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QCO to raise cost without covering all aspects of Patient Safety: MTaI

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Medical Technology Association of India (MTaI), which represents leading research-based medical technology companies having a large footprint in manufacturing, R&D and training in India, has said QCO Orders for medical device regulation do not fit in government's broader plan to ensure patient safety or lower cost of healthcare.

Bureau of Indian Standards (BIS) through Department of pharmaceuticals (DoP) is in the process of finalising a quality control mechanism for medical devices. It had issued a draft Quality Control Orders (QCO) for six categories of devices including blood glucose monitoring system, surgical blades, gloves, and clinical electric thermometer, seeking stakeholder views. MTaI has submitted its inputs to the government.

"The proposed Quality Control Orders has a limited scope as it does not adequately address all aspects of quality, safety and performance and only covers the product safety standard of medical devices. Conforming to the order would mean increase in compliance cost for companies that are already adhering to essential checklist requirements of CDSCO or USFDA/CE norms as well as for domestic companies looking to export, since products must first conform with BIS standards, then qualify for global ISO/IES standards and then go for CE/ USFDA for eligibility for global markets" said MTaI

The Central Drugs Standard Control Organisation (CDSCO), which is the present regulatory authority for medical devices, certifies a device for usage after a rigorous process of evaluation which includes conformity with standards, real time clinical data on efficacy, safety and performance of the device.

CDSCO has already embarked on regulating all medical devices under Drugs & Cosmetic Act as well as under theprovisions of newly introduced Medical Device Rules 2017, in a phase-wise manner. A separate vertical consisting of medical device specialists is also being set up for this purpose.

"There is duplication in what CDSCO and the Quality Control Orders seek to do which will lead to multiplicity of authorities as well as increase red tape for medical devices. While our demand for having a separate Act for regulation of medical device remain, we feel CDSCO should continue taking the lead in regulating the sector as it has the maximum expertise and

experience in governing the medical device universe," MTaI statement added.

At present only 37 medical devices are regulated. CDSCO has proposed a regulatory road map, which aims at bringing all categories of medical devices under regulation over a span of 4-5 years. As per the roadmap, all devices needs to be registered with CDSCO in the first phase of 12-18 months and then detailed due diligence of the devices will be carried out in the next 2-3 years. The proposal has already been approved by the Drug Technical Advisory Board (DTAB) which is the highest statutory decision-making body on technical matters related to Drugs in the country.