



What's New

19.12.2017

DoP comes forward for Ease of doing business for Pharma manufacturers - NPPA will not link price approval of new drug under Para 2 (u) of DPCO 2013 with IPDMS and any other conditions.

NPPA has decided not to link price approval of new drug under Para 2 (u) of DPCO 2013 with IPDMS and any other conditionality even when linking of New drug approval with IPDMS did help in speeding up the process of data submission and data bank updation as the Department of Pharmaceuticals had instructed NPPA not to consider the issue of IPDMS or WPA for deciding of the price approval of new drug vide its letter dated 23rd November 2017.

Accordingly, in a meeting held on 15.12.2017, NPPA approved the retail prices for 59 such new drugs where the price of the similar drug was already approved by NPPA by extending the same price already notified by NPPA.

Remaining applications of new drugs are being examined and if all the information as per NPPA's office memorandum F.No.19(76)/2014/Div.II/ NPPA dated 07.02.2017 are complete, same will be cleared within the time prescribed under DPCO 2013.

Earlier , the Form I applications of manufacturers who were non IPDMS compliant were kept pending as per the decision of the Government in a meeting held on 18.02.2017 wherein it was clearly stipulated that applications for price fixation of new drugs of the companies failing to complete the IPDMS information shall not be cleared till that is done nor would their review petitions will be attended. The companies which complied with the IPDMS data submission got their prices approved.

Further, on analysis of the market data, it had been noted by NPPA that many pharmaceutical companies had launched their new drug formulations without seeking price approval from NPPA. In order to enforce strict compliance of DPCO provisions in the larger public interest, NPPA issued show cause notices to these pharmaceutical companies and also decided to keep their Form I applications pending till completion of proceedings.

In a meeting held on 6th December,2017, NPPA has decided to proceed to take necessary action as per guidelines issued vide F.No. 28(10)/2016/Div.II/NPPA and uploaded on NPPA's website. Violation of DPCO 2013provisions shall be taken very seriously and the manufacturers are advised to desist from it.

Office memorandum F.No.19(78)/2014/DP/ NPPA / Div.II dated 19.12.2017