

20(1)/2014/Div-III/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority
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5th/3th Floor
YMCA Culture Centre Building
1, Jai Singh Road, N. Delhi-110001
Date: 10.06.2016

Notice

This has reference to the activities regarding submission of information through Integrated Pharmaceutical Database Management System (IPDMS), details of which are as follows:

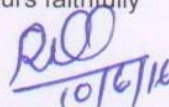
1. The Departments of Pharmaceuticals and the NPPA have taken initiative to make online submission of data mandatory for all the pharmaceutical manufacturing / marketing companies under DPCO, 2013 in the Integrated Pharmaceutical Database Management System (IPDMS). The IPDMS is also referred as Pharma Data bank.
2. Notice for online registration under DPCO, 2013 was issued on 18.09.2014 directing all pharmaceutical manufacturing/marketing companies to register themselves online under IPDMS before 31.10.2014.
3. The timeline was extended up to 30.11.2014 and further extended up to 31.12.2014 on the request of the industry.
4. Meetings were held on 20.10.2014, 10.11.2014 and 05.12.2014 for improvement and remedial action in respect of difficulties if any, experienced by the companies were properly addressed wherever required.
5. The final notice was issued vide letter dated 01.05.2015, directing all pharma companies to register on IPDMS immediately.
6. Notice for online submission of data in Form II, III, V as prescribed under second Schedule of the Drugs (Price Control) Order, 2013 (DPCO, 2013) was notified on 04.06.2015.
7. On 25.06.2015, the Hon'ble Union Minister of Chemicals and Fertilizers Shri Ananth Kumar formally launched IPDMS. The same was given widespread publicity through Press Information Bureau.
8. Vide order S.O No. 1910(E) dated **13.07.2015**, online submission of data was mandatory in terms of paragraph 9 (2) of the DPCO, 2013. A meeting was held with industry associations at Mohali on **19.08.2015** and at Mumbai on **27.10.2015**.
9. As per the notice issued on **16.11.2015** all the Pharma manufacturing / marketing companies were again requested to register themselves in IPDMS and file all the forms as required under the DPCO, 2013 on or before 15.12.2015.

10. Further, a notice was issued on **21.12.2015** to all the Pharma manufacturing / marketing companies and were given time up to **15.01.2016** to submit the requisite information.
11. Companies sought more time as there is large volume of data to be entered. Keeping in view the request of various stakeholders, the last date to file all the forms as required by the above mentioned notice was further extended to 15th February 2016 via notice dated **18.01.2016**.
12. The problems of the industry were again addressed in the meeting held at New Delhi with representatives of Indian Drug Manufacturers Association, Organization of Pharmaceutical Producers of India, Confederation of Indian Pharmaceutical Industry, Federation of Indian Chambers of Commerce and Industry, Indian Pharmaceutical Association and Association of Chambers of Commerce, etc. on 11.08.2015. Further meeting was held with industry associations at Mumbai on 27.10.2015.
13. The software of IPDMS was designed, developed and fine tuned after detailed and extensive consultation with the industry. However, despite all efforts by the Government/ National Pharmaceutical Pricing Authority, many of the companies have neither registered nor filed mandatory forms/ returns as per above said orders.
14. The IPDMS when fully operationalised will be a useful tool for collection of data and information and for monitoring and analysis of data for the industry, the consumer and the regulator, and from which data on production, import and pricing of scheduled and non scheduled formulations can be accessed, analyzed and reports generated.
15. Pharmaceutical companies are legally bound to report information through IPDMS under the provisions of DPCO, 2013 issued under section 3 of Essential Commodities Act, 1955 (EC Act, 1955).
16. Non submission of return/ information through IPDMS tantamount to violation of the provisions of DPCO, 2013 read with EC Act, 1955.
17. In view thereof, the companies were given a final opportunity to register themselves in IPDMS vide notices issued on **16.11.2015** directing all the Pharmaceutical manufacturing / marketing companies to register themselves in IPDMS and file all the forms as required under the DPCO, 2013 on or before 15.12.2015. The deadline was extended **15th Jan 2016** with further extension up to **15th Feb 2016** and finally up to **31st Mar 2016**.
18. Even after expiry of two months of the extended period for furnishing information under IPDMS, It is seen that there is a significant gap between the number of products registered under IPDMS and returns filed under Form II, III, and V and the frequency of filing as required under DPCO 2013. NPPA has taken a serious view about the willful violation of DPCO, 2013, by the company. Form II is to be submitted for revised prices for scheduled formulations. Form V is to be filed for all formulations whether scheduled or non-scheduled under IPDMS after registration so that information under IPDMS for PTR and MRP can be incorporated initially.

Subsequent changes in price are also to be filed and submitted through IPDMS as and when the change occurs.

19. NPPA has issued many price notifications, especially during March-June 2016. But many pharma companies have not submitted the forms as required under DPCO, 2013 in IPDMS.
20. In this regard, NPPA is now constrained to issue show cause notices to individual companies for not having registered their pharmaceutical products under IPDMS and for not having filed the mandatory returns in Form II, III and V through IPDMS. NPPA shall also be constrained to take necessary legal action against the companies including the exercise of its powers under Para 29, Para 30 of DPCO, 2013 including the prosecution under E.C. Act under unavoidable circumstances. Industry associations are requested to sensitize their members on this compliance urgently.

Yours faithfully



(Roshni Sohni)
Director (M&E)

To,

All Industry Associations/ All Pharmaceutical Companies

C.C to PPS to Secretary DOP (for info only)