National Pharmaceutical Pricing Authority

Subject: Guidelines regarding discontinuation of scheduled formulations under para 21(2) of DPCO, 2013.

1 Paragraph 21 of the Drugs (Prices Control) Order, 2013 provides for monitoring the availability of scheduled formulations. In this regard, manufacturers of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulations are required to furnish the information in respect of production and sales data of such drugs in Form-III as stipulated in paragraph 21(1) of this order on quarterly basis.

2 Paragraph 21(2) of the DPCO, 2013 provides that any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market shall issue a public notice and also intimate the Government in Form-IV of this order in this regard at least six months prior to the intended date of discontinuation and the Government may, in public interest, direct the manufacturer of the scheduled formulation to continue with required level of production or import for a period not exceeding one year, from the intended date of such discontinuation within a period of sixty days of receipt of such intimation. A copy of the draft public notice is attached.

3 Form IV applications received earlier were processed and finalized for granting permission under para 21 (2) of DPCO, 2013 considering the details as available with NPPA such as number of market players, usage of the drug, market share/sales data of the company etc. In a few cases, permission for discontinuation of the product was granted where number of market players was found to be ten or more and the market share of the applicant company was one percent or below. In few cases, where market share was more than one percent, the respective companies were advised to lower the production / import and sales over a period of next twelve months, in order to ensure gradual substitution by other brands and also to avoid any shortage in the market.

4 Taking the above into consideration, the Authority approved the internal guidelines to dispose of Form-IV applications of discontinuation of production/import of scheduled formulations under paragraph 21 (2) of the DPCO, 2013 for issuance of "no objection certificate" by the NPPA as per the following:

4.1 No objection will be granted by the NPPA without referring the cases to the Authority for gradual discontinuation and the applicant company will be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture / import and sell the drug for a period of minimum six months from the intended date of discontinuation, wherever MAT (in units) of the applicant company is upto ten percent. The company should not reduce level of production by more than 40% (of last year's production in each quarter) after getting permission from NPPA. During this period the company shall follow the ceiling price fixed by the NPPA and notified from time to time. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice in the attached format in atleast two national newspapers (one in English and one in Hindi newspaper).

4.2 In cases where Form-IV application is received for a formulation which is legally banned, "no objection" will be issued by the NPPA after being satisfied in this regard without referring the cases to the Authority.

4.3 No objection will be granted by the NPPA for gradual discontinuation and the applicant company will be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture / import and to sell the drug for a period of minimum nine months from the intended date of discontinuation, wherever MAT (in units) of the applicant company is more than ten percent but less than twenty five percent subject to approval of the Authority. The company should not reduce level of production by more than 40% (of last year production in each quarter) after getting permission from NPPA. During this period the company shall follow the ceiling price fixed by the NPPA and notified from time to time. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice in the attached format in atleast two national newspapers (one in English and one in Hindi newspaper).

4.4 No objection will be granted by the NPPA for gradual discontinuation and the applicant company may be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture/import and to sell the drug for a period of twelve months from the intended date of discontinuation, wherever MAT (in units) of the applicant company is more than twenty five percent subject to approval of the Authority, if no other issues are involved.

4.5 In exceptional circumstances like where the manufacturer under consideration has more than 50% of share and other, the cases will be examined on case-to-case basis and decided on merits, subject to approval of the Authority. NPPA will also explore the possibility of alternative arrangements to supplement the production gap likely to be caused by such withdrawl by referring the matter to DoP to request the Government PSU's to produce such drug. NPPA may also consider an upwards price revision under Para 19 if the drug is being discontinued because of non-remunerative pricing. The company in any case, should not reduce level of production by more than 40% (of last year's production in each quarter) after getting permission from NPPA. During this period the company shall follow the ceiling price fixed by the NPPA and notified from time to time. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice in the attached format in atleast two national newspapers (one in English and one in Hindi newspaper).

4.6 Authority observed that in some of the discontinuation cases, the manufacturers had not followed the ceiling price. It was decided that NPPA shall follow up all such cases on priority and recover the overcharged amount, if any, within a period of three months.

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(Dr. Sharmila Mary Joseph K)
Member Secretary

Public Notice

(Under paragraph 21(2) of the Drugs Price Control Order, 2013)

Name of the company
Registered office Address of the company
with their contact details

CIN no.
Website:
E-mail:
Phone no:

Attention of general public is drawn to the fact that (name of company) having registered office at aforesaid address is manufacturing / marketing scheduled formulations namely (brand name) with (composition and strength / dosage) (hereinafter referred to as medicine). (Name of company wants to discontinue and stop the manufacture / marketing of the above said product after a period of six / twelve months from the date of this notice.

After discontinuation of the above medicine, the same may not be available in the market. Therefore, patients using such medicine may consult their doctor for prescribing alternate medicine. All the doctors / Medical Personals may also make note of this.

<Name of the company Secretary/Authorised person>
Designation
Name of the company

Date:
Place: