India's New Medical Device Regulations

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Substances used for *in vitro* diagnosis, medical device, mechanical contraceptives, disinfectants and insecticides and other notified devices in India are now regulated by the Medical Device Rules, 2017, which became effective from January 1, 2018.

Prior to the introduction of 2017 Rules, medical devices were not largely regulated in India, except for 10 devices notified by the Central Government to be within the ambit of definition of "devices" as defined by the Drugs and Cosmetics Act, 1940 and if a medical device producer wanted to operationalize in Indian market, all it needed was an import license. However, with the introduction of Medical Device Rules, the company interested in importing, manufacturing and selling medical devices in India must now adhere to regulatory framework laid down by the Rules, which are largely in consensus with regulation in major jurisdictions of the world and are harmonized with Global Harmonization Task Force framework (GHTF) and the international practices. The process for regulatory approvals required under the Medical Device Rules can be conveniently availed, processed and completed on online system.

This is seen as welcome move for medical device market, which is steadily having an increased annual growth rate. The Rules have grouped all medical devices into four classes based on the intended use and the potential risk that comes with their use. The classes are named as Class A as low risk, Class B as low moderate risk, Class C as moderate high risk, and Class D as high risk. Each class has different regulatory processes.

The Medical Device Rules also requires that from January 1st, 2022, medical devices that are approved for import, sale, or distribution in India must bear two different types of unique identifiers: the device identifier and the production identifier. The device identifier is a global trade item number and the production identifier is the device's serial number, lot/batch number, software version, and/or manufacturing and/or expiration date.

The Medical Device Rules provide an exemption in cases where the device does not have its predicate device on India's medical device market before it is sold or distributed in India but has been approved by the regulatory authority in the U.S., the U.K., Australia, Canada, or Japan, the device has been marketed in that country for at least 2 years, and the data of safety, performance, and pharmaco vigilance of the device complies with the standards of the Central Licensing Authority and the additional clinical investigation may not be required for that device while granting the permission.

Similarly, if a Certificate of Free Sale has already been issued for a medical device by the regulatory authority of the U.S., the European Union countries, Australia, Canada, or Japan, clinical investigation is not required for that medical device. For the medical devices that have not been approved in the aforementioned countries, different requirements have been laid down. Published safety and performance data or clinical investigation in the country of origin and a Certificate of Free Sale from the country of origin are required for all Class A and Class B devices. However, clinical investigation in India is required for all Class C and Class D devices.

As per 2017 Rules, the medical device shall conform to the standards laid down by the Bureau of Indian Standards or as may be notified by the Ministry of Health and Family Welfare from time to time. However, where no relevant standard of any medical device has been laid down, such device shall conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards. Further, the Rules make no requirement for compliance to GMP, but there is need for compliance to Quality Management System (QMS) and other rules. Therefore,

GMP certificates for Medical Devices & IVDs are not essential for regulatory approvals.

The Medical Device Rules, 2017 also prescribe that auditing of medical devices and their manufacturing sites to verify that they conform to the Quality Management System and all other applicable standards prescribed by the Bureau of Indian Standards shall be carried out by Notified Bodies, which shall be nationally accredited third-party entities licensed by the government. The Rules also provide that manufacturing sites that are not located in India may be inspected by the Central Licensing Authority or a federally appointed and registered entity. After the operationalization of the Medical Device Rules, 2017, the insecticides, which earlier use to require Finished Formulation Registration Certificates, fall under the definition of medical device and are accordingly regulated under the Medical Devices Rules. The license renewal process in India is much simplified over that of many other countries. To maintain the indefinite validity of the certificate, its holder must pay a license retention fee every five years.

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