Quality Council of India (QCI) launches Indian Certification of Medical Devices (ICMED) Plus Scheme;

An end to end quality assurance scheme for the medical devices sector in India

Posted On: 18 JUN 2021 9:29PM by PIB Delhi

The Quality Council of India (QCI), and the Association of Indian Manufacturers of Medical Devices (AiMeD) have added further features to the ICMED the Scheme that had been launched for Certification of Medical Devices in 2016. The ICMED 13485 PLUS, as the new scheme has been christened, will undertake verification of the quality, safety and efficacy of medical devices. The ICMED 13485 PLUS Scheme was launched digitally today . The Chairperson, Quality Council of India graced the occasion along with other dignitaries.

ICMED 13485 Plus has been designed to integrate the Quality Management System components and product related quality validation processes through witness testing of products with reference to the defined product standards and specifications. This is the first scheme around the world in which quality management systems along with product certification standards are integrated with regulatory requirements. This scheme will be an end to end quality assurance scheme for the medical devices sector in India.

This scheme provides the much-needed institutional mechanism for assuring the product quality and safety. It will go a long way in assisting the procurement agencies to tackle the challenges relating to the menace of counterfeit products and fake certification. This will also help in eliminating the circulation and use of sub-standard medical products or devices of doubtful origin that could prove to be serious health hazards.

Mr. K. L. Sharma, Joint Secretary (retd.), MoH&FW and Chair of the ICMED Steering Committee stated that ‘The launch of the ICMED Plus is a watershed moment. Coming, as it does, in the aftermath of the COVID-19 pandemic and at a geostrategically crucial time when the world looks beyond a few monopolistic countries, it could shepherd India to be one of the leading global manufacturers of quality medical devices’.

Dr. Jitendar Sharma, MD, AMTZ, Andhra Pradesh has commented that COVID pandemic has reiterated the need to strengthen the healthcare system in the key areas - quality assurance and patient safety. ICMED Plus, one of the recent initiatives by the QCI, help in assuring the quality in medical devices. He strongly advocated integration of work of various regulators which impinge on the quality of medical devices sector. He also stressed that while pharmaceuticals are regulated in India, it is an irony that medical devices were not regulated till 2017 which make for a sizable investment in the healthcare system.

Dr. Girdhar Gyani, SG, Association of Healthcare Providers (India) has indicated that the AHPI will encourage implementation of ICMED Plus among its members and stake holders’. He reminded the gathering that many organizations around the world have succeeded by reducing regulatory compliance through voluntary efforts. It would be in the interest of India manufacturing sector, if the DCGI starts using Certification bodies for verification of compliance in the medical devices.

Prof. Bejon Misra, Founder, Patient Safety and Access stated that yet another milestone has been created by QCI in providing value addition to medical devices to consumers. ICMED Plus launch has demonstrated a strong commitment by the medical devices manufacturers in India to not only provide medical devices products to consumers in India, but also compete globally by adopting global best practices for medical devices and enhancing the value for the end users. He also congratulated Dr. VG Somani, DCGI for not only being present but encouraging voluntary initiatives in the country.

During the launch of the schemes, Mr. Adil Zainulbhai, Chairman, QCI, commented that 'The agility of the Indian medical device manufacturers to respond effectively to the COVID pandemic encouraged the QCI to further design an integrated product quality framework to support the medical device industry during these trying times'. QCI will always respond effectively to the requirements of the Industry and make sure that such voluntary efforts improve the regulatory requirements in the country.

Dr. Ravi P. Singh, SG, QCI while welcoming the guests laid emphasis on regulatory gap which existed in India prior to 2017 and how the next 23 months of transition will continue to have regulatory gaps. To fill such gaps in the medical devices Industry, it is essential that ICMED Plus scheme, be recognized as a pre-requisite to show compliance by manufacturers under MDR-2017 and to reduce the load on regulators, ICMED Plus certification should be considered as deemed compliance for one year under MDR-2017.

Mr. Rajiv Nath, Forum Coordinator, AiMeD explained the details of the scheme and responded to all questions that were raised during multi-stakeholder committee meetings. He also said that 'The need for an Indian Quality Certification System was never felt as strongly as during the current pandemic. Access to affordable and quality medical devices can be realised through ICMED Plus certification'.

*****

YB/SS

(Release ID: 1728368)