What's New **09.01.2018**

NPPA partially revises Form I for applications of new drug under para 2 (u) of DPCO 2013

NPPA has partially revised Form I for applications of new drug under para 2 (u) of DPCO 2013 w.e.f. 09.01.2018 vide its OM F.No. 19(78)/2014/Div.II/NPPA dated 09.01.2018.

In order to expedite price approval for new drug, NPPA has requested all the manufacturers / marketing companies to comply with the formalities and submit the information / documents along with the Form I application for retail price fixation of new drug.

The manufacturers / marketing companies have to submit the following information / documents:

1. Information as per Schedule –II of the DPCO 2013:

   a) Name of the formulation

   b) Name and address of the manufacturer / importer

   c) Name of the Marketing Company, if any

   d) Composition as per label claimed and approved by Drug Control Authorities

   e) Drugs Control Authority Permission Number and Date (Copy enclosed)

   f) Proposed date of commencement of production / import

   g) Type of formulation (Tablets/Capsules/Syrup/Injection/Ointment/Powder etc)

   h) Size of Packs (10's/100's/1 ml/2 ml/10 ml/5 gms. etc)

   i) Therapeutic category /use of the formulation

   j) The Retail Price claimed for approval (with / without GST, if any)

   k) Name of the scheduled drug/ drugs proposed to be part of the new drug.

   l) Whether NPPA has already approved price of similar drug, if yes, the name of the company, S.O.number and the date.

   m) Any other information relevant to product and its process of manufacturing / packaging/ distribution

2. Other information / documents to be provided under Paras (9) , (20) ,(21) and (29) etc. of DPCO, 2013:

    a) Status of drug category (a,b,c,d, etc) as per the report of the Kokate Committee for FDC's.

    b) Status of drug as per Drug Technical Advisory Board.

    c) Whether there is any proposal by the company to discontinue or reduce production of Scheduled Formulation already being manufactured by it under NLEM, 2015, which has been combined with the new drug or if the strength is proposed to be changed.

    d) Provide details of quarterly production, sales etc. in the last six quarters duly certified by CA/CMA for the scheduled drug component of the proposed new drug as per Form III of IPDMS, if being made as per ©.

    e) Joint undertaking between Manufacturer and Marketing Company for the new drug, duly attested by their respective authorized signatories (without any trade secret).

NPPA has asked all the manufacturers / marketing companies who have already submitted their application but not compliant these instructions to submit the remaining documents by 16.01.2018 to avoid rejection of their applications.

NPPA shall not consider any proposal for retail price fixation of new drug unless complete in all respect as per these instructions in future.

Click the below link for the copy of the Office Memorandum

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