NPPA Regulation on Medical Devices

July 4, 2020

In the wake of COVID-19 pandemic, the Ministry of Health & Family Welfare (MoH&FW) has identified a list of critical medical equipments for the same and has requested National Pharmaceutical Pricing Authority (NPPA) to ensure availability of the same in the country.

NPPA Regulation

All the medical devices have been notified as drugs and have come under the **regulatory regime of the Drugs & Cosmetics Act, 1940 and Drugs Prices Control Order, 2013** w.e.f. 1st April 2020. A stakeholders consultation with Medical Devices Industry Associations and civil society groups was held by NPPA wherein it was stressed that **all the manufacturers/importers of critical medical equipments shall ensure sufficient availability** of the same in the country.

In order to keep check on the price rise of critical medical equipments, NPPA in exercise of powers conferred under DPCO 2013, has called for price related data from manufacturers/importers of **(i) Pulse Oximeter and (ii) Oxygen Concentrator** to ensure that prices existing as on 1st April 2020 should **not be increased more than 10% in a year.**

Chairman, NPPA also urged the industry that it is not business as usual and **not the time to profiteer in the public health emergency.** The Medical Devices Industry Associations have been urged to bring down the retail price of critical medical equipments in larger public interest in the prevailing situation as has been done by the manufacturers/importers of N-95 masks.

[The quality and safety of drugs sold in India is regulated by

the Drugs and Cosmetics Act, 1940. There was no equivalent legislation for medical devices. Prior to the notification, the Government used to regulate the quality and safety of medical devices in a piecemeal manner. There were only 37 categories of medical devices and medical equipments that had been notified as drugs under DCA].