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

5th / 3rd Floor, YMCA Cultural Center Building,
No.1, Jai Singh Road,
New Delhi – 110 001

Date: 27th February, 2018

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

Para 20 (1) of the DPCO, 2013 provides for monitoring the Maximum Retail Prices (MRPs) of all the drugs, including the non scheduled formulations in order to ensure that no manufacturer/importer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months. As per para 20(2), the manufacturers/importer 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. In order to monitor the price movement of 19 medical devices (list annexed) out of 23 medical devices notified as drugs under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, NPPA vide its Office Memorandum dated 12th May, 2017 directed all Medical Device Manufacturers/importers /marketers / Associations to submit data as per the prescribed format in respect of all the 19 medical devices by 31st May, 2017. However, the deadline for submitting the data was extended up to 09th June, 2017 vide OM dated 01st June, 2017.

3. It has been observed that many manufacturers/ Importers have not submitted the requisite price data in prescribed format in respect of medical devices as per annexure. The manufacturers/importers who have not submitted the data so far are hereby given a last opportunity to submit the requisite data as per prescribed format in respect of Medical Devices as per Annexure by March 15, 2018. They are also required to send hard copy of the data as per attached format to NPPA by March 15, 2018. The hard copy should be duly signed by the

authorized representative of the companies with official seal giving details about the name of 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 **jp.ray89@gov.in** .

4. The DPCO, 2013 has been issued by the Central Government in exercise of the powers conferred by Section 3 of the Essential Commodities Act, 1955 and any contravention of the provision of the DPCO, 2013 is punishable in accordance with the provisions of the Essential Commodities Act, 1955.

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. Failing compliance by manufacturers/ importers, NPPA may request CDSCO to revoke the manufacturing/ import licenses issued, apart from taking legal follow up action under Para 29 & 30 of DPCO, 2013 and also under Essential Commodities Act.

Encl: As stated

Yours faithfully

Ray

(Jay Prakash Ray)
Asst. Director(M)

To

1. All Manufacturers and importers of Medical devices

2. CDSCO, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhavan, ITO, Kotla Road, New Delhi -110002,
E-mail:- dci@nic.in

Annexure

The following notified medical devices are considered as drugs under Drugs and Cosmetics Act.

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 (Hip Implants)
12. Internal Prosthetic Replacements (Dental Implants, Cochlear Implants etc.)

The following products are also regulated as 'drugs' under Drugs and Cosmetics Act.

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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Format for Collecting Data on Medical Devices for Monitoring

Name of the Medical Device:

Name of the Manufacturer/Importer with address, contact Numbers and Email id:

Product Name/ Specification as per DCGI approval	Product name/brand and other specifications relating to its material/size/application or any other specification.	Date of launch in India	Minimal Unit of Sale/ Retail pack size	Price to Stockist/ Distributor (excluding local taxes) as on April 1st, 2017	Price to Retailers/ Hospitals as applicable (Excluding local taxes) as on April, 1st 2017	Applicable VAT/ GST rate	Moving Annual turnover (MAT) * (₹ in lakhs)	MRP (year to year in the last four years) Inclusive of all Taxes. (As on April 1st)				Remarks if any
								2014	2015	2016	2017	
1	2	3	4	5	6	7	8	9	10	11	12	13

* Moving Annual Turnover in a particular month means cumulative sales value for twelve months in domestic market, where the sales value of that month is added and the corresponding sales of the same month in the previous year are substracted.

The information furnished aboave is correct and true to the best of my knowledge and belief.

Place:

Date

Name:

Designation with office seal:

Mobile No:

Email id: