F.No.19(78)/2017/DP/NPPA/Div.II
Government of India
Ministry of Chemicals & Fertilizer
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

5th/3rd Floor
1, Jai Singh Road,
YMCA Cultural Building,
New Delhi – 110 001.

Dated 05.02.2018

OFFICE MEMORANDUM

Subject: Partially Revised format of Form I for application of new drug under para 2(u) of DPCO, 2013.

Reference is invited to NPPA OM of even number dated 09.01.2018 on the above subject. As per para - 12 of the Form I under DPCO, 2013, other relevant information could be provided by the concerned company applying for the retail price of new drug. Based on the experience of handling such cases in the past and in order to avoid delay in decision making, some additional information are being sought with the purpose of expediting the price approval process. Some Pharma Associations have raised concern about the procedure and it is found necessary to issue the following clarification.

2. It is clarified that in order to expedite the retail price approval of new drugs by NPPA, applicant company has been asked to indicate drug category as per report of Kokate Committee and as per Drug Technical Advisory Board (DTAB) to save time spent by NPPA on seeking this information from DCG(I). However, in case applicant company/companies is/are not able to provide this information in view of the non applicability or non availability, they may mention these facts in their application and their application for retail price approval will also be considered and processed for price approval as per the process as within the first in first out (FIFO) basis.

(A.P.S.Sawhney)
Director

To : All Apex Pharma organization/Association i.e Indian Pharmaceutical Alliance, OPPI, IDMA, FICCI, CII, ASSOCHEM and FOPE for information.