F. No. 31(67)2016/Div III/NPPA

Dated: 23.01.2017

National Pharmaceutical Pricing Authority

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

1 Paragraph 21 of the Drug (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 the 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 Paragraph 3 of the DPCO provides that the Government may, - (i) with a view to achieving adequate availability and to regulate the distribution of medicines, in case of emergency or in circumstances of urgency or in case of non-commercial use in public interest, direct any manufacturer of any active pharmaceutical ingredient or bulk drug or formulation to increase the production and to sell such active pharmaceutical ingredient or bulk drug to such other manufacturer(s) of formulations and to direct formulators to sell the formulations to institutions, hospitals or any agency as the case may be; (ii) for the purpose of giving any direction under sub-paragraph (i), call for such information from manufacturers of active pharmaceutical ingredients or bulk drugs or formulations, as it may consider necessary and such manufacturer shall furnish the required information within such time the Government may fix.

4 Taking the above into consideration, the Authority in its 39th meeting held on 21.12.2016 approved the revised 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. The Authority discussed the issue in the light of recent acute shortage of some essential medicines and modified these guidelines in supercession of the earlier guidelines .The guidelines are as follows:

4.1 Wherever MAT (in units) of the applicant company is less than ten percent of the total MAT (unit) value of the formulation, no objection may be granted by NPPA with the approval of the Chairman without referring the case 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 application to continue to manufacture / import and sell the formulation for a period of minimum six months from the intended date of discontinuation, as the case may be. The company should not reduce level of production by more than 25% (of previous 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 at least two national newspapers (one in English and one in Hindi newspaper).

4.2 Wherever MAT (in units) of the applicant company is ten percent or more but less than twenty five percent, "no objection" may be granted by the NPPA with the approval of the Chairman, for gradual discontinuation and the applicant company will be advised within a period of 60 days from the receipt of Form-IV application to continue to manufacture/import and to sell the formulation for a period of minimum 09 months from the intended date of discontinuation, as the case may be. The company shall not reduce level of production by more than 25% (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 at least two national newspapers (one in English and one in Hindi newspaper).

4.3 All cases where the MAT volume of the formulation intended for discontinuation is 25% or more, shall be put up for the decision of the Authority. No objection may be granted by the Authority, for gradual discontinuation after ascertaining the availability and the applicant company may be advised within a period of 60 days from the receipt of Form-IV application to continue to manufacture/import and to sell the formulation for a maximum period of twelve months from the intended date of discontinuation. The required level of maximum reduction in production shall not be more than 25% in a quarter as in Para 4.1. The manufacturer will also follow other conditions as may be prescribed.

4.4 In exceptional circumstances as where the formulation intended for discontinuation has more than 25% share and the proposed discontinuation may cause short supply of the drug, and public inconvenience, cases will be decided on merit and will be subject to approval of the Authority. NPPA will explore the possibility of alternative arrangements to supplement the production gap likely to be caused by such withdrawal by referring the matter to other manufacturers of the same formulation and also to Department of Pharmaceuticals for a direction to Government PSU's under Para 3 of DPCO, 2013 to produce the formulation if possible. NPPA may also consider an upward price revision under Para 19 if the formulation is proposed to be discontinued on account of non-remunerative pricing, a ground which needs to be established by the manufacturers. The no - objection for discontinuation in such cases will either be deferred till alternative arrangements are ensured, or the Authority may allow partial discontinuation on case-to-case basis.

4.5 Notwithstanding provisions of Para 4.1 – 4.4 above, whenever a formulation is found to be critical for public health, based on circumstances and also in cases where established, based on evidence with NPPA that the manufacturer is intending to discontinue production of a scheduled formulation and has already launched or intends to launch 'a new drug' just to evade price control and where the continuation of production of that formulation is critical for public health, NPPA will refer such cases to Government for exercising powers under Para (3) of the DPCO, 2013 to ensure supply of such formulations for such period as it considers necessary.

4.6 In cases where Form-IV application is received for a formulation which is legally banned, "no objection" may be issued by the NPPA with the approval of Chairman, after being satisfied in this regard, without referring the case to the Authority.

4.7 NPPA shall ordinarily not allow discontinuation of a scheduled formulation where the manufacturer had not complied with notified ceiling price or where there is an ongoing overpricing case pending against the pharmaceutical company. In all such cases, the manufacturers shall be asked to deposit the overpriced amount with interest for availing the benefit of discontinuation.

4.8 The manufacturers, shall submit along with Form IV application copies of Form-II, III and V for the last two years filed in Integrated Pharmaceutical Database Management System (IPDMS) in respect of formulations being discontinued, without which the application (Form-IV) shall be summarily rejected by NPPA.

4.9 The public notice should be issued by the manufacturer only after it has communicated its intention to discontinue the formulation to the Government and after receipt of intimation from NPPA to do so. The public notice as prescribed shall be issued by the manufacturer in such a way that the general public gets enough time to make alternate arrangements by consulting doctor etc.

These guidelines will be effective with immediate effect and be applicable to all cases under consideration and future cases.

Sharmilajoseph

(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: