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

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वाई.एम.सी.ए. सांस्कृतिक केन्द्र बिल्डिंग
YMCA Cultural Center Building,
1, जय सिंह रोड़, नई दिल्ली-110001
1, Jai Singh Road, N. Delhi – 110001.
दिनांक : 07.02.2017

OFFICE MEMORANDUM

Subject: **Revised format of Form-I for applications of new drug under Para 2(u) of DPCO, 2013 (effective from 23.01.2017).**

The undersigned is directed to refer to this office OM of even no. dated 03.3.2016 and OM F. No. 20(1)/2014/Div. III/NPPA dated 01.02.2017 and to request all the manufacturers/ marketing companies to comply with the following formalities and submit the information/ documents as mentioned below, alongwith the Form-I application for retail price fixation of new drug.

1. Information as per Schedule-II, Form I 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 to be enclosed)
f) 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/10 gms etc.)
i) Therapeutic category/use of the formulation
j) The Retail Price claimed for approval (with/without VAT/local taxes, if any)
k) Reason for submission of application for price fixation /revision
l) 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 whether banned by the MoH&FW or not.

b) Status of registration and filing of necessary data online on IPDMS as per the prescribed formats viz. Form-II/III/V i.e. hard copies of last Forms submitted on IPDMS along with date of submission and the certificate to the effect that they have filed all the requisite forms for all their formulations through Integrated Pharmaceutical DataBase Management System (IPDMS) with NPPA,.

c) Whether there is any proposal by the company to discontinue or reduce production of scheduled formulation 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 under Form-III of IPDMS.

3. The manufacturers who have already submitted their applications

a) but not compliant with these instructions may submit the remaining documents **by 15.02.2017** to avoid rejection of their applications.

b) No proposal for retail price fixation of new drug shall be considered unless complete in all respects as per this O.M. in future.

(ए. के. खुराना)
निदेशक

Copy to: All Apex Pharma organizations/Associations i.e. OPPI, IDMA, AISSPMA, PICCI, CII, IPA and FOPE for necessary action please.