National Pharmaceutical Pricing Authority
3rd Floor, YMCA Cultural Centre
1 Jai Singh Road
New Delhi 110001

File No. 13 (01)/ 2015/ Div-III/ NPPA

Dated: 16.02.2015

Show Cause Notice to all Manufacturers (including Importers/ Marketers) of Medical Devices that are notified as 'Drugs' under Section 3(b) (iv) of the Drugs and Cosmetics Act, 1940 who have failed to submit Price list/ Supplementary Price list in Form V of Schedule II to the Drugs (Prices Control) Order (DPCO) 2013

Whereas every manufacturer (including importer/ marketer) of a scheduled drug/ non-scheduled drug is required by law, under paragraphs 24 and 25 of the DPCO 2013 to issue a price list and supplementary price list, if any, in Form V of Schedule II to the DPCO 2013, to all dealers (including retailers), State Drug Controllers, and Government/ National Pharmaceutical Pricing Authority (NPPA) indicating the name of product, composition, pack size (inclusive of applicable duties) and maximum retail price (MRP);

And whereas the Government/ NPPA shall revise and notify revised ceiling price in respect of scheduled drugs as per wholesale price index (WPI) for preceding calendar year on or before 1st April every year;

And whereas manufacturers may increase MRP of a scheduled drug once a year in the month of April if there is an increase in WPI subject to notifying the same to the Government/ NPPA within 15 days of the revised ceiling price being notified under paragraph 16(1) of the DPCO 2013 by the NPPA, and in case of decline in WPI, there shall be a corresponding reduction in MRP; and overcharged amount, if any, shall be recoverable along with interest under the Public Demand Recovery Act if they fail to deposit the same on demand;

And whereas, similarly, the NPPA is mandated by law, under paragraph 20(1) of the DPCO 2013, to monitor the MRP of non-scheduled drugs and no manufacturer (including importer/ marketer) is allowed to increase the price beyond ten percent of MRP during preceding twelve months and where it is so done the amount so overcharged along with interest and penalty is recoverable from the manufacturer under the Public Demand Recovery Act if they fail to deposit the same on demand;

And whereas no person as per law, under paragraph 26 of the DPCO 2013, shall sell any drug to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less;

And whereas the Ministry of Health and Family Welfare, Government of India by way of the following notifications in the Gazette of India Extraordinary has specified the following medical devices as 'Drugs' under Section 3(b) (iv) of the Drugs and Cosmetics Act, 1940:-

Sl.No.	Name of the Medical Device	Notification No.	Date of Gazettte Notification
1	Disposable Hypodermic Syringes	GSR 365(E)	17.03.1989
2	Disposable Hypodermic Needles	GSR 365(E)	17.03.1989
3	Disposable Perfusion Sets	GSR 365(E)	17.03.1989
4	In-vitro Diagnostic Devices for HIV, HBsAg and HCV	GSR 601(E)	27.08.2002
5	Cardiac Stents	S.O. 1468 (E)	06.10.2005
6	Drug Eluting Stents	S.O. 1468 (E)	06.10.2005
7	Catheters	S.O. 1468 (E)	06.10.2005
8	Intra-Ocular Lenses	S.O. 1468 (E)	06.10.2005
9	I.V. Cannulae	S.O. 1468 (E)	06.10.2005
10	Bone Cements	S.O. 1468 (E)	06.10.2005
11	Heart Valves	S.O. 1468 (E)	06.10.2005
12	Scalp Vein Set	S.O. 1468 (E)	06.10.2005
13	Orthopaedic Implants	S.O. 1468 (E)	06.10.2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	06.10.2005

And whereas, further the following products are also regulated as 'Drugs' under the Drugs and Cosmetics Act, 1940 and Rules made thereunder:-

1. Blood Grouping Sera
2. Ligatures, Sutures and Staplers
3. Intra-Uterine Devices (Cu-T) (Scheduled Drug)
4. Condoms (Scheduled Drug)
5. Tubal Rings
6. Surgical Dressings
7. Umbilical Tapes
8. Blood/ Blood Component Bags

And whereas as it is seen that majority of the manufacturers (including importers and marketers) are not at all, or not regularly issuing price list/ supplementary price list in Form V of Schedule II to the DPCO 2013, to State Drug Controllers and the Government/ NPPA;

And whereas the monitoring of prices and enforcement of the relevant provisions of the DPCO with regard to prices of medical devices that are notified as 'drugs', as detailed above, is becoming difficult in the absence of information to be furnished by manufacturers (including importers and marketers) in Form V of Schedule II to the DPCO 2013;

And whereas, as a result of this lapse on the part of majority of the manufacturers (including importers and marketers) the consumer stands highly vulnerable to being overcharged, which severely undermines public interest; and

Therefore all defaulters in this regard are given a final opportunity to file within two weeks from the date of this show cause notice, necessary information with regard to medical devices notified as drugs, as may be applicable, in Form V of the DPCO 2013 to all State Drug Controllers and Government/ NPPA without fail. The current price list/ supplementary price list sent to NPPA may in addition to being sent by Speed Post/ Courier to the Director (Monitoring & Enforcement), National Pharmaceutical Pricing Authority, 5th Floor, YMCA Cultural Centre, 1, Jai Singh Road, New Delhi 110001, also be sent by email to the Chairman, NPPA at chairman.nppa@nic.in. It may be kindly noted that wherever Price to Retailer (PTR) may not be applicable, i.e., if the supply is made by the wholesaler to the hospital directly, the column related to PTR in the Form V may be left blank and in lieu of it the Price to Wholesaler (including applicable duties) may be mentioned separately as a footnote. Apart from furnishing information in Form V, the Year-on-Year increase in MRP during the past three years may also be furnished with respect to backlog period. Failure to submit the required information within the stipulated time will attract stringent action under the Essential Commodities Act, 1955.

(Injeti Srinivas)
Chairman, NPPA
16.02.2015

Copy to all State Drug Controllers for information and necessary action with a request to inform the NPPA regarding instances of non-compliance, if any

(Injeti Srinivas)
Chairman, NPPA
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