Changes Brought In The Pharmaceutical Industry: Three Hits And No Miss By The Health Ministry

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In the month of February 2020, the Ministry of Health and Family Welfare brought in significant amendments in the regulations governing the medical sector that comprises the inclusion of the medical devices in the definition of drugs, mandating registration of medical devices and regulating the marketing of drugs in the country.

In India, the Drugs and Cosmetics Act, 1940 ("Act") regulate the standard and quality of medical devices and the rules made under this Act i.e. the Medical Devices rules, 2017 ("Rules") lay down the quality requirements to be followed by entities/persons dealing with various medical devices.

Extension of Definition of Drugs to Medical Devices

Government vide its notification dated February 11, 2020,[1] modified the definition of ''Drugs'' as provided under subclause (iv) of clause (b) of Section 3 of the Act. Amended definition of "Drugs" is inclusive enough to cover all kinds of medical devices including instruments, apparatus, appliance, material or any other article.

Prior to this notification, only 37 categories of medical devices were considered as drugs. However, post this notification, all other than the 37 already notified shall now be regulated as drugs under the Act.

Mandatory registration of Medical Devices

On February 11, 2020 amendments to the Rules were brought in vide the Medical Devices (Amendment) Rules, 2020[2] ("Amendment Rules") wherein the medical devices shall be regulated in a phase-wise manner over the period of 3.5 years. The Amendment Rules shall be applicable on Class A and Class B medical devices after a period of thirty months and on Class C and Class D medical devices after a period of forty-two months starting from February 11, 2020 (collectively referred to as "New Medical Devices").

Compliance snags

All medical devices, as already being regulated by the Rules, are required to obtain requisite permission by way of licenses from the appropriate authority for various stages such as for importing, for manufacturing, for sale, for any clinical investigation and for clinical performance evaluation. The Amendment Rules are likely to increase the burden on the manufacturer and the importer to ensure compliance with the Rules for all additional devices as and when brought under the ambit of Rules.

As per the Act, the Central Government[3] and the State Government[4] have the power to prohibit the import and manufacture of the drugs respectively, as they deem fit. Further, the Central Government also has the power to prescribe the test for determining the standard quality of a drug (which now is inclusive of medical devices). Such regulatory powers in the hand of the government shall affect the functioning of the manufacturer and importer who are suddenly scrutinized by both the Central Government and authorities under the Act. Further, the Act also empowers the Central Drugs Standard Control Authority to inspect the premises where the drugs are being manufactured, sold, or stocked or exhibited or offered for sale or distributed.[5] Amendment Rules ask for leaving the gates of the premises of the manufacturer and importer of all medical devices open at all hours for inspection, thereby, increasing the cost of vigilance.

Keeping in mind the fact that all drugs including the notified medical devices are subject to price regulation under the Drugs (Prices Control) Order, 2013, the Amendment Rules may act as a deterrent to the manufacturers of such devices who would apart from abiding by the ceiling price would also have to incur additional expenses in procurement of adequate permissions and maintaining the quality standards.

Registration Process

The Amendment Rules require the importer and the manufacturer to voluntarily register the New Medical Devices with Central Licensing Authority within 18 months from the the day such respective provisions are brought into effect. Post expiry of the voluntary period, each manufacturer and importer shall be mandated under this Amendment Rule to register their New Medical Devices. Manufacturer and importer are mandated to provide their respective registration number as generated to them by the "online system for medical devices" on the label of their medical devices. While the timeline for registration does seem inadequate to ensure compliance, the manufacturer and importer are more worried about the abstruse process of registration. The manufacturers and importers have been provided with a separate process of registration. However, the Amendment Rules fail to comprehend that certain medical devices may be partly manufactured in the country and partly imported. In such cases, it would not be possible to register them either by the manufacturer or by the importer unless the government intends to ban all partial import and manufacture of such devices.

Marketing of Drugs

The Government of India has brought in the Drugs and Cosmetics (Amendment) Rules, 2020[6] ("DCAR") which is due to come into force on March 01, 2021, wherein responsibility of the quality of drugs being sold has been extended to the marketer of such drugs as well. The government has extended the principle of *caveat venditor* in the pharmaceutical industry even more stringently wherein along with the manufacturer, the marketer who sells or distributes any drug shall also be responsible for the quality of that drug and ensuring regulatory compliance of it. A marketer under this Act and DCAR is a person who acts as an agent or in any other capacity adopts any drug manufactured by another manufacturer for marketing of such drug. However, two essential criteria of being considered as a marketer for the purpose of application of DCAR is firstly having an agreement with the manufacturer of the drug and secondly labelling or affixing his/her name on the label of the drug with a view for its sale or distribution. The DCAR has clearly prohibited the marketing of any drugs by a marketer without executing an agreement for this purpose and ensuring the right labelling on the drug in its name.

Conclusion

The medical industry is one of the sensitive industries for the government given its deep connection with public safety. The government has attempted to bring in uniformity in the medical device sector and ensured no essentials of the medical industry is below a standard quality, be it drugs or basic medical devices. This is going to be a herculean task with a tight deadline for both, the government and the manufacturer/importer. Apart from the pressure on the manufacturer/importer of registration and compliance, Central Drugs Standard Control Organisation ("CDSCO") shall be under pressure to ensure it, prior to the expiry of 18 months, provides a classification for all medical devices and ensures all registered devices are safe and efficacious for use in the country. The journey from registering to being classified and being approved as safe for use, the public may witness problems in the use and availability of certain medical devices in the market. Further, the "Online system for medical devices" portal does not seem to be in consonance with the Amendment Rules yet and would have to be updated at the earliest to avoid any hindrance to bringing the Amendment Rules into practical effect.

Fate of the above amendments clearly lies in the hand of the government by way of its implementation. While a delayed implementation of the amendments may have a grave unforeseeable impact on public health and safety, an effective and timely implementation may bring in a revolutionary change in medical history. .

- [1]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA==
- [2]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OQ==
- [3] Section 10 of the Act

- [4] Section 18 of the Act
- [5] Section 22 of the Act
- [6]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU1OA==

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