Regulating Of Medical Devices To Be Center Stage In 2020

Concerns raised by industry

By **Gurdip Singh** On **Jan 24, 2020**

It is also clear that the draft rules to regulate all medical devices in India will take the center stage in 2020, according to a report by Nishith Desai Associates, a Mumbai headquartered legal consultancy.

Currently, there are many ambiguities with respect to how these rules would be implemented and industry representatives have raised concerns regarding some of the compliances required under the rules.

Therefore, we hope to obtain some clarity on this subject from the regulator this year. We are especially excited to see whether these rules are indeed notified in 2020 and how the implementation of these rules may play out.

The Central Drugs Standard Control Organization (CSDCO) in 2019 has been very receptive to industry feedback on taking a different approach to regulation of medical devices as compared to the approach for regulating drugs, said Nishith Desai in “Pharma and Healthcare Update” released on 23 Jan 2020.

For instance, the CDSCO set up the Medical Devices Technical Advisory Group earlier this year, issued clarifications upon the request of industry representatives and also forwarded a proposal to the Drug Testing Advisory Board (DTAB) to amend the Medical Device Rules (MDR) based on the request of industry representatives.

However, the primary concern of the medical device industry, that medical devices be regulated separately from drugs continues to remain unaddressed.

Interestingly, the NITI Aayog released the Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019 which provides for the establishment for a separate regulator for medical devices.

However, this development coincides with the CDSCO releasing a roadmap to regulate all medical devices in India. As a result, there remains some ambiguity on the future of medical device regulation in India.

While there has been some significant development in the healthcare sector (specifically in the area of regulating doctors), medical devices sector has clearly witnessed the largest number of developments in 2019.

The most significant and far-reaching of these developments is the introduction of draft rules to regulate all medical devices in the country in a phase-wise manner.

Ironically, while releasing draft rules to regulate all medical devices, the drug regulator has simultaneously postponed the regulation of 12 medical devices that were set to be regulated in 2020-21.

Over the past year, we have also observed that the drug regulator is showing a growing inclination to lend a willing ear to the industry's grievances and issue clarifications and amendments in the law to ensure that the medical device industry in India keeps developing.

The National Medical Commission Act, 2019 (NMC Act), which received Presidential assent earlier in 2019, is in the process of being implemented.

The NMC Act was enacted with the intention to repeal the Indian Medical Council Act, 1956 (IMC Act) which comprises the current regulatory framework governing medical colleges and the medical practice in India.

The NMC Act will also establish the National Medical Commission (NMC) to replace the Medical Council of India (MCI) as the apex regulatory body for the governing the medical education and profession in India. *fiinews.com*