F.No.20 (8)/2013/Div-III/NPPA/Part-2
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

3rd & 5th Floor,
YMCA Culture Centre Building,
No. 1, Jai Singh Road, New Delhi-110001

Date: 12th May 2017

OFFICE MEMORANDUM

Sub: Monitoring of price movement of notified medical devices as 'Drugs' under the Drugs and Cosmetics Act, 1940 *and* the Drugs and Cosmetics Rules, 1945

The undersigned is directed to invite a reference to Para 20 of the DPCO, 2013 which provides for monitoring the prices of non scheduled formulations and to ensure that no manufacturer/ importer/ distributor is allowed to increase the MRP of a non scheduled drug more than ten percent of MRP during preceding twelve months and where the increase is beyond ten percent, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months. The manufacturers/ importer/ distributor shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty.

2. Further, Para 25 of DPCO, 2013 provides that every manufacturer /importer shall issue a price list and supplementary price list in Form V to the dealer, State Drugs Controller and the Government from time to time. As provided in Para 26 of the said Order, no person is authorised to sell any formulation 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.

3. In order to monitor the price movement of 19 medical devices out of 23 medical devices notified as drugs under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, NPPA has developed a format and the same was shared with the Medical Devices Industries and Associations for their comments/views. A series of meetings have been held with the Medical Devices Industries and Associations for the purpose of arriving at a consensus on the format which will be used for collecting Data on Medical Devices for Monitoring. However, based on the feedbacks received from the members of Medical Devices Associations, it has been found that reaching a consensus on classification may not be possible due to diverse opinions about the classifications among the medical devices industries. In view of this, a new format based on Form-V prescribed under DPCO, 2013 has been prepared and the same is enclosed as Annexure to this letter. Now each company has to give the information as per all the medical devices it is selling in the market with all necessary details.

4. All Medical Device Associations and Manufacturers/importers /marketers are hereby requested to submit data as per the prescribed format in respect of all the 19 medical

devices as per list attached irrespective of their classification. It is requested to send hard copy of the data as per the attached format to NPPA by May 31,2017. The hard copy should be duly signed by the authorized representative of the companies with office seal giving details about the name of the person, designation, mobile number and email id. Copies of the license issued by Drug Controller General of India for each medical device must be attached along with the data. A soft copy of the data and license may be sent through email to nihalpedric@nic.in

5. All manufacturers/importers of medical devices are advised to ensure compliance of provisions of DPCO, 2013 to avoid action against any violation under the provisions of DPCO, 2013 read with Essential Commodities Act, 1955.

(Kalyan Nag)
Adviser
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To:

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9 The President,
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10 All Manufactures/ Importers/ Marketers of Medical Devices

List of 19 Medical Devices for which the data is to be sent to NPPA

1. Disposable Hypodermic Syringes
2. Disposable Hypodermic Needles
3. Disposable Perfusion Sets
4. In vitro Diagnostic Devices of HIV, HBsAg and HCV
5. Catheters
6. Intra Ocular Lenses
7. I.V Cannulae
8. Bone Cements
9. Heart Valves
10. Scalp Vein Set
11. Orthopedic Implants
12. Internal Prosthetic Replacements
13. Blood Grouping Sera
14. Ligatures, Sutures and Staplers
15. Tubal Rings
16. Surgical Dressings
17. Umbilical Tapes
18. Blood/Blood Component Bags.
19. Ablation Devices

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