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# MTaI suggests measures to ensure MedTech growth

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**Landed cost for importer and standard cost for local manufacturer are equitable as all sales & marketing expenses, general overheads, inventory cost, training, demo, interest cost, taxes, etc. are incurred post landed cost and standard cost.**

Medical Technology Association of India (MTaI), which represents leading research-based medical technology companies with significant investments in Manufacturing in India, states that broad-brush criteria for public procurement will cause proliferation of manufacturing of low quality products in India while high quality components retain their axis abroad.

At present, India has got 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 like heart lung machines, pacemakers, complex catheters, etc.

“Unlike several other sectors, medical devices are comprised of thousands of very varied products in engineering and design complexity. A uniform 25-50% local content ask, preceding any meaningful scaling up of the missing sophisticated component ecosystem will create a risk of ‘garage manufacturing’ with low cost – low quality Chinese knocked-down kits based assembly.” **MTaI Director Mr. Probir Das** said at a press conference.

“This is compounded by the fact that India’s medical devices regulatory regime is new, the rules and their implementation is nascent, and the country’s materio-vigilance programme will take time to scale up. Any preferential provisions for public procurement at this stage must only be limited to products where India has existing manufacturing capacity. The capacity should be validated by credible third parties like PWC & KPMG,” he added.

**MTaI Chairman and Director General Mr. Pavan Choudary** said MTaI members applaud the government’s Ayushman Bharat initiative and are committed to support all initiatives that ensure growth of the sector.

“But somewhere there is an over-simplification of a complex problem. Measures like price capping and preferential market access without taking into account the complexity of the sector are going to create obstacles in realization of ‘Make in India’ goal,” Mr. Choudary said. “This year the FDI in medical devices was clearly pipped to cross USD 1 billion, thanks to this government’s move of bringing it on the automatic route. However, it has dipped to just USD 184 million. Why did the FDI lose it trajectory of growth is what the government should ask,” He added. (See attached enclosure)

Mr. Das said, “It has clearly been evidenced that the arbitrary price control mechanism has created uncertainty among global MedTech majors about India. This weakening sentiment is certainly counterproductive to Make in India. Also, the growth of the high quality, organised private hospital segment in India was on the back of the availability of globally the best/innovative products. If the same products exit India, there will certainly be a shrinkage of the organised private sector healthcare. This will have a detrimental effect on the market size, and thus on Make in India.”

**MTaI Director Mr. Sanjay Bhutani** said that trade margins should be rationalised on the basis of price to trade in case of imported products and price to distributor in case of locally manufactured products. “Different medical devices have different market adoption investment requirements (e.g. a hypodermic syringe may not have the same physician training investment needs as a trans-catheter heart valve). Therefore, different marketers require different levels of profitability that is both fair and logical. Hence, TMR should be based on Price to Trade, which takes into account investments in training, localisation R&D, government taxes and surcharges.”

“If TMR is based on landed cost in case of imports none of these intermediate costs would be accounted for and the whole ecosystem would lose money, which is detrimental for the overall health of the sector. Similarly ex-factory cost as a starting point for domestic manufacturers is prone to huge manipulation as observed by the CDSCO. If the government still chooses to base margins on cost, it should consider landed cost for imported products and standard cost for locally manufactured products to create a level-playing field for all players,” Mr. Bhutani added.

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In summary, MTaI suggests the following to achieve the objective of quality healthcare delivery in the country and simultaneously encourage Make in India for medical devices:

1. MTaI strongly believes that the visionary and powerful programme of ‘Ayushman Bharat’ should focus on the longest pending area of Indian healthcare -- ***Healthcare Access through a Healthcare Financing Model***. When compounded with value-based care and pricing, this will create a strong tailwind for Make in India, not price controls.

2. MTaI supports recommendations of The Committee on High Trade Margins, which is under the consideration of the Department of Pharmaceuticals. The report has asked for Trade Margin Rationalisation (TMR) from the level of Price to Trade or Distributor. Once implemented, this will significantly reduce MRPs and yet keep innovative, high quality products available for all sections of Indian patients.

a. TMR should be based on Price to Trade / Distributor, which takes into account investments in training, localisation R&D, government taxes and surcharges, etc.

b. If TMR is based on landed cost in case of imports or manufacturing cost in case of local manufacturing, none of these intermediate costs would be accounted for and the whole ecosystem would lose money, which is detrimental for the overall health of the sector.

c. Ex-factory cost as a starting point for domestic manufacturers is prone to huge manipulation as observed by the CDSCO. Instead of ex-factory cost, standard cost should be taken into account which makes it equitable with landed cost.

d. If margins are based on cost, it should consider landed cost for imported products and standard cost for locally manufactured products to create a level-playing field for all players.

e. Any preferential provisions for public procurement at this stage must only be limited to products where India has existing manufacturing capacity. The capacity should be validated by credible third parties like PWC & KPMG.