

**Ministry of Chemicals and Fertilizers**

**Medical Devices notified as Drugs w.e.f. 1st April 2020 vide Notification dated 11th February 2020 issued by Ministry of Health & Family Welfare to be governed under the provisions of Drugs (Prices Control) Order, 2013**

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Government is regulating 24 class of medical devices which have been notified/regulated as drugs under Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945. Of the above, 4 medical devices viz. (i) Cardiac Stents (ii) Drug Eluting Stents (iii) Condoms and (iv) Intra Uterine Device (Cu-T) are scheduled medical devices for which ceiling prices have been fixed. These 4 medical devices are under price control. As regard remaining non-scheduled medical devices which are notified/regulated as drugs, NPPA is currently monitoring Maximum Retail Prices (MRPs) under Para 20 of the DPCO, 2013 to ensure that no manufacturer/importers can increase the price more than ten percent in preceding twelve months.

2. The NPPA vide Notification dated 31st March, 2020 in pursuance of Notification No. SO 648(E), dated 11th February, 2020, stated that all medical devices shall be governed under the provisions of the Drugs (Prices Control) Order, 2013 (DPCO, 2013)w.e.f. 1st April 2020.
3. Thus, with effect from 1st April, 2020, all Medical Devices shall be regulated by the Government as Drugs for quality control and price monitoring. Therefore, the Maximum Retail Prices (MRPs) of all the Medical Devices would be monitored by the Government under the provisions of Para 20(1) of the DPCO, 2013 to ensure that no manufacturer/importer increases the MRP of a drug more than ten percent of MRP during preceding twelve month 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.

Further, as per Para 20(2) of the DPCO, 2013 read with the Essential Commodities Act, 1955, the manufacturer/importer shall also be liable to

deposit the overcharged amount along with interest thereon from the date of increase in price in addition to penalty.

**National Pharmaceutical Pricing Authority, Department of Pharmaceuticals,  
Ministry of Chemicals & Fertilizers, Government of India**

New delhi: 31stMarch, 2020