
50. PANTHONATES & PANTHENOLS
51. FURAZOLIDONE
52. PYRITHIOXINE
53. SULPHADIAZINE
54. FRAMYCETIN
55. VERAPAMIL
56. AMIKACIN SULPHATE *
57. GLIPIZIDE
58. SPIRONOLACTONE
59. PENTOXYFYLLINE
60. AMODIAQUIN
61. SULPHAMOXOLE
62. FRUSEMIDE
63. PHENIRAMINE MALEATE
64. CHLOROXYLENOLS
65. BECAMPICILLIN
66. LINCOMYCIN
67. CHLORPROPAMIDE
68. MEBHYDROLINE
69. CHLORPROMAZINE
70. METHENDIENONE
71. PHENYL BUTAZONE
72. LYNESTRANOL
73. SALAZOSULPHAPYRINE
74. DIOSMINE
75. TRIMIPRAMINE
76. MEFENAMIC ACID *

Application for Bulk Drug prices : Form I

THE SECOND SCHEDULE – FORMS

FORM -I : Form of information/application for fixation or revision of prices of Scheduled bulk drugs.

Name of the Bulk Drug.
Name of the manufacturer.
Address of the Registered/Head Office of the Manufacturer.
Address of the Factory.
Capacity under Industrial Licence/Small Scale Industry
Registration/Industrial Entrepreneure Memorandum acknowledgement:-

No. and date of Industrial Licence/Small Scale Industry Registration/Industrial Entrepreneure Memorandum acknowledgement;
Production Capacity (Tonnes/Kgs./Litres etc.)
6. Installed Capacity:-

Number of shifts per day;
Number of operating days per year;
Maximum production per shift (Tonnes/Kgs./Litres etc.);
Date of commissioning;
Annual installed capacity.
7. Date of Commencement of Commercial Production.

8. Actual production achieved during the last accounting year (preferably monthwise) 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 sagewise 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 achievable.

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 drug(s):-

Net fixed assets;
Working Capital;
Total.
15. Please state how the above capital employed is financed by net worth and borrowings.

(In the case of 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 the 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 Practicing Cost Accountant/Chartered Accountant.

19. Please furnish number of persons employed/to be employed, gradewise, 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 product in question.

21. If this item is manufactured/to be manufactured in a multi-product plant, the method adopted for allocations to individual drugs for common expenses viz. process hours, equipment hours etc. may be furnished.

22. Please also furnish the following:-

The types of packing materials used and their average rates;
Basis and calculations of profit margin;
Photocopies of invoices of raw materials having substantial consumption and also for power, fuel ofi etc.;
Details of the fixed assets, method of depreciation, rate of depreciation alongwith, working capital required for the product;
A copy each of Audit & Balance Sheet and Profit & Loss Account for the last three years and in the case of a company copies of the latest Cost Audit Report & Annual Report.
Notes :

Any hold up affecting production to be shown clearly against Serial No.8.
In case the same plant facilities are used for production of more than one product, the information as per serial No.6 may be given product wise.
Annexure

(See Item No. 18 of the Form I of the First Schedule)

I. Name of the Bulk Drug.

II. (a) Production in Tonnes/Kgs. /litres etc.
(b) Sales In Tonnes/Kgs./litres etc.
(c) Despatches In Tonnes/Kgs. /litres etc.

III. Details of Cost:-
(a) Period;
(b) Cost Data:

Sl. No. Particulars Norms of Consumption guaranteed by the know how supplier or as per standards developed unit Actual Consumption
(Per kg/Lit etc. of the product)
Quantity Rate/Unit (Rs.) Amount (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 (Oil/Coal)
(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 Other factory overheads
(f) 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 alongwith supporting documents.)

13. Total cost of sales.

14. Profit Margin.
(Basis of calculations be submitted)

15. Selling Price (13+14)

16. Place notified by the Govenunent, if any. (Please give No. and date of Notification)

17. Actual sale price, or Notional price, if used captively.

NOTES:-

1. Items of expenses to be excluded from costs

Bonus in excess of statutory minimum,
Bad debts and Provisions
Donations and charities
Loss/Gain on sale of assets
Brokerage and commission Expenses not recognised by Income Tax authorities
(Salary, perquisities, advertisements etc.)
Adjustments relating to previous years.
2. In the case of imported raw materials, please furnish seperately the c. i. f. price, duty of customs and other charges totalling to the landed cost adopted against 8. No. 1 (a).

3. Cost of intermediates Manufactured for captive use should be on the basis of factory cost of production inclusive of administration overheads and shown separately against 8. No. 1(b). A separate cost-sheet in the same proforma may please be appended.

4. Cost of generated utilities like power, steam etc. should be separately given furnishing the details of purchased utilities consumed, rate and cost with other expenses incurred on generation with reference to S. No. 2 .

5. Details in respect of factory overheads, administration overheads and selling expenses should be furnished against S.No. 3(d), 3(e) and 8.

6. The basis of depreciation adopted in your financial accounts may please be given against S.No. 3(f).

7. Please indicate clearly whether the existing price is notified by the Government or notional price against S. No. 16 and 17.

8. The information furnished above is correct and true to the best of my knowledge and belief.

FORM II

Form of information in respect of price of non-Scheduled bulk drugs.

Name of the bulk drug.
Name of the manufacturer.
Address of the Registered/Head Office of the Manufacturer.
Address of the Factory.
Capacity under Industrial Licence/Small Scale Industry Registration/Industrial Entrepreneure Memorandum acknowledgement;
Number and date of Industrial Licence/Small Scale Industry Registration/Industrial Entrepreneure Memorandum acknowledgement;
(b) Production Capacity (Tonnes/Kgs./Litres etc.)
Annual Installed Capacity.
Date of commencement of commercial production.
Actual production achieved during the last accounting year/current year (Tonnes/Kgs./Litres etc.).
Brief note on the manufacturing process.
Estimated production of the bulk drug for next three years.
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. NO. 8 and 10.
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.
Please furnish the cost of production of the bulk drug as under: –
Name of the Bulk Drug.
Period.
Major Raw Materials :-
Name;
Quantity consumed per Kg. of Product;
Cost per Kg. of Product;
Total Raw Material Cost.
Cost of production
Cost of Sales
Profit Margin
Selling Price (VI+VII).
Existing price with effective date
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.
NOTE : The information furnished in this form is to be certified by the authorised signatory of the company and by the cost accountant/chartered accountant.

Authorised Signatory :
Place :
Name :
Date :
Designation :

Information for non-Scheduled Bulk Drugs : Form II

FORM II

Form of information in respect of price of non-Scheduled bulk drugs.

Name of the bulk drug.
Name of the manufacturer.
Address of the Registered/Head Office of the Manufacturer.
Address of the Factory.
Capacity under Industrial Licence/Small Scale Industry Registration/Industrial Entrepreneure Memorandum acknowledgement;
Number and date of Industrial Licence/Small Scale Industry Registration/Industrial Entrepreneure Memorandum acknowledgement;
(b) Production Capacity (Tonnes/Kgs./Litres etc.)
Annual Installed Capacity.
Date of commencement of commercial production.
Actual production achieved during the last accounting year/current year (Tonnes/Kgs./Litres etc.).
Brief note on the manufacturing process.
Estimated production of the bulk drug for next three years.
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. NO. 8 and 10.
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.
Please furnish the cost of production of the bulk drug as under: –
Name of the Bulk Drug.
Period.
Major Raw Materials :-
Name;
Quantity consumed per Kg. of Product;
Cost per Kg. of Product;
Total Raw Material Cost.
Cost of production
Cost of Sales
Profit Margin
Selling Price (VI+VII).
Existing price with effective date
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.
NOTE : The information furnished in this form is to be certified by the authorised signatory of the company and by the cost accountant/chartered accountant.

Authorised Signatory :
Place :
Name :
Date :
Designation :

Application for Formulation Prices : a) Form III

FORM III

Form of Application for approval or revision of price of Scheduled formulations.

Name of the Formulation.
Name of the Manufacturer.
Address of Registered/Head Office/ Administrative Office.
Address of the Factory.
Composition as per label claim and approved by Drug Control Authorities.
Drug Control Authority Permission Number and Date (copy to be enclosed).
Number and date of Industrial Licence/Small Scale Industry Registration/ Industrial Entrepreneure Memorandum acknowledgement (copy to be enclosed).
Date of Commencement of Production.
Type of formulation: –
Type [Plain/ Coated Tablets, Multi-layered sustained release/ Soft/ Hard/ Printed capsules (without/ with/ sealing band) / sterile/ non-sterile Liquid/ Powder/ Ointment/ Cream etc.];
In case of Tablets please furnish average weight of 100 Tablets;
In case of Capsules please furnish size of capsule.
Type of packing [Aluminium/ Paper/ Cellophane/ Strips/ Blister/ Vials/ Ampoules/ White Colour Bottles/ Tins/ Jars/ with/ without dropper/ cutting blades/ catch cover etc.].
Size of packs [10's/ 100's/ etc; 1ml/ 2ml/ 10 ml/ etc.; 5 gms/ 10 gms/ etc.].,
Number of Packs sold during the last accounting year and details of other packs of the same formulation with their retail prices.
Break-up of Retail Price :-

Details Existing Price if any* (Rs./Pack) Now Claimed (Rs./Pack)

(a) Material Cost (as per S.No. 14d);
(b) Conversion Cost (as per norms);
(c) Packing Material Costs (as per S.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
Batch Size (Nos./Litres/Kgs./etc);
No. of packs that can be theoretically obtained from the batch size as in (a) above;
Material Cost for the batch size as in (a) above;
S.No. Name of the Material Unit Theoretical Quantity Actual Overages (4+5) Total Quantity Rate/Unit Cost for the Batch(6 x 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
Material Cost per Pack = ——————————
Theoretical No. of Packs
15. Packing Material Costs:-

Packs of ……

Batch Size : …… Tablets/Gms/etc. each

S.No. Name of the
Packing Material Unit Rate per
Unit (Rs.) Qty. Required
per Batch Value of Packing
Materials/Batch
(Nos/Kgs etc)(Rs.)
(1) (2) (3) (4) (5) (6)
Imported
1.
2.
3.
etc.
Indigenous
1.
2.
3.
etc.
Total …… :

Add: Process loss as per norms ……..% :

Total Packing Material Cost …… :

Total Packing Material Cost
Packing Material Cost per Pack = ——————————————
No. of Packs as per Batch size
Note :

The information furnished in this form is to be certified by the authorised signatory of the company and Cost Accountant/Chartered Accountant.
In respect of bulk drug and major raw materials the following documents shall be enclosed :-
A Statement indicating the purchases made during the last three months with copies of invoices certified by Cost Accountant/Chartered Accountant shall be enclosed.
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.
The rates claimed shall be net of modvat, wherever applicable.

Basis and calculation of excise duty [S. No. 13(g)] to be given.
Drug Control Authority Permission Number and Date (copy to be enclosed).

Authorised Signatory :
Place :
Name :
Date :
Designation :

Application for Formulation Prices : a) Form IV

FORM IV

Form of Application for approval or revision of price of Scheduled formulations imported in finished form.

Name of the company.
Address of the Registered/ Head Office/ Factory, if any.
Reference to Permission, if any, given by Drug Control Authorities for import/ sale of the item.
Name of the imported formulation/ therapeutic group.
Type of formulation (capsule/ tablet/ inj. etc.).
Composition of the formulation.
Type of Packs (strip/ vial/ ampoule etc.).
Pack size (10's etc/ 10 ml etc/ 5 gms etc.).
Country from which imported and date of import.
(Quantity/ Number of packs imported with Batch/ Lot Number.)
C.I.F. Value in Foreign Currency.(Not to include bank commission, interest etc.)
C.I.F Value in Rs. actually paid. (Not to include bank commission, interest etc.)
Duty of customs, if any, actually paid.
Clearing Charges (with details) actually incurred.
Landed cost (12+13+14).
Packing Materials, if any, as per norms. (Applicable in case of repacking)
Packing Charges, if any, as per norms.
Landed Cost (including repacking cost, if any). (15+16+17)
Margin @ 50%.
Duty of Excise, if any.
Retail price claimed (18+19+20).
Existing retail price, if any : (copy of approval letter to be enclosed)
NOTES:-

Information furnished should be certified by the Authorised Signatory of the company and a Cost/ Chartered Accountant.
In respect of SI. Nos. 11 to 14 and 16, the claims shall be supported by certified copies of documentary evidence.
The Information furnished above is correct and true to the best of my knowledge and belief.

Authorised Signatory:
Place :
Name:
Designation:

Application for Formulation Prices : a) Form V

FORM V

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. No.	Name of the Product (Bulk Drug/ Formulation and its dosage form)	Composition approved by Drug Control Authorities	Specifications of the pack	
			Type (*)	Size (**)
1.	2.	3.	4.	5.
A. BULK DRUGS				
1.				
2.				
3. etc				
B. FORMULATIONS				
I. Own Production				
1.				
2.				
3. etc				
II. Purchased				
1.				
2.				
3. etc				

Excise Duty, if any		Local Tax, if any	Price to be Retailed (inclusive of Excise Duty) (Rs.)	Retail Price (inclusive of Excise Duty) (Rs.)	Maximum Retail Price inclusive of All Taxes (Rs.)	Effective Batch Number and Date
Rate (Rs.)	Amount (Rs.)	Amount (Rs.)				
6.	7.	8.	9.	10.	11.	12.

(*) Strip, Bottle etc.

(**) 10’s, 100’s, 1 ml, 1 gm etc

NOTES:

1. Information to be given separately for Scheduled and Non-Scheduled Items.
2. In case of purshased formulation, name of the manufacturer shall be indicated.
3. The price list must be signed by the authorised signatory of the manufacturers, importer or distributor

Application for Formulation Prices : a) Form VI

FORM VI

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 :-

Sl. No.	Name of the Bulk Drug	Unit	Prod. Quality	Captive Consumption	
				Quantity	Value Excl. ED (Rs. Lakhs)
1.	2.	3.	4.	5.	6.
I. SCHEDULED BULK DRUGS					
1.					
2.					
3. etc.					
II. NON-SCHEDULED BULK DRUGS					
1.					
2.					
3. etc.					
TOTAL					

Domestic Sale		Exports	
Quantity	Sale Value Excl. ED (Rs. Lakhs)	Quantity	FOB Value (Rs. Lakhs)
7.	8.	9.	10.

5. Turnover of Formulations: –

Sl. No.	Description	Value of Domestic Sales excluding Excise Duty and Local Taxes (Rs. Lakhs)	Exports FOB Value (Rs. Lakhs)	TOTAL (Rs. Lakhs)
1.	2.	3.	4.	5.
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 & Loss Account (In Rupees)

A. INCOME

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

TOTAL (1+2+3)

B. EXPENSES

1. Raw Materials
2. Packing Materials
3. Power & Fuel
4. Salaries and Wages
5. Stores and Spares
6. Repair and Maintenance
7. Insurance
8. Depreciation
9. Royalty
10. Interest
11. Head Office Expenses
12. Dealer’s Commission and Discount
13. Research and Development Expenses
14. Other Expenses

TOTAL (4 to 17)

C. PROFIT BEFORE TAX (A-B)

D. PROFIT BEFORE TAX (As a %age of Sales Income)

[C X 100/A]

NOTES :

- The basis of allocation should be reasonable and followed consistently.
- The figures against S.NO. A under Cols. 4 to 9 of item 6 should tally with the figures under items 4 and 5 respectively of this Form.
- This Form should be certified by the Company's Auditors.

The information furnished above is correct and true to the best of my knowledge and belief.

Authorised Signatory :
Place :
Name :
Date :
Designation

THE THIRD SCHEDULE

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	……..nine 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	……..ten per cent.

CATEGORY B :

Medium sized units with turnover between Rs. 1 Crore to Rs. 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	……..ten 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	……..eleven per cent.

CATEGORY C:

Other units with turnover of less than 1 Crore 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.

sd/-
VINOD VAISH
Joint Secretary to the Government of India
(No. 5(4)/94-PI-II)