Drugs (Prices Control) Order, 1995

Government of India
Ministry of Chemicals and Fertilizers
Department of Chemicals and Petrochemicals

Dated 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:-

(c) **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.

(d) **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:

(e) "capital employed" means net fixed assets plus working capital of a manufacturer in relation to manufacture of bulk drugs:

(f) "ceiling price" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of paragraph 9:

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

(h) "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:

(i) "drug" includes

(i) 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;

(j) "Form" means a form specified in the Second Schedule;

(k) "formulation' means a medicine processed out of, or containing one or more bulk drug or drugs with or without the use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but shall not include –

(i) any 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;

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

(m) "Government" means the Central Government:

(n) "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;

(o) "manufacturer" in relation to any drug, includes any process or part of a process for making, altering, finishing, packing, labeling, 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:

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

(q) "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.

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

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

(t) "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:

(u) "price list" means a price list referred to in paragraphs 14 and 15 and includes a supplementary price list;

(v) "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;

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

(x) "Scheduled bulk drug" means a bulk drug specified in the First Schedule;

(y) "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;

(z) "sale turn-over" means the product of units of formulations sold by a manufacturer or an importer, as the case may be, in an accounting year multiplied by retail price inclusive of sales tax, if any, paid on direct sales by the manufacturer or importer but does not include excise duty and local taxes, if any;

(aa) "Schedule" means a Schedule annexed to this Order;

(bb) "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.

(cc) **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 maximum sale price of a bulk drug under sub-paragraph (1), 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 post-tax return of eighteen per cent on net worth or a return of twenty six per cent 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, 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 I 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.

(dd) **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, -

(i) 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 drug in Form I :

(ii) 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.

(ee) **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, -

(i) 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 drug in Form II:

(ii) 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 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 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.

(ff) 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: -

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

(ii) the requirement of other manufacturers.

(gg) 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.

(hh) **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 there on 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 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 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 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 paragraph 7.

(2) Where the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilizes such bulk drug in his Scheduled formulation 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.

(ii) 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.

(jj) 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 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.

(kk) Notwithstanding anything contained in the foregoing sub-paragraphs, the retail price of a Scheduled formulation, of a manufacturer shall, until the retail price there of 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.

(ll) 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.

(mm) 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 formulation, - (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 an 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.

(nn) 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, -
Notwithstanding anything contained in this order:

(oo) 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 :

(pp) 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;

(qq) 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 circumstances, - Where any manufacturer, importer of a 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 Control) Order, 1979 and to deposit the same into the Drugs Prices Equalisation Account : -
(rr) Notwithstanding anything contained in this Order, the Government may by notice, require the manufacturer, importer or distributors, 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.

(ss) 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 utilized for,-

(i) paying to the manufacturer, importer or distributor, as the case may be, the short-fall between his retention price and the common selling price or, as the case may be, the pooled price for the purpose of increasing the production, or securing the equitable distribution and availability at fair prices, of drugs;

(ii) meeting the expenses incurred by the Government in discharging the functions under this paragraph; and

(iii) 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 may be, 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.

(tt) 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 a 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 pro-rata retail price of main pack rounded off to the nearest paisa.

(uu) 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.

(vv) 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.

(ww) **Display of prices of non-Scheduled formulations and price list thereof, -**

(i) 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 "retail price not to exceed" proceeding it and the words "local taxes extra" 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 pro-rata retail price of the main pack rounded off to the nearest paisa.

(ii) 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.

(iii) 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.

(xx) **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.*

(yy) **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.

(zz) **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 there under –

(a) no manufacturer or distributor shall without from sale or refuse to sell to a dealer any drug without good and sufficient reasons:

(aaa) no dealer shall withhold from sale or refuse to sell any drug available with him to a customer intending to purchase such drug.

(bbb) **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 there under, 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 per cent there of 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 wholesaler or retailer in respect of any formulation the price of which has been fixed or revised under this Order.

(ccc) **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 authorized in this behalf by the Government.

(ddd) **Power of entry, search and seizure, -** (1) Any Gazetted Officer of the Central Government or of a State Government authorized by a general or special order by the Central Government or, as the case may be, by the State Government in this behalf may, with a view to securing compliance with this Order or to satisfy himself that the provisions of this Order have been complied with –

(a) enter and search any place:

(eee) seize any drug, along with the containers, packages or coverings in which the drug is found, in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened, and thereafter take all measures necessary for securing production of the drug, containers, packages or coverings, so seized, in a court of law and for their safe custody pending such production :

(fff) 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.

(ggg) **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.

(hhh) **Power to issue guidelines and directions, -** (1) The Government may for the purpose of implementing the provisions of this Order, authorize 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 authorized 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.

(iii) **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).

(jjj) **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 -

(i) number of workers employed;

(ii) amount of capital invested;

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

(iv) sales turnover;

(v) 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.

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

(kkk) **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 paragraph 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.

(lll) **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.

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

THE FIRST SCHEDULE

[See paragraphs 2 and 3]

BULK DRUGS

(2) SULPHAMETHOXAZOLE
(3) PENICILLINS
(4) TETRACYCLINE
(5) RIFAMPICIN
(6) STREPTOMYCIN
(7) RANITIDINE
(8) VITAMIN C
(9) BETAMETHASONE
(10) METRONIDAZOLE
(11) CHLOROQUINE
(12) INSULIN
(13) ERYTHROMYCIN
(14) VITAMIN A
(15) OXYTRACYCLINE
(16) PREDNISOLONE
(17) CEPHAZOLIN
(18) METHYLDOPA
(19) ASPIRIN
(20) TRIMETHOPRIM
(21) CLOXACILLIN
(22) SULPHADIMIDINE
(23) SALBUTAMOL
(24) FAMOTIDINE
(25) IBUPROFEN
(26) METAMIZOL (ANALGIN)
(27) DOXYCYCLINE
(28) CIPROFLOXACIN
(29) CEFOTAXIME
(30) DEXAMETHASONE
(31) EPHEDRINE
(32) VITAMIN B1 (THIAMINE)
(33) CARBAMAZEPINE
(34) VITAMIN B2 (RIBOFLAVIN)
(35) THEOPHYLLINE
(36) LEVODOPA
(37) TOLNAFTATE
(38) VITAMIN E
(39) NALIDIXIC ACID
(40) GRISEOFULVIN
(41) GENTAMICIN
(42) DEXTROPROPOXYPHENE
(43) HALOGENATED HYDROXYQUINOLINE
(44) PENTAZOCINE
(45) CAPTOPRIL
(46) NAPROXEN
(47) PYRENTAL
(48) SULPHADOXINE
(49) NORFLOXACIN
(50) CEFADROXYL
(51) PANTHONATES & PANTHENOLS
(52) FURAZOLIDONE
(53) PYRITHIOXINE

(54) SULPHADIAZINE
(55) FRAMYCETIN
(56) VERAPAMIL
(57) AMIKACIN SULPHATE
(58) GLIPIZIDE
(59) SPRIONOLACTONE
(60) PENTOXYFYLLINE
(61) AMODIAQUIN
(62) SULPHAMOXOLE
(63) FRUSEMIDE
(64) PHENIRAMINE MALEATE
(65) CHLOROXYLENOLS
(66) BECAMPICILLIN
(67) LINCOMYCIN
(68) CHLORPROPAMIDE
(69) MEBHYDROLINE
(70) CHLORPROMAZINE
(71) METHENDIENONE
(72) PHENYL BUTAZONE
(73) LYNESTRANOL
(74) SALAZOSULPHAPYRINE
(75) DIOSMINE
(76) TRIMIPRAMINE
(77) MEFENAMIC ACID

* * *

THE SECOND SCHEDULE

FORMS

FORM I
(To be submitted in Duplicate)
[See Paragraphs 2, 3 and 4]

Form of information/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 Enterpreneure Memorandum acknowledgement:-

(mmm) No. and date of Industrial Licence/Small Scale Industry Registration/Industry Enterpreneure Memorandum acknowledgement:

(nnn) Production Capacity (Tonnes/Kgs./Litres etc.)

6. Installed Capacity

   (ooo) Number of shifts per day

   (ppp) Number of operating days per year

   (qqq) Maximum production per shift (Tonnes/Kgs/Litres etc.)

   (rrr) Date of commissioning

   (sss) 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 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 achievable.

12. Estimated production of the bulk during the next three years.

13. If the production is proposed to be captively consumed for manufacture of the formulation, please furnish the quantity to be so consumed out of the production given against Serial No. 8 and Serial No. 12

14. Capital employed for the manufacture of the bulk drug (s):-

   (ttt) Net fixed assets

   (uuu) Working Capital

   (vvv) 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 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, grade-wise, and their average monthly emoluments including contribution on account of Provident Fund etc.

20. Please furnish the total amount of expenses under each of the element of other conversion costs viz. stores, factory and administration overheads and depreciation and the basis adopted for allocation to the product in question.

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

22. Please also furnish the following:-

(www) The types of packing materials used their average rates;

(xxx) Basis and calculations of profit margin;

(yyy) Photocopies of invoices of raw materials having substantial consumption and also for power, fuel oil etc.

(zzz) Details of the fixed assets, method of depreciation, rate of depreciation alongwith working capital required for the product.

(aaaa) 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.

Notes :

(1) Any hold up affecting production to be shown clearly against Serial No. 8

(2) 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)

1. Name of the Bulk Drug.

II. (a) Production in Tonnes/Kgs./litres etc.

(bbbb) Sales in Tonnes/Kgs./litres etc.

(cccc) Despatches in Tonnes/Kgs./litres etc.

III. Details of Cost:-

(dddd) Period

(eeee) 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

(c) Imported

1.

2.

3. etc.

(d) Indigenous

1.

2.

3. etc.

Total raw materials cost;
Less Recoveries of Solvents;
Net Raw Materials Cost;

2. Utilities:-

(e) Power

(f) Water

(g) Fuel (Oil/Coal)

(h) Others (To be specified)

Total Utilities Cost.

3. Conversion Cost.

(i) Salaries and wages

(j) Operating supplies or consumable stores.

(k) Repairs and Maintenance

(l) Quality Assurance

(m) Effluent treatment

(n) Other factory overheads

(o) Administration overheads

(p) Research and development expenses

(q) 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

(r) Materials

(s) 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.

NOTES

1. Items of expenses to excluded from costs;

(t) Bonus in excess of statutory minimum

(u) Bad debts and Provisions

(v) Donations and charities

(w) Loss/Gain on sale of assets

(x) Brokerage and commission

(y) Expenses not recognized by Income Tax authorities (Salary, perquisities, advertisements etc.)

(z) Adjustments relating to previous years.

2. In the case of improved raw materials, please furnish separately the c.i.f. price, duty of customs and other charges totaling to the landed cost adopted against S.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 S. 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 IN THIS FORM IS TO BE CERTIFIED BY THE AUTHORISED SIGNATORY OF THE COMPONAY AND BY THE COST ACCOUNTANT/CHARTERED ACCOUNTANT.

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

Place:
Date:

Authorised Signatory:
Name:
Designation:

FORM II

(To be submitted in duplicate)
[See Paragraphs 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 Registration/Industrial Etrepreneure Memorandum acknowledgement;

(aa) Number and date of Industrial Licence/Small Scale Industry Registration/Industrial Entrepreneure Memorandum acknowledgement;

(bb) 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 SL. No. 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 an 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 Material Cost.

V. Cost 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.

NOTE: THE INFORMATION FURNISHED IN THIS FORM IS TO BE CERTIFIED BY THE AUTHORISED SIGNATORY OF THE COMPANY AND BY THE COST ACCOUNTANT/CHARTERED ACCOUNTED.

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

Authorised Signatory:
Place: Name:
Date: Designation:

FORM III

(To be submitted in seven copies)
[See paragraphs 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 Entrepreneure Memorandum acknowledgement (copy to be enclosed).

8. Date of Commencement of Production.

9. Type of formulation

(cc) 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;

(iii) In case of Capsules please furnish size of capsule.

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: 1ml/2m//10ml etc. 5gms/10gms/etc.]

12. Number of Packs sold during the last accounting year and details of other packs of

the same formulation with their retail prices.

13. Break-up of Retail price:-

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

(dd) Materials Cost (as per S. No. 14d)

(ee) Conversion Cost (as per months).

(ff) Packing Materials Costs (as per S. No. 15 or as per norm);

(gg) Packing Charges.

(hh) Ex-factory cost (a to d)

(ii) MAPE 100% on (e) above;

(jj) Excise Duty

(kk) Retail Price (R.P.) (e+f+g).

*Existing Retail Price Approved Letter No. and Date – copy to be enclosed

14. Material Cost

(ll) Batch Size (Nos/Litres/Kgs/etc)

(mm) No. of packs that can be theoretically obtained from the batch size as in (a) above;

(nn) Materials Cost for the batch size as in (a) above;

S. No.	Name of the Material	Unit	Theoretical Quantity	Actual Overages	Total Quantity (4+5)	Rate/Unit	Cost for the Batch (6x7)
(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 …….

$$\text{Material Cost per pack} = \frac{\text{Total Material Cost}}{\text{Theoretical No. of Packs}}$$

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

Packing Material Cost Pack = Total Packing Material Cost/No. of Packs as per Batch Size.

Note :

1. The information furnished in this form is to be certified by the authorized signatory of the company and Cost Accountant/Chartered Accountant.

2. In respect of bulk and major raw materials the following documents shall be enclosed :-

   (c) A Statement indicating the purchases made during the last three months with copies of invoices certified by Cost Accountant/Chartered Accountant shall be enclosed.

   (d) 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 [S. No. 13(a)] to be given.

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

Authorised Signatory:
Place: Name:
Date: Designation:

FORM IV

(To be submitted in seven copies)
[See Paragraphs 2,8,9 and 10]

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

1. Name of the company.

2. Address of the Registered/Head Office/Factory, if any

3. Reference to Permission, if any, given by Drug Control 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/5 gms 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 (Rs.)	Per Pack (Rs.)

12. C.I.F. Value in Rs. Actually pad.
(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 Materials, 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 retail price, if any:
(copy of approval letter to be enclosed)

NOTES

i) Information furnished should be certified by the Authorised Signatory of the company and a Cost/Chartered Accountant.

ii) In respect of Sl. No. 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:
Date: Designation:

FORM V
(See Paragraph 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.* (*Amended by Notfn. No. S.O. 642(E) dated 19th July 1995)

Sl. No.	Name of the product (Bulk Drug/Formulation and its dosage form)	Composition approved by Drug Control Authorities	Specifications of the pack		Excise Duty, if any		Price to be Retailed (Inclusive Excise Duty (Rs.)	Retail Price (Inclusive of Excise Duty) (Rs.)	Effective Batch No. and Date
			Type (0)	Size (00)	Rate (Rs.)	Amt. (Rs.)			
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)

A. BULK DRUGS
1.
2.
3. etc.

B. FORMULATIONS

I. OWN PRODUCTION
1.
2.
3. etc.

II. PURCHASED
1.
2.
3. etc.

(i) Strip Bottle etc.
(ii) 10's, 100's, 1ml, 1gm 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 authorized signatory of the manufacturer, importer or distributor.

FORM VI
[See Paragraph 2 and 20 (2)]

YEARLY INFORMATION OF 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:-

S. No.	Name of the Bulk Drug	Unit	Production Quantity	Captive Consumption		Domestic Sales		Exports	
				Quantity	Value Excl. E.D. (Rs. Lakhs)	Quantity	Sale Value Excl. E.D. (Rs. Lakhs)	Quantity	FOB Value (Rs. 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

S. No.	Description	Value of Domestic Sales excl. Excise duty and local taxes (Rs. Lakhs)	Exports FOB Values (Rs. Lakhs)	Total (Rs. Lakhs)
(1)	(2)	(3)	(4)	(5)

I. SCHEDULED FORMULATIONS

1. Own Produced

2. Purchased

(c) Indigenous

(d) Imported

II. NON-SCHEDULED BULK DRUGS

1. Own Produced

2. Purchased

(e) Indigenous

(f) Imported

TOTAL

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

S. No.	Particulars	Total as Per P& L Acct.	Allocation To bulk Drugs	Allocation to Formulations					Other Activities if Any	Basis Of Allocation
				Own Produced	Purchased Indigenous	Purchased Imported	Export Sales	Total		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)

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

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

TOTAL (4 to 17)

C. PROFIT BEFORE TAX
(A-B)

D. PROFIT BEFORE TAX
(As a % age of Sale Income) Cx100/A

NOTES

(i) The basis of allocation should be reasonable and followed consistently.

(ii) 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.

(iii) 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

(See Paragraph 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 ……..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 ……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 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 …… ……nine per cent

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

Ministry of Chemicals and Fertilizers
Department of Chemicals and Petrochemicals
New Delhi the 2nd March 1995

ORDER

S.O. 134(E) – In exercise of the powers conferred by paragraph 25 of the Drug (Prices Control) Order, 1995, the Central Government hereby exempts every drug manufacturing unit registered as small scale industry unit with any Central Authority or State Directorate of Industries or any other appropriate Authority under the Industries (Development and Regulation) Act, 1951 (65 of 1951), from the operation of paragraph 8 of the said Order relating to fixation of retail price of Scheduled formulation if such Scheduled formulation is not covered under paragraph 9 of the said Order relating to fixation of ceiling price of Scheduled Formulation subject to the conditions that :-

(i) it is an independent unit/company and not a subsidiary of or owned or controlled in any manner by any other undertaking which is not so exempted from the provisions of the Drugs (Prices Control) Order, 1995;

(ii) the formulations are marketed by the concerned unit/company in their own brand names and trade marks or in the brand or trade name of any other small scale industry unit;

(iii) a declaration complying with conditions (i) and (ii) above alongwith a copy of Registration Certificate as a small scale industry unit is submitted to the Government within sixty days from the date of this notification in case of existing units and sixty days from the date of commencement of production in case of new units.

Notes :

(i) The above exemption to a small scale industry unit or company will no longer be admissible as soon as it ceases to be a small scale industry unit/company.

(ii) The exemption is granted only to those products manufactured in their own factory under their own Registration Certificate or in the factory of any other small scale industry unit.

(iii) Unit/company availing exemption in violation of this Order shall be liable for penal action and to deposit dues to Government with retrospective effect.

[F. No. 5 (4) 95-PI.II]

K. L. Gupta, Under Secretary to the Government of India

Guidelines to Bulk Drug Units Manufacturing from Basic Stage

F. No. 32 (2)/95-PI.I Dated 2nd June, 1995
Government of India
Ministry of Chemicals and Fertilizers,
Deptt. Of Chemicals and Petrochemicals

GUIDELINE NO. 1/1995

1. In exercise of the powers conferred by Paragraph 23 of the Drugs (Prices Control) Order, 1995 (hereinafter called the "Said Order"), the Central Government hereby issue guidelines for the purpose of grant of exemption under Paragraph 25 of the said order to such drug manufacturing unit from the Provisions of Paragraph 3, 8 and 9 of the said Order, in respect of:

I. Such bulk drug (s) as is/are produced by that unit from the basic stage by a process of manufacture developed through its own Research and Development efforts, for a specified period not exceeding five years, subject to the following namely:-

(c) The process development activities are registered with the Department of Scientific and Industrial Research (hereinafter referred to as DSIR) and a certificate is issued by DSIR to the

effect that the manufacturer has developed the process of manufacture through its own R&D efforts.

(ii) The process so developed is significantly different from the known/available technology in the country, leading to substantial cost reduction.

OR

The process so developed is significantly different from the known/available technology in the country and there is significant import substitution leading to indigenous availability of the drug at a reasonable price.

(iii) In case of processes developed by National Laboratories, which are purchased and actually used by a manufacturer, such activity shall also be taken into consideration for the purpose of granting exemption.

(iv) The manufacturer shall have furnished to the Government complete information in Form No. I as prescribed in Para 4 of the DPCO, 1995.

(v) The manufacturer shall make an application to the Government within 30 days of the commencement of the commercial production of such bulk drug or within 30 days of the date of issue of these guidelines in the case of bulk drugs already under production, as the case may be, along with information in the Annexe-I and such other information, as may be required by the Government and/or such additional information as the company may voluntarily furnish.

(vi) The Government, after considering the details furnished by the applicant manufacturer and any other relevant information that may be available, if satisfied, may by a Notification in the Official Gazette, exempt such manufacturer from fixation of price or compliance with the price already fixed, if any, for such a bulk drug, under the provisions of the said order, for a period not exceeding five years subject to the following:

(d) For bulk drugs prices of which had been notified by the Government and were being followed by the manufacturer, the period of exemption will start from the date on which exemption is notified.

(e) For bulk drugs, which have no notified price, the period from the date on which the commercial production started based on the new process, till the date on which the drug price is notified or the date on which the exemption is granted whichever is earlier, will be deducted from the period of exemption granted.

(f) If the benefit of price exemption for a specific know-how has been given to a company, it shall not be given to any other company.

II. Such new bulk drug, which has not been produced elsewhere if developed and produced by that unit through indigenous research and development, for a period of ten years reckoned from the date of commercial production of such bulk drug subject to the following namely:-

(g) The new drug invented is registered with the Department of Scientific and Industrial Research (hereinafter referred to as DSIR) and a certificate is issued by DSIR to the effect the new drug has been developed through own R&D efforts of the manufacturer or in collaboration with National Laboratories, and that such new drug has not been produced elsewhere.

(ii) The manufacturer shall have furnished to the Government complete information in Form I as prescribed in Para 4 of the Drugs (Prices Control) Order, 1995.

(iii) The manufacturer shall make an application to the Government within 30 days of the commencement of the commercial production of such bulk drug or within 30 days of the date of issue of these guidelines in the case of bulk drugs already under production, as the case may be, along with the information in the Annexe-I, and or such additional information as the company may voluntarily furnish.

(iv) The Government, after considering the details furnished by the applicant manufacturer and any other relevant information that may be available, if satisfied, may, by a notification in the Official Gazette, exempt such manufacturer from fixation of price for such a bulk drug under the provisions of the said Order.

III. For the purpose of granting exemption under Para 25 (c) of said Order, to such drug manufacturing units from the provisions of Para 8 and 9 of the said Order in respect of such formulations having 'New Delivery System' developed indigenously by that unit a specified period **not exceeding 5 years** reckoned from the date of exemption notification, subject to the following, namely:-

(h) A manufacturer may apply to the Government for exemption of a drug having new delivery system from price control by furnishing information in accordance with the Annexe-II along with the copy of the approval of the Drugs Controller (India) obtained under Schedule Y of Drugs & Cosmetics Act.

(ii) The Government, if satisfied with the application mentioned above may, by an Order, exempt the manufacturer from price control subject to the following conditions, namely:-

(i) The New Delivery System developed has resulted in a substantial reduction in quantity of use of a particular drug bioequivalence efficacy remaining the same or further improved.

(j) The New Delivery System developed should reduce the cost of therapy substantially as compared to the prevailing cost or there should be substantial therapeutic benefits with evidence of minimal side effects.

(i) The exemption shall be available for a period not exceeding five years from the date of approval by the Government. The exemption from price control for new delivery system shall be applicable not to new cases and shall not apply retrospectively.

2. The Government shall have the liberty to withdraw the exemption granted as above at any time.

3. (i) The manufacturer who has been given such price exemption for a bulk drug shall submit application (s) in Form III of the Drugs (Prices Control) Order, 1995 for fixation of price of such bulk drug (s) and formulations respectively under the provisions of the said Order, four months before the expiry of the period of exemption. However if there is an existing notified price for bulk drug or ceiling price for formulations, the manufacturer shall follow the same on the expiry of the exemption and obtain price approval for non-ceiling packs of formulation (s) based on that bulk drug.

(ii) The manufacturer who has been given price exemption for a new delivery system shall submit application in Form III, of the Drugs (Prices Control) Order, 1995, for fixation of price of such formulation (s) under provisions of said Order, two months before the expiry of the period of exemption. However, if there is an existing notified price, he shall follow the same on the expiry of the exemption.

(Shantanu Consul)
Joint Secretary to the Government of India

PROFORMA

COMPARISION OF COST OF TREATMENT WITH SLOW/CONTROLLED RELEASE FORMULATION VIZ-A-VIZ CONVENTIONAL FORMULATION BASED ON SAME BULK DRUG

SL. NO.	Details	Slow/Controlled Release	Conventional
1	2	3	4
1.	Name of formulation		
2.	Composition		
3.	Pack Size		
4.	Price per pack (Rs.)		
5.	Disease treated		
6.	Duration of treatment		
7.	Doses required:		
	(i) Per day		
	(ii) For total duration treatment		
8.	Cost per dose (Rs.)		
9.	Total Cost (Rs.)		
	(i) Per day (Rs.)		
	(ii) For total duration of treatment (Rs.)		

List of the therapeutic advantages over the conventional System:-

Annexe – 1
Annexure for application for exemption for bulk drugs

(Information to be furnished (in five copies) for exemption of bulk drug from Price Control under Para 25 (e) & (f) of DPCO, 1995

1. Name and Address of the applicant:

2. Status and activities:

3. Details of recognition granted by DSIR:

4. (i) Date of recognition and validity period:

   (ii) Research and Development Programmes proposed in the application for recognition with DSIR:

(iii) Date of issue of certificate by DSIR regarding development of processes for the manufacture of bulk drug
(copy to be enclosed).

5. Information on the bulk drug for which exemption is claimed:

(i) Name of the bulk drug and therapeautic use;

(ii) Number and Date of Approval by Drugs Controller (I)/State Drug Controller (copy to be enclosed)

(iii) Number and Date of Industrial Licence/IEM/Registration Certification from Director of Industries:

6. Dates of commencement and completion of R&D:

(i) Laboratory scale:

(ii) Pilot scale:

(iii) Commercial trial

7. Date of commencement of commercial production and quantity produced year-wise:

8. Brief details of the process developed and how it constitutes an improvement over existing process:

or

Brief details of the new drug, which has not been produced elsewhere and which has been developed through indigenous R&D:

9. Quantity benefits in terms of:

(i) Import substitutions:

(ii) Cost reduction:

(iii) Any other:

10. Details of cost data explaining in detail how the R & D efforts have resulted in substantial cost reduction and the proposed price as per Form II of DPCO, 1995.

11. Any other details in support of the claim for exemption:

12. Details of International or National Patent obtained, if any:

13. Date of filling the information in Form I:

(information furnished in this Form I is to be certified by the authorized signatory of the company and by a Cost Accountant/Chartered Accountant.)

(Shantanu Consul)
Joint Secretary to the Government of India

ANNEXE-II

Annexure for exemption for New Delivery System

(information to be furnished (in 5 copies) for exemption of a drug with new delivery system from price control under Para 25 of DPCO, 1995.)

(1) Name and Address of the manufacturer

(2) Name of the formulation

(3) Category of formulation

(4) Composition as per label claimed and approved by Drug Authority

(5) Drug Control Authority permission/number and date (copy to be enclosed)

(6) Type of formulation

(7) Details of approval from Drug Controller (I), obtained under Schedule Y (copy of approval letter to be enclosed)

(8) Date of commencement of commercial production (if any, to be supported by documentary evidence)

(9) Details of cost data as per Form III of DPCO, 1995 and comparative statement showing reduction in cost of therapy.

(10) Details of substantial reduction in quantity of use of the drug bio-equivalence & other comparative efficacy features with lesser side effects, supported by documentary evidence.

(11) Any other details in support of the claim exemption.

NOTE : Information furnished in this Form is to be certified by the authorized signatory of the company and by a Cost Accountant/Chartered Accountant.

(Shantanu Consul)
Joint Secretary to the Government of India