

Industry wants ICMED certification mandatory for all medical devices marketed in India

Suja Nair Shirodkar, Wednesday, May 11, 2016, 08:00 Hrs [IST]

Experts have urged the Centre to make Indian Certification of Medical Devices Scheme (ICMED), country's first indigenously developed quality assurance system for medical devices mandatory for all medical devices marketed in the country. This was proposed in recently concluded meeting called to draft (separate) rules for medical devices with the top government officials with special focus on drafting regulatory framework for granting manufacturing licenses for medical devices.

The meeting deliberated on the modalities for going ahead with registration of medical devices manufacturers and importers on an online Gol portal. Most importantly, the meeting stressed upon the need for registration of low risk and moderate risk devices on basis of 3rd Party (CAB) certification and grant of manufacturing license to high risk device manufacturers and importers on basis of defined criteria and inspection. This according to sources will be done by CDSCO medical devices officers with a predefined competency or through 3rd party certification bodies.

Association of Indian Medical Devices Industry (AIMED) strongly advocated that ICMED certification should be made mandatory as the scheme will be able to fill big regulatory vacuum in quality certification space for medical devices in the country and will enhance the competitiveness and profitability of Indian medical device industry. Currently, there is no India-specific official quality assurance system, due to which Indian medical device manufacturers encountered loss of competitiveness to foreign companies while consumers ended up paying extra premium with no concomitant benefits, ICMED also fills a big regulatory void.

Launched in March, ICMED has two certification options, ICMED 9000 certification (an ISO 9001 plus additional requirements) for low risk medical devices and ICMED 13485 (An ISO 13485 plus additional requirements) for medium and higher risk devices. A third level, to additionally prescribe medical device specifications developed by health ministries NHSRC is still under development and would be launched later this year.

"Why not make ICMED certification mandatory, as it is aimed at enhancing patient safety, provide enhanced consumer protection along with much needed product credentials to manufacturers for instilling confidence among buyers and users. This Scheme is intended to significantly eliminate trading of sub-standard products or devices of doubtful origins, a widespread and injurious phenomenon in the Indian market. Most importantly, it will bring down the substantial time and cost-run to obtain globally accepted quality certification for Indian companies, thereby ensuring substantial savings, enhanced credibility," stressed Rajiv Nath, forum coordinator, AIMED and chairman, technical committee, QCI-AIMED.

ICMED is the first home developed international class certification scheme for the medical devices in the country. It is a joint initiative of AIMED, Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB).

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