



What's New

09.02.2018

Partially revised format of Form-I for application of new drug para 2(u) of DPCO, 2013

NPPA has issued a clarification in relation to additional information required in Form I for application of new drug para 2(u) of DPCO,2013 which were sought with the purpose of expediting the price approval process.

It is clarified that in case applicant company/ companies is/are not able to provide this information in view of the non applicability or non availability , they may mention these facts in their application and their application for retail price approval will also be considered and processed for price approval as per process as within the first in first out (FIFO) basis.

Earlier, NPPA in its OM dated 09.01.2018 had required additional information like applicant company has to indicate drug category as per report of Kokate Committee and as per Drug Technical Advisory Board (DTAB) to save time spent by NPPA on seeking this information from DCG(I) and some Pharma associations had raised concerns about the procedure.

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[Partially revised format of Form-I for application of new drug para 2\(u\) of DPCO, 2013](#)