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

तीसरी/पांचवी मंजिल 5th / 3rd Floor,
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 : **09.01.2018**

OFFICE MEMORANDUM

Subject: Partially Revised format of Form-I for applications of new drug under Para 2(u) of DPCO, 2013 (effective from 09.01.2018).

The undersigned is directed to refer to this office OM of even no. dated 07.02.2017 and 01.05.2017 and to request that in order to expedite price approval for new drugs 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) 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/10 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 (C).
e) Joint undertaking between the manufacturer and marketer company for the new drug, duly attested by their respective authorized signatories (without any trade secret).

3. The manufacturers who have already submitted their applications

a) but not compliant with these instructions may submit the remaining documents **by 16.01.2018** 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.

(APS Sawhney)
Director (Pricing)

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