F.NO.32(2)/95-PI.I
Government of India
Ministry of Chemicals & Fertilizers
Deptt. of Chemicals and Petrochemicals

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New Delhi, the 2nd June, 1995

GUIDELINES 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 :-

(i) 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, alongwith the 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:

(a) 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.

(b) 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. .

(c) 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:-

(i) 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 that 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, alongwith 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 the 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 for a specified period not exceeding 5 years reckoned from the date of exemption notification, subject to the following namely:-

(i) 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 Drug 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:- '

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

(b) 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.

(iii) 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 I and 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 the 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. .

Sd/-
(SHANTANU CONSUL)
JOINT SECRETARY TOTHE GOVERNMENT OF INDIA

1. All Pharmaceutical Industry Associations.
2. Bureau of Industrial Cost & Prices, Lok Nayak Bhavan, New Delhi.
3. Department of Scientific and Industrial Research, New Delhi.
4. Indian Council of Medical Research, New Delhi.
5. PIB, Information Officer, Ministry of Chemicals & Fertilizers, Shastri Bhavan, New Delhi.

Annexe-I

Annexure for application for exemption of 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 therapeutic 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 filing 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).

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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-equivalance & 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.

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P R O F O R M A

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

S.No.	DETAILS	SLOW/ CONTROLLED RELEASE	CONVENTIONAL
1.	2	3	4
1.	Name of the 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 of 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:-