SQUIRE PATTON BOGGS

India Notifies New Medical Devices Rules

On January 31, 2017, the Indian government notified the Medical Devices Rules 2017 under the Drugs and Cosmetics Act 1940. The rules simplify the process of introducing new medical devices to the Indian market while setting norms for ensuring high-quality devices for patient care and safety. The rules will be effective on January 1, 2018.

Distinguishing Medical Devices from Drugs

The rules distinguish drugs from medical devices and eliminate regulatory ambiguities on what constitutes a medical device. Prior to the introduction of the rules, the definition of a "drug" included medical devices, which resulted in medical device manufacturers having to comply with stringent clinical trial guidelines that were suited to pharmaceuticals.

Licenses and Standards for Manufacture and Import of Medical Devices

The rules require manufacture and import of medical devices to be licensed and approved by regulatory authorities prior to such devices being placed in the Indian market. As part of the approval process, applicants are required to have manufacturing facilities audited for quality management systems and to ensure that medical devices conform to the standards set out by the Bureau of Indian Standards. For applicants that seek to import medical devices, regulatory authorities are required to issue a license if the imported devices carry a free sale certificate in the US, European Union, Canada, Australia and Japan.

Classification of Devices

In keeping with guidance developed by the Global Harmonization Task Force, the rules classify medical devices into four risk classes. According to the risk level, medical devices are categorized as class A, B, C or D, where classes A and B are low-risk devices and classes C and D are high-risk devices. The licensing authority for class C and class D medical devices will be the central government and for class A and class B medical devices it will be the state government.

Post-approval Controls and Enforcement

The registrants of medical devices are required to notify the regulatory authorities of changes to particulars provided in relation to the registration of the medical devices, or changes that may affect the safety, quality or efficacy of a registered medical device. In addition, registrants must report any defects or adverse effects that occur in connection with the medical device. The regulatory authorities may suspend or cancel the registration of a medical device if a registrant fails to comply with the rules.

Impact

While the rules rationalize the approval process for medical devices, they ensure that a wider range of products will be classified as medical devices. As a result, a larger group of manufacturers may now find themselves being governed by the rules. Additionally, manufacturers and importers of medical devices should be prepared to (i) improve documentation for existing and new devices; (ii) improve procedures for complaint management and reporting; and (iii) be prepared for unexpected audits by regulatory authorities.

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