NATIONAL PHARMACEUTICAL PRICING AUTHORITY

Notice to all Manufacturers to register themselves under the Integrated Pharmaceutical Database Management System (IPDMS) for Online filing of Returns in Form II, III and V under DPCO 2013

The National Pharmaceutical Pricing Authority (NPPA), which is the implementing authority for the National Pharmaceutical Pricing Policy (NPPP), 2012 and the Drugs (Prices Control) Order (DPCO) 2013 is required to take all necessary measures for smooth and efficient implementation of the NPPP, 2012 and the DPCO, 2013.

2. Availability of reliable database is a necessary pre-requisite for carrying out the functions of price fixation & price revision in respect scheduled drugs; price fixation in respect of new drugs; monitoring the production and availability of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulations; and monitoring the prices of non-scheduled formulations.

3. With the transition from DPCO 1995, which followed cost-based mechanism for price fixation, to the DPCO 2013, which follows market-based mechanism for price fixation, reference data and source of market based data has assumed critical importance. Due to the absence of a robust in-house data base in this regard, the DPCO 2013 has permitted that initially the required market based data may be sourced from IMS Health subject to necessary validation exercise by the NPPA wherever considered necessary. It has been decided that whenever the data of IMS Health is not available or found to be inadequate, it would be supplemented by sourcing market based data from Pharma Trac, which like IMS Health is another specialised pharmaceutical market-based data source. In addition to that, data is also obtained from manufacturers directly and from several other secondary published sources.

4. The objective of the DPCO 2013 is that the Government should in due course come out with an appropriate mechanism of obtaining market-based data related to drugs. Based on this objective the NPPA in collaboration with the National Informatics Centre have developed the Ingredient Pharmaceutical Data Base Management System (IPDBMS), which is aimed at facilitating on-line submission of mandatory returns/ reports under the DPCO, 2013 by manufacturers as defined under 2(1) (n) of the DPCO, 2013, wherein "manufacturers for the purpose of this Order means any person who manufactures, imports and markets drugs for distribution or sale in the country.

5. The DPCO 2013 prescribes various forms in Schedule II to the Order, which is required to be complied with by all drug manufacturers. Out of the five forms prescribed under the DPCO, 2013, Form II (under Paragraph 16), Form III under Paragraph 21(1), and Form V (under Paragraph 2(x), 24, 25 and 26 relate to market based data in respect of production, import, sale and price to retailer (pre-revised and revised) in respect of scheduled formulations and price list in respect of both scheduled and non-scheduled formulations. The prescribed forms also seek details of sourcing of drugs in case they are not manufactured by the marketer.

6. The IPDMS is being launched on the NPPA web site with immediate effect for the purpose of registration for which a self-contained guide is also uploaded on the web site. All manufacturers are requested to register themselves and complete all registration formalities, which include inputting of company details, details of production/ procurement sources, and product list. The registration process will be kept open up to 30th October, 2014 after which the data inputting facility shall be made available to all registered users for submission of on-line reports in respect of Form II, III and V under the DPCO 2013.

7. The above mentioned reporting obligation on the manufacturers is a legal obligation, which they are required to carry out with full and correct disclosure of information in a timely manner at prescribed intervals. Any default in reporting would be deemed to be an act of contravention of the DPCO 2013 and therefore, attract penalties under the Essential Commodities Act, 1955.

8. The cooperation of all manufacturers is solicited in order to make this extremely important initiative successful for the purpose of smooth, efficient and effective implementation of the DPCO. 2013

(Injeti Srinivas)
Chairman
National Pharmaceutical Pricing Authority

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