F.No. 31(67)/2016/Div. III/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

5th / 3rd Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, Delhi – 110001
Date: 01.06.2020

Subject: Inviting comments on Draft Guidelines for dealing cases of discontinuation of Scheduled formulations under para 21 (2) of DPCO, 2013.

National Pharmaceutical Pricing Authority (NPPA) has formulated Draft Guidelines for dealing cases of discontinuation of Scheduled formulations under para 21 (2) of DPCO, 2013.

NPPA invites comments and suggestions of Stakeholders on Draft Guidelines for dealing cases of discontinuation of Scheduled formulations under para 21 (2) of DPCO, 2013 by **15th June, 2020** to the undersigned at NPPA Office, 5th Floor, YMCA Cultural Centre Building, 1, JAI Singh Road, NEW Delhi-110001. The comments can also be emailed at monitoring-nppa@gov.in.

(Encl: Draft Guidelines)

(Manjesh Porwal)
Deputy Director (M&E)

Guidelines for dealing cases of 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 of Schedule II as stipulated in paragraph 21(1) of DPCO, 2013 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. Taking the above into consideration, the Authority in (*Next Authority Meeting*) held on (*Date of next Authority Meeting*) will be approved the following guidelines to deal with intimations received in Form-IV (Schedule-II of DPCO, 2013) for discontinuation of production/import of scheduled formulations under Paragraph 21(2) of the DPCO, 2013.

3.1 In cases where the company intending to discontinue scheduled formulation has not issued public notice, it will be directed to issue such public notice in the attached formats in at least two national newspapers (one in English and one in Hindi newspaper).The date of discontinuation shall be treated six months from the date of public notice, further subject to 3.2 to 3.6 of these guidelines.

3.2 Wherever Moving Annual Turnover (MAT) (in units) of the company is less than ten percent of the total MAT Value (in unit), company will be advised that intimation request has been noted and directed to continue production / import and sale of the formulation for a period of six months from the date of issue of public notice and to ensure that there is no shortages of the formulation during this period.

3.3 Wherever MAT (in units) of the company is ten percent or more but less than twenty five percent of the total MAT Value (in unit), company will be advised that intimation request has been noted and directed to continue production / import and sale of the formulation for a period of nine months from the date of issue of public notice and to ensure that there is no shortages of the formulation during this period.

3.4 Wherever MAT (in units) of the company is more than twenty five percent of the total MAT Value (in unit) but less than forty percent and there are five or more market players having more than 5% market share each, company will be advised that intimation request has been noted and directed to continue production / import and sale of the formulation for a period of twelve months from the date of issue of public notice and to ensure that there is no shortage of the formulation during this period.

3.5 Wherever MAT (in units) of the company is more than forty percent and in all the other cases, directed to continue production / import and sale of the formulation for a period of twelve months from the date of issue of public notice and to ensure that there is no shortage of the formulation during this period. Simultaneously, the case will be put up for the decision of the Authority / Committee to inform whether there is any urgency or emergency requiring invocation of Para 3 of DPCO, 2013.

NPPA may also consider an application for 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.

3.6 Notwithstanding provisions of Paras 3.1-3.5 above, whenever a formulation is found to be critical for public health, based on circumstances and also in cases where it is established, that the company is intending to discontinue production/import and sale of a scheduled formulation and has already launched or intends to launch 'a new drug' to evade price control. NPPA will refer such cases to Committee for exercising powers under Para (3) of the DPCO, 2013 to ensure supply of such formulations for such period as it considers necessary, which provide as under:

> *"With a view to achieve adequate availability and to regulate the distribution of drugs, in case of emergency or in circumstances of urgency or in case of non-commercial use in public interest, Govt. may 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"*

3.7 Market share reports are determined by Market Database referred by this office.

4. Exemption from any condition prescribed in these Guidelines for discontinuation of scheduled formulations may be considered, e.g., in cases of unforeseen situations which are beyond the control of manufacturers/importers, cases in which import license gets expired or marketing/distribution agreement between the manufacturer/importer and marketing company gets terminated prior to the period of six/nine/twelve months for which Company is asked to continue production/import and sale beyond the intended date of discontinuation. Such exemption may be approved by Chairman, NPPA.

5. The provisions of these guidelines are applicable to scheduled formulations only. All Form-IV intimations for discontinuation of medical devices, which are part of NLEM and Schedule-I of DPCO, 2013, shall be put up before the Authority. Such cases shall be examined on case-to-case basis.

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

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