National Pharmaceutical Pricing Authority

NPPA invites the comments of all the Stake Holders / Industry Associations within a period of three weeks on the following draft Guidelines for disposal of Form IV application under para 21(2) of DPCO, 2013 :

11/07/14

(Jagdish Kumar)
Director (M&E)

Draft Guidelines for discontinuation of scheduled formulations under para 21(2) of DPCO, 2013.

1.0 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 formulation are required to furnish the information in respect of production and sale of such drugs in Form-III as stipulated in para 21 (1) of this order quarterly.

2.0 Paragraph 21(2) Of the DPCO 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 month 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.

3.0 Form IV applications received earlier were processed and finalised 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 / sale of the company etc. In a few no. of the cases, permission for discontinuation of the product have been granted where no. of market players were found ten or more and the market share of the applicant company was one percent

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or below. In respect of two cases of M/s Astrazeneca and one case of M/s BMS, where market share was more than one percent, the respective companies were advised for lowering down the production / import and sale over the period of next twelve months, in order to ensure graduation substitution by other brands and also to avoid any shortages in the market .

4.0 Taking the above into consideration, the following internal guidelines is submitted for consideration and approval of the authority to dispose of the cases of discontinuation of production / import of scheduled formulations under 21 (2) of the DPCO, 2013.

4.1 Permission for discontinuation may be granted by the NPPA wherever no. of market players are ten or more and the market share of the applicant company is below one percent.

4.2 Permission may 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 sale the drug during the next six months, wherever number of market players are ten or more and the market share of the applicant company is one percent to three percent.

4.3 Permission may 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 sale the drug during the next twelve months, wherever number of market players are more than five and less than ten and the market share of the applicant company is above three percent but less than five percent. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice.

4.4 Permission for discontinuation may be granted by the NPPA only after approval of the Authority where number of market players are less than five and the applicant company holds five percent or more of market share. In this regard, an agenda note should be put up of consideration of the Authority within one month of the receipt of Form-IV application.

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