

F. No. 19(78)/2014/DP/NPPA/Div.II  
भारत सरकार  
Government of India  
रसायन एवं उर्वरक मंत्रालय  
Ministry of Chemical and Fertilizers  
औषध विभाग  
Department of Pharmaceuticals  
राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण  
National Pharmaceutical Pricing Authority

5<sup>th</sup>/3<sup>rd</sup> Floor,  
YMCA cultural Centre Building  
1, Jai Singh Road, N. Delhi- 11001  
Dated: 19.12.2017

**OFFICE MEMORANDUM**

**Subject: Form - I application for price fixation of new drug under Para 2(u) of DPCO, 2013.**

Undersigned is directed to refer to the OM of even number dated 20.09.2017 on Status price approval of Form - I applications of new drug under Para 2(u) of DPCO, 2013 uploaded on NPPA website on 20.09.2017 and to state that **some** form I applications had been pending due to non compliance of submission of requisite data under Integrated Pharma Database Management (IPDMS) by the applicant companies or because of launch of new drug by these companies without prior approval (WPA) or in several cases because of incomplete information.

2. Launching of new drugs has been a widely used practice by pharmaceuticals manufacturers. Though the prime rational of these drugs is enhanced dosage compliance, there is added benefits of the drug going out of Schedule I and entitlement for price control and availing upto 10% annual increase in MRP as non-scheduled drug. The rationality and safety of some new drugs has been an area of concern for Ministry of Health&Family Welfare which had found certain drugs to be unsafe and the matter has also been subjudice in the Hon'ble Supreme Court.

3. The form I application 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. NPPA has so far approved 266 new drug prices under NLEM, 2015.

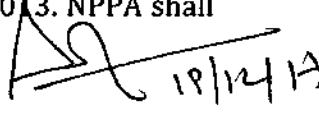
4. Further, on analysis of the market data, it has also been noted that many pharmaceutical companies had launched their new drug formulations without seeking price approval from NPPA. In order to enforce strict compliance of DPCO provisions in the

larger public interest, NPPA issued show cause notices to these pharmaceutical companies and also decided to keep their form 1 applications pending till completion of the proceedings.

5. Subsequently, as per the Department of Pharma's letter No. dated 23<sup>rd</sup> November, 2017 the issue of IPDMS or WPA is not to be considered for deciding of the price approval of new drugs. Accordingly it was decided by NPPA that price approval of new drugs shall need not be linked to IPDMS and any other conditionality's. Linking of New drugs approval with IPDMS did help in speeding up the process of data submission and data bank updation.

Accordingly, in a meeting of the Authority held on 15.12.2017, the Authority 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. This decision is as per the decisions take in a high level meeting on December 6, 2017 In case of new drugs launching without price approval, NPPA is proceeding to take necessary action as per its guideline issued vide F.No. 28(10)/2016/Div IV/NPPA and uploaded on NPPA's website. Violation of DPCO, 2013 provisions shall be taken very seriously and the manufacturers are advised to desist from it.

5. Remaining applications of new drugs are being examined and if all the information as per NPPA's office memorandum F.No. 19(78)/2014/Div.II/NPPA dated 07.02.2017 are complete, same will be cleared within the time prescribed under D.P.C.O, 2013. NPPA shall also update the status of applications fortnightly.

  
(APS Sawhney)  
Director (Pricing)

Copy to: All Apex Pharma organization / Associations i.e. OPPI, IDMA, AISSPMA, PICCI, CII, IPA and FOPE for information.