NPPA ISSUES GUIDELINES FOR STOPPAGE OF SCHEDULED FORMULATIONS

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NPPA has issued draft guidelines for the disposal of Form-IV application under paragraph 21(2) of DPCO 2013 for discontinuation of scheduled formulations from the market by the pharmaceutical companies. In the draft guidelines, paragraph 21(2) provides that any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market shall (i) issue a public notice and also (ii) intimate the government in Form-IV of this order in this regard at least six month prior to the intended date of discontinuation and (iii) 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 a 60 days of receipt of such intimation. As per the guidelines, permission for discontinuation may be granted by the NPPA wherever number of market players are 10 or more and the market share of the applicant company is <1%. Permission may also 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 10 or more and the market share of the applicant company is 1%-3%. The guidelines further say that 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 manufacture/import and sale the drug during the next 12 months, wherever the number of market players are more than 5 and less than 10 and the market share of the applicant company is >3%-<5%. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice. Permission for discontinuation may be granted by the NPPA only after approval of the Authority where number of market players are less than 5 and the applicant company holds 5%/< of market share. In this regard, an agenda note should be put up for consideration of the Authority within one month of the receipt of Form-IV application.

PSA view – The proposed guidelines will streamline the discontinuation of scheduled formulations.

“Price to retailer” only basis for deciding the ceiling price of the drugs under DPCO

A Mumbai based pharma major had filed a review application with the DoP against NPPA’s fixation of ceiling prices for Dexamethasone Injection 4mg/ml and Gentamycin 40mg/ml through its notification S.O. No. 1157(E) dated 28.4.2014 under DPCO 2013. Aggrieved by the notifications, the company sought review against this price fixation orders. After thorough examination of the issue, the DoP rejected company’s plea and ordered that once the brands/generic versions of a particular medicine, having MAT of >1% have been identified, it is only simple averaging of prices of all such versions, which determines ceiling price for that

medicine per Para 4 of DPCO 2013. The DPCO 2013 does not distinguish between sales through retailer shop or through hospital outlets. It is only the “Price to retailer”, which is captured by IMS, that is taken into account for calculation of ceiling price. Therefore, any such further classification or exclusion of hospital sales may not be in line with provisions of DPCO 2013, the DoP order said.

PSA view – This order of DoP has brought in clarity for deciding the ceiling price of the drugs.

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