

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, New Delhi-110001
Date: 01.05.2017

Notice


This has reference to submission of information through Integrated Pharmaceutical Database Management System (IPDMS) or Pharma Data Bank. In this connection, it is stated as under the provisions of the DPCO, 2013:

1. Government have taken initiative to make online submission of data mandatory for all the pharmaceutical manufacturing / marketing companies under the DPCO, 2013 in the Integrated Pharmaceutical Database Management System (IPDMS). The IPDMS is also referred to as Pharma Data bank.
2. Notice for online registration under the 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. Another 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 (Prices Control) Order, 2013 (DPCO, 2013), was issued on **04.06.2015**.
7. On **25.06.2015**, IPDMS was launched formally. The same was given wide publicity through Press Information Bureau.
8. Vide order S.O No. 1910(E) dated **13.07.2015**, online submission of data was made mandatory in terms of paragraph 9 (2) of the DPCO, 2013.
9. The problems of the industry were addressed in the meeting held on 11.08.2015 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.

10. A meeting was held with industry associations at Mohali on **19.08.2015** and at Mumbai on **27.10.2015**.
11. As per the notice issued on **16.11.2015** all Pharma manufacturing / marketing companies were again requested to register themselves on IPDMS and file all the forms as required under the DPCO, 2013 on or before **15.12.2015**.
12. Further, a notice was issued on **21.12.2015** to all the Pharma manufacturing / marketing companies and they were given time up to **15.01.2016** to submit the requisite information.
13. Companies sought more time as there was 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 vide notice dated **18.01.2016**.
14. 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.
15. 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.
16. Pharmaceutical companies are legally bound to report information through IPDMS under the provisions of the DPCO, 2013 issued under section 3 of Essential Commodities Act, 1955 (EC Act, 1955).
17. Non-submission of return/ information through IPDMS tantamount to violation of the provisions of the DPCO, 2013 read with EC Act, 1955.
18. In view thereof, a final opportunity was given to companies to register themselves in IPDMS and file all the forms as required under the DPCO, 2013, by **31st March 2016**.
19. It was seen that there was however 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. 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 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.
20. Taking a serious view of the willful violation of DPCO, 2013, by pharmaceutical companies, a general notice dated **10.06.2016** was also issued to all the pharmaceutical companies and uploaded on NPPA's website directing them to register all the products and for filing mandatory returns in Form II, III & V through IPDMS.

21. Further, NPPA vide its notice dated **3 August 2016** had informed Industry Associations and Pharmaceutical Companies that physical method of submitting mandatory forms prescribed under Schedule II of DPCO, 2013 shall not be accepted with effect from 1st September 2016.
22. NPPA has issued many price notifications, especially during March-October 2016. But many pharma companies have wilfully and knowingly not submitted the requisite and mandatory forms as required under DPCO, 2013 in IPDMS. A consolidated summary report of Form II and Form V is made available in IPDMS under "reports" menu for all the products registered by the companies.
23. As regards submission of information, it is stated the Hon'ble Supreme Court in its judgment pronounced on 21.10.2016 in Civil Appeal 329/2005 (UOI vs. Cipla Ltd.) has held as such:
"102. There is certainly a moral and social obligation on them to furnish information so that appropriate norms could be notified not only for their benefit but also for the benefit of the consumers. The preamble to the Essential Commodities Act, 1955 cannot be forgotten."
- Similarly, the Hon'ble Supreme Court has also upheld the importance and necessity of the submission of the information required as per the provisions of the DPCOs by the Pharma Companies to the NPPA/Govt. In Union of India v. Swiss Garnier Life Sciences reported in (2013) (8) SCC 615 and Secretary, Ministry of Chemicals and Fertilizers v. Cipla Ltd reported in (2003) 7 SCC 1, the Hon'ble Supreme Court also upheld the price fixation notification issued on the basis of available information in view of failure/refusal of manufacturers to submit requisite information.
24. Further NPPA vide its notice dated 12.01.2017 again instructed all the companies to register themselves in IPDMS and file all the mandatory forms as prescribed under DPCO, 2013, but still a huge no. of companies are still unregistered. List of such 635 companies is attached herewith (Annexure I).
- 25. All the pharmaceutical companies are directed to register themselves on IPDMS and file all mandatory forms as required under DPCO, 2013 by 10.05.2017 positively, failing which appropriate action against companies shall be initiated under the provisions of Essential Commodities Act, 1955 read with DPCO, 2013.**
26. In view of foregoing industry associations are requested to sensitize their members on this matter urgently.

Yours faithfully


(Roshni Sohni)
Director

To

All Industry Associations/ All Pharmaceutical Companies
C.C to PPS to Secretary DOP (for info)
State Drug Controllers, All States / U.T's