

Centre's Public Procurement Directive to States may end up restricting competition: MTaI

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The Central Government's directive to states to prefer indigenously manufactured medical devices for public procurement may end up restricting competition rather than creating a level-playing field. The timing of the directive, issued this month, is surprising as the industry is actively discussing the means to streamline public procurement of medical devices without disturbing the demand-supply equation.

It is noteworthy that more than 70% of the demand for medical devices is being met by global companies with a large footprint of investment in manufacturing, R&D and training of healthcare workers in India. These companies operate in multiple countries and therefore adhere to international standards such as USFDA or CE that are recognised in India as well as all other nations.

The recent directive seems to have ignored these facts in asking states to prefer Indian drug regulatory certification for public procurement. In a way, the directive limits the export potential of Indian companies by allowing them to conform to Indian certification alone, because USFDA and CE are considered as the standard for procurement in the global arena.

In 2018, the Central Government had issued draft guidelines for public procurement, stipulating that medical devices should have a minimum local content of 25-50 per cent to qualify for public procurement. At that time, MTaI had said a uniform requirement of 25-50 per cent local content without considering the missing ecosystem for manufacturing sophisticated medical devices and equipment will create a risk of 'garage manufacturing' with low cost low quality Chinese knocked-down kits based assembly.

At present, India has got adequate manufacturing capabilities for products like syringes, cannulae, stop cocks, dressings, hospital furniture, etc. but lacks the desired ecosystem for devices like heart lung machines, pacemakers, complex catheters etc. The government has shown interest in developing this ecosystem and is engaging with stakeholders to understand the nurture and nudge it requires.

"The definition of local content in public procurement tenders need to be reworked. Keeping the wide spectrum of products in the medical device sector in mind as well as staying mindful of the fact that no large company makes its entire range in one destination, a company that's making any part of this wide range of products in significant volume should be considered as

domestic manufacturer. The range which a company chooses will naturally depend on the ecosystem available. Also, at present India does not have adequate manufacturing capacity of manufacturing Class C & D devices, therefore these should be exempted from PPO" says Pavan Choudary, MTal Chairman and Director General.

Choudary adds that the DoP (Department of Pharmaceuticals) is taking an inclusive approach to understand the concerns of all stakeholders in the industry but measures such as the recent directive on public procurement seems to ignore the concerns of global companies, which are the largest stakeholder at present. The DoP had recently called for a stakeholders meeting to discuss regulation of tariffs on medical devices as well as to take suggestions to increase FDI and promote manufacturing in India. FDI in medical devices had dipped to \$66 million in 2018 from \$439 million in 2016.

"It is reassuring to see that the government is taking an inclusive approach to understand the concerns of the industry. MTal has been engaging with the Department of Pharmaceuticals and the Invest India team closely to work on several corrective measures which will help bring FDI back on track and promote investments in the medical device sector. The government needs to evaluate which group brings investments and which only bring promises. This is a capital intensive and technology intensive sector which is why for the growth of this sector, the participation of western countries and countries like Japan and Korea is vital," says Choudary.