

F.No. 20(1)/2014/Div-III/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority
Ph:23345116,23345118,23345122
Website: www.nppaindia.nic.in

5th / 3rd Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, N. Delhi – 110001
Dated 1st February 2017

OFFICE MEMORANDUM

Subject: Submission of information through Integrated Pharmaceutical Database Management System (IPDMS) / Pharma Data Bank under the provisions of the DPCO 2013.

The undersigned is directed to refer to this office notice no. 20(1)/2014/Div-III/NPPA dated 03.08.2016 wherein the industry associations and pharmaceutical companies were informed that physical methods of submitting mandatory forms prescribed under Schedule II of Drug (Prices Control) Order 2013(DPCO,2013) shall not be accepted with effect from 1st September 2016 and all the requisite forms are to be filed mandatorily through IPDMS.

Further, notice of even no. dated 12.01.2017 was issued to pharmaceutical companies mentioning that NPPA had issued various price notifications during March-October 2016 and that many pharmaceutical companies had wilfully and knowingly not submitted the requisite and mandatory forms as required in IPDMS. All the pharmaceutical companies were also instructed vide notice dated 12.01.2017 to register themselves in IPDMS and to file all mandatory forms as required under DPCO, 2013 by 21.1.2017 positively through IPDMS, failing which appropriate action against companies shall be initiated under the provisions of Essential Commodities Act, 1955 read with DPCO, 2013.

In spite of various notices to pharmaceutical companies / associations, it is seen that companies are still sending physical forms and enclosing copies of physically filed Form-II /III / V in this office as supporting documents with reference to their various submissions. NPPA in its 40th meeting held on 23.1.2017 took a serious note on the issue and gave following directions :

- The requisite forms (viz, Form-II /III /V) filed through Integrated Pharmaceutical Database Management System (IPDMS) will only be considered. The companies may submit only the IPDMS system-generated forms in support of their submissions.
- Submission of Forms II/ III/ V in physical format will not be taken as compliance of provisions under DPCO 2013.

The Authority also directed that unless information is submitted online through IPDMS for all products/formulations, NPPA would not consider the following applications/ representations from pharmaceutical companies as complete and subject to consideration:

- i. Representations against draft proposed calculation sheets (prior to notification) of ceiling price.**
- ii. Form-I applications for retail price fixation of new drugs under para 2(u) of DPCO, 2013.**
- iii. Form-IV applications for discontinuation of scheduled formulations.**
- iv. Forms filed through IPDMS by companies subsequent to issue of Preliminary Notices/ Show Cause Notices/Demand Notices by this office in cases of overpricing.**

Pharmaceutical companies applying for (i), (ii) and (iii) above may submit a certificate to the effect that they have filed all the requisite forms for all its formulations, through IPDMS.

Compliance / non-compliance of various provisions under DPCO, 2013 will be assessed by NPPA only through IPDMS and computation of overpricing liability will be done on the basis of information available in market database referred by NPPA, if requisite forms are not filed by companies through IPDMS.

Many companies have not yet registered on IPDMS and the status list of all such companies is already uploaded on NPPA's website. List of products/formulations of all pharmaceutical companies as per market data provided by AIOCD Pharmatrac is attached herewith. Many companies have registered in IPDMS, but have not submitted the required forms for all their products. Few of these companies, to whom Show Cause Notices were issued have informed that they have discontinued many products in the list. In this regard it is stated that these companies should submit the list of such products with the proof of discontinuation, along with the reference of permission, if any, taken from NPPA for such discontinuation, and deletion from this list can be done only with sufficient evidence as stated.

The pharmaceutical companies are again directed to file all the requisite forms under DPCO,2013 at prescribed intervals, through IPDMS. The industry associations are also requested to sensitize their members on this matter urgently.

This O.M will take immediate effect.

Yours faithfully



(Roshni Sohni)

Director

To,

All Industry Associations / All Pharmaceutical Companies

Copy to : PPS to Secretary, DoP (For kind info.)
State Drugs Controllers, All States/UTs