MEDICAL LAW UPDATE

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The Ministry of Health and Family Welfare notifies the Medical Devices Rules, 2017

The Ministry of Health and Family Welfare has notified the Medical Devices Rules, 2017 (hereinafter referred to as "the Rules" or "the new Rules") on January 31, 2017 which will come into effect from January 1, 2018. The new Rules have been framed in conformity with Global Harmonisation Task Force (GHTF) framework and conform to best international practices. The new Rules seek to remove regulatory bottlenecks to make in India, facilitate ease of doing business while ensuring availability of better medical devices for patient care and safety.

The salient features of the Rules are provided below:-

1) 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.

2) Medical devices will, under the new Rules, be classified as per GHTF practice, based on associated risks, into Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk). The manufacturers of medical devices will be required to meet risk proportionate regulatory requirements that have been specified in the Rules and are based on best international practices.

3) The industry will no longer have to follow stringent clinical trial guidelines spanning four phases, like in case of drug trials. Clinical trials norms have been relaxed.

4) As part of an initiative to improve the ease of doing business, the new Rules allow medical device manufacturers to apply for many licenses and accreditations through digital platforms. This is designed to limit the number of touch points between bureaucrats and businesspeople.

5) Further, many licenses will now remain valid until the medical device manufacturer cancels the license. This measure will allow regulators and medical device manufacturers to focus on maintaining compliant operations, rather than routine licensing requirements.

6) This interest in compliant operations will likely be further aided by another unique measure in the new Rules: the government will notify third party bodies to audit the manufacture, sale, or distribution of medical devices for compliance to the new Rules.

7) As per the Rules**,** following particulars must be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely,-

a) name of the medical device;
b) the details necessary for the user to identify the device and its use;
c) the name of manufacturer and address of manufacturing premises where the device has been manufactured;
d) the correct statement about the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package expressed in metric system;
e) the month and year of manufacture and expiry (alternately the label will bear the shelf life of the product).

However, in case of sterile devices, the date of sterilization may be given as date of manufacture of the device, and where the device is made up of stable materials such as stainless steel or titanium, and supplied non-sterile or in case of medical equipment or instruments or apparatus, the date of expiry may not be necessary.

8) 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.

Please feel free to write to us should you like additional information and/or any clarifications on the said Rules or for that matter any other aspect of Indian law.
