What's New **12.05.2017**

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

Para 20 of the DPCO,2013 provides for Monitoring the prices of non-scheduled formulations and to ensure that no manufacturer/importer/distributor increases the maximum retail price of a non scheduled 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. The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty.

Para 25 of the DPCO,2013 provides that Every manufacturer/importer shall issue a price list and supplementary price list, if required, of the non-Scheduled formulations in Form-V to the dealers, State Drugs Controllers and the Government indicating changes, from time to time.

Para 26 of the DPCO,2013 provides that No person shall 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.

NPPA has requested all Medical Device Associations and Manufacturers/Importers/ marketers to submit data as per the prescribed format in respect of all the 19 medical devices as listed below irrespective of their classification in a hard copy 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 along with the copies of the license issued by Drug Controller General of India for each medical device.

A soft copy of the data and license may be sent through email to nihalpedric@nic.in.

NPPA has advised all Manufacturers/Importers of medical devices to ensure compliance of provisions of DPCO 2013 to avoid action against any violation under the provisions of DPCO 2013read with Essential Commodities Act, 1955.

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, HB_sAg and HCV
5. Catheters
6. Intra Ocular Lenses
7. I.V.Cannulae

8. Bone Cements
9. Heart Valves
10. Scalp Vain Sets
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 Bagas
19. Ablation Devices

Prescibed Format

In order to monitor the price movement of 19 medical devices out of 23 medical devices notified as drugs under 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 Device 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 possibledue to diverse opinions about classifications among medical devices industries.

NPPA has prepared a new format based on Form V prescribed under DPCO,2013 and each companyhas to give the information as per all the medical devices it is selling in the market with all necessary details.

Prescibed Format Collecting Data on Medical Devices for Monitoring

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