What's New **16.08.2020**

NPPA issues Guidelines for Discontinuation of Scheduled Formulation

The National Pharmaceutical Pricing Authority (NPPA) has issued final guidelines regarding discontinuation of scheduled formulations under paragraph 21(2) of Drugs Prices Control Order (DPCO), 2013.

The Authority in its 209th (overall) and 77th meeting held on August 6, 2020 has approved the guidelines for dealing with cases of discontinuation of scheduled formulations under para 21(2) of DPCO, 2013.

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

Para 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 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 60 days of receipt of such intimation.

As per the guidelines, companies may submit duly filled Form-IV (as per Schedule-II of DPCO, 2013) for intimation, duly signed and stamped by authorized signatory, for the discontinuation of the production of scheduled formulation with all the requisite documents on email ID: monitoring-nppa@gov.in at least six months prior to the intended date of discontinuation.

Confirmation of the receipt of Form-IV along with acknowledgement number would be provided via return email. Incomplete intimation without the requisite documents would be returned for re-submission and the same shall be informed to the applicant via email within 10 working days.

Wherever moving annual turnover (MAT) of the company is 1% or less than 1% of the total MAT value, the company has to inform at least six months prior to the proposed/intended date of discontinuation and to issue public notice in at least one newspaper. Such cases will be noted without issuing any direction to the company and case will be deemed approved except where intimation has not been submitted six months prior to the proposed/intended date of discontinuation or the market share of the company is more than 1%.

Wherever moving annual turnover (MAT) of the company is more than 1% of the total MAT value, company will be directed, with the approval of the chairman, NPPA, within a period of 60 days from the receipt of Form-IV that intimation request has been noted and further directed to issue public notice in the prescribed formats in at least two national newspapers one in English and one in Hindi. The company will also be directed to continue production/import and sale of the formulation for a period of up to twelve months from the date of issue of public notice and to ensure that there is no shortage of the formulation during this period.

Notwithstanding the provisions as discussed above, whenever concerns regarding shortage is apprehended or 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; cases requiring continuance of production/import and sale beyond 12 months or any other case; with the approval of chairman, NPPA will be referred to a standing committee. The standing committee will consist of advisor (cost), NPPA and representatives from CDSCO and Directorate General of Health Services (DGHS) as members of the committee. The recommendation of the committee will be put up to the authority.

MAT shall be calculated in value terms as defined in para 2 (s) of DPCO, 2013, except in cases where market share cannot be calculated by MAT in value, the same will be calculated by MAT in units. Market share is determined from the market database referred by NPPA.

The company shall not reduce the level of production by more than 25% (of last year production in each quarter) after getting direction from NPPA.

The provisions of these guidelines are also applicable to scheduled medical devices which have been notified as drugs by the government from time to time.

NPPA will upload a list of discontinuation of scheduled formulations filed by pharmaceutical companies and approved by competent authority, on its website on a monthly basis.

Guidelines for Discontinuation of Scheduled Formulation