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National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

5th / 3rd Floor,
YMCA Cultural Centre Building,
No.1, Jai Singh Road,
New Delhi-110 001.
Date: 16.11.2015

**Sub: Integrated Pharmaceutical Database Management System
(IPDMS) - Reg.**

Notice

Whereas the Department 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 (herein after referred to as IPDMS). The IPDMS is also known as Pharma Data Bank.

Whereas notice for online registration under DPCO, 2013 was issued on 18.09.2014 directing all the Pharma manufacturing / marketing companies to register themselves online under IPDMS before 31.10.2014.

Whereas the timeline was extended up to 30.11.2014 and further extended up to 31.12.2014 on the request of the industry.

Whereas 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 pharmaceutical companies. The problems raised by the companies were properly addressed wherever required.

Whereas the final notice was issued vide letter dated 01.05.2015, directing all the companies to register on IPDMS immediately.

Whereas 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 notified on 04.06.2015.

Whereas 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.

Whereas 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.

Whereas the problems of the industry were again addressed in the meeting held at New Delhi with representatives of Indian Drug Manufacturers Association, Organisation 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.

Whereas further meeting was held with industry associations at Mumbai on 27.10.2015.

Whereas the software for 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.

Whereas 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.

Whereas 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 (i.e. EC Act 1955).

Whereas non-submission of return / information through IPDMS tantamount to violation of the provisions of DPCO, 2013 read with EC Act, 1955.

In view thereof, the companies are hereby given a final opportunity to register themselves in IPDMS and file all the forms as required by the above notice on or before 15th December 2015. The latest Form-V should also be filed by the companies online for all the formulations manufactured / marketed by them, irrespective of whether they have submitted the same in hard copy or not.

In this regard, it is emphasized that online information regarding price, production, import and sales of scheduled formulations and discontinuation of scheduled formulations provides consumers with information on different price-points facilitating informed decision making for efficacious and cost-effective treatment. Non-submission of mandatory information will therefore tantamount to harming public interest.

It is also hereby stated that failure to submit mandatory data IPDMS or mandatory returns prescribed under the Drugs (Prices Control) Order, 2013 through the IPDMS will attract penal action under the provisions of the DPCO, 2013 read with EC Act 1955. It shall be noted that, NPPA may be constrained to initiate prosecution proceedings under

the provisions of the Essential Commodities Act, 1955, against companies which fail to submit requisite and mandatory form under the DPCO 2013, through IPDMS.



(Kalyan Nag)
Adviser (Cost)