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MTaI suggests gradual rollout of public procurement guidelines

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Medical Technology Association of India (MTaI) today said the Department of Pharmaceuticals (DoP) should prepare a road map for implementation of its guidelines on public procurement in a phased manner to enable optimum patient access to advance medical devices.

“Given that India’s medical devices regulatory regime is fairly new and its implementation is nascent, any preferential provisions for public procurement applied to all segments of devices will only limit patient access and forbid several kinds of medical technology that is not locally being produced. In view of the above, we strongly urge the Department of Pharmaceuticals to carve out a road map for a phased implementation of local content requirements in order to boost local manufacturing rather than imposing local content requirements where adequate ground work for promoting localization has not taken place,” MTaI said in the press release.

The DoP had issued Draft Guidelines for Implementation of Public Procurement (Preference to Make in India) Order 2017 last month. It had asked for response from stakeholders before finalizing the guidelines. In its response, MTaI has raised concerns on the implementation of preferential market access policy in the medical devices sector.

“Make in India for medical devices is a long-drawn approach that will require calibrated steps for enhancement of local capacity of medical devices ranging from less advanced technology to most sophisticated ones. This journey also needs to be meticulously made organic with identification of sub-segments where enough incentives and local resource pool lie and can be garnered with the country-specific capabilities, failing which disruptions in availability and accessibility of life-saving medical devices will only hamper patient access and jeopardize patient safety. MTaI would like to extend all support in working with the government to create a road map for realizing the goal for Make in India in medical devices.”

At present, India has adequate manufacturing capabilities for products like syringes, cannulae, stop cocks, extension lines, blood bags, dressings, hospital furniture, and suction machines, but lacks the desired ecosystem for devices requiring complex research, design and engineering support, it added.

“If the government feels the dire need to implement such preferential policy, it should exempt devices that are used in critical health conditions where quality and safety cannot be compromised,” the association said.

“The government should also mandate requirement of 3-year market presence and verification of financial standing of bidders in order to ensure their credibility. In this, global standards of certification / quality management and product standards such as USFDA approval / CE mark / CDSCO standards should be adhered to,” it added.

It is important to note that huge costs are incurred by innovation-based companies in ensuring safety and efficacy of medical devices and therefore these costs should be considered for calculating the percentage of local content, MTaI said. “The costs are being incurred on activities like R&D, cold chain management, and maintenance in India, which generate local employment and hence should be included in calculation of local content,” the association added.

MTaI said the government should also exempt all procurements by premium research institutes, teaching institutes, tertiary hospitals of Central or State Government such as AIIMS, SGPGI, PGIMER, Sree Chitra, Army Research and Referral, Railways and Defense Departments from the purview of the order.

“Since the basic objective of these research Institutes and hospitals is to train the clinicians on use of medical devices, new technologies and do research on new therapies, preferential procurement provisions for such institutions will limit their reach to most latest and cutting edge technology for want of local content,” MTaI said.