Ministry of Health and Family Welfare

Health Ministry Notifies Medical Devices Rules, 2017

Posted On: 02 FEB 2017 6:20PM by PIB Delhi

The Ministry of Health and Family Welfare has notified Medical Devices Rules, 2017 on 31.01.2017. The new Rules have been framed in conformity with Global Harmonisation Task Force (GHTF) framework and conform to best international practices. Only 15 categories of medical devices are, at present, regulated as drugs and to that extent, the current regulatory practices in India were not fully geared to meet the requirements of medical devices sector in the country. 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.

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.

With a view to bring in the highest degree of professionalism in regulation of medical devices, a system of 'Third Party Conformity Assessment and Certification' through Notified Bodies is envisaged. The Notified Bodies will be accredited by the National Accreditation Board for Certification Bodies (NABCB). The NABCB will, before accrediting Notified Bodies, assess their competence in terms of required human resources and other requirements. These Bodies will undertake verification and assessment of Quality Management System of Medical Device Manufacturers of Class A and Class B category and may, on as required basis, be called upon to render assistance for regulation of Class C and D medical devices also.

The Rules also seek to evolve a culture of self-compliance by manufacturers of medical devices and, accordingly, the manufacturing licences for Class A medical devices will be granted without prior audit of manufacturing site. The manufacturer will, in such a case, be required to do self-certification of compliance with the requirements and based on such certification, the licence will be issued. However, post approval audit of manufacturing site will be carried out by the Notified Bodies to check conformance with Quality Management System. Manufacture of Class A and Class B medical devices will be licenced by State Licensing Authorities concerned after Quality Management System audit by an accredited Notified Body. For all manufacturing sites, Quality Management System will need to be aligned with ISO 13485. Manufacture of Class C and Class D medical devices will be regulated by the Central Licensing Authority and, where required, assistance of experts or notified bodies will be taken. Import of all medical devices will continue to be regulated by CDSCO. A network of NABL accredited laboratories will be set up both, by the Government and by other entities, for testing medical devices.

Separate provisions for regulation of Clinical Investigation (clinical trials) of investigational medical devices (i.e. new devices) have also been made at par with international practices and, like clinical trials, these will be regulated by CDSCO. Conduct of clinical investigations will, while following the international practices, be conducted in a manner that ensures realization of the twin objectives of patient safety and welfare and discovery of new medical devices. Medical management and compensation will be provided to the subjects of clinical investigation in accordance with the predefined and objective criteria laid down by the Government.

The new rules have many other unique features. It will be for the first time that there will be no requirement of periodic renewal of licences. Accordingly, manufacturing and import licences will remain valid till these are suspended or cancelled or surrendered. Further, the entire process starting from submission of application to grant of permission/licence will be processed through online electronic platform. Timelines have been defined for most activities at the regulators end. The issuance of licences for Class A medical devices on the basis of self-certification coupled with a system of checks and balances for ensuring compliance is a departure from the inspection based regulatory regime. Risk based audit of manufacturing units will be carried out to assess conformance with standards and quality parameters. These Rules envisage creation of a robust eco-system for all stakeholders including innovators, manufacturers, providers, consumers, buyers and regulators.

The Rules will provide a conducive environment for fostering India specific innovation and improving accessibility and affordability of medical devices across the globe by leveraging comparative cost advantage of manufacturing in India. The objective, transparent and predictable regulatory framework will boost the confidence of investors and, as a consequence, the quality and range of products and services will improve and business burdens will be reduced. The new Rules will help in developing a quality standardization framework in India at par with international standards. The implementation of these Rules will provide the assurance of the best quality, safety and performance of medical devices. These Rules coupled with other measures, taken by the Government in the recent past, are expected to sharpen the competitive edge and provide incentives to firms to become more efficient, innovative, and competitive. All this will support entrepreneurship, market entry and economic growth that, in turn, would produce high-paying, high-quality jobs.

***

MV