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MedTech Industry urges authorities to replace exclusive FDA requirement

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Domestic medical device industry has urged the Centre and States to do away with the insistence on USFDA approval in tendering process for public healthcare system and to replace it with more democratic options to eliminate discrimination against domestic manufacturers and to catalyze 'Make in India' mission.

"Insistence on a Exclusionary USFDA certification requirement is a grossly discriminatory clause as it only favours large US companies in domestic public healthcare procurement process. This insistence is a pure absurdity and has resulted in exclusion of domestic manufacturers and manufacturers from other countries from bidding and hiking up the healthcare costs," said Mr Rajiv Nath.

"No other country insists on only one certification and that also USA FDA and all major countries have their own domestic or alternate international certification e.g. Canada has CDMAS , Australia has TGA and Europe has CE. We have very competent manufacturers with European Certification or CE Mark Or it could be ISO 13485 certification from a reputed, competent and accredited Certification Body. USFDA could be an alternate option but why this insistence on only USFDA," added Mr Nath.

"This insistence of US FDA Certification by reputed Indian Government Institutions like AIIMS and PGI Chandigarh, seriously undermines the credibility of our own Regulators. It also allows dumping of outdated products in India just because they are USFDA approved and denies the patients access to latest technologies offered by Indian Manufacturers" said Mr Gurmit Singh Chugh, MD, Translumina Therapeutics, manufacturer of Drug Eluting Stents. "I have attained more respect and acceptability of our products in Europe and other developed markets due to our high quality and clinical data but are treated "second grade" in our own country just because we manufacture in India and its not USA FDA approved."

Similar sentiments are expressed by Mr Vijay Paliwal, Managing Director, Janak Healthcare a reputed manufacturer of Hospital Beds ; Mr Rajesh Patel, Head Business Operations, Meril Life, Mr Prakash Teckchandani, Mr A Manickam, Director - International Relations & CSR, Trivitron Group of Companies and host of other domestic industry representatives.

It may be known that many of Central and State run hospitals have made USFDA approval as mandatory in its tendering process for supply of medical equipments, despite the fact that there are many other equally competent certification that are used by the industry and countries around the world at large. But insistence for exclusively on USFDA has meant in-built planned bias in favour of large foreign companies as getting a USFDA is a lengthy, cumbersome and costly process and may not be needed by many manufacturers not targeting to access the USA market.

Industry had long been advocating more options of certification/approvals including our own IC MED Certification as an equivalent to CE Mark or ISO 13485 so that tendering process becomes more democratic and participatory to enable wider open competition and a lower procurement cost . But a blind insistence on USFDA had resulted in award of contract only to select players till date and by implication discouragement to local manufacturing leading to India's increasing import dependency which is now over 70 percent. Thankfully, Moh&FW has realized this lacunae and the specifications under National Health Mission were corrected last year by NHSRC (National Health System Resource Centre) to catalyze 'Make in India' mission and to make tendering process more inclusive and democratic.

However still Central Govt and State Government and Defence establishments continue to ignore these specifications and guidelines. These are voluntary specifications and as yet have not become mandatory under any Regulation.

Mr Nath has further advocated a 'Buy India Policy' in line with what many other countries including USA & China & Malaysia do to encourage domestic manufacturing.

"Many Countries have a Policy to encourage Domestic Manufacturing even USA has a Buy American Policy. Along with 'Make in India' Policy, it will be good if Indian Public Healthcare System has a 15 percent Price preferential 'Buy Indian Policy' or Preferential Market Access Policy in line with this and to counter the 17 percent subsidy of China on Export of Medical Devices," pointed out Mr Nath.

The Task Force led by Dept of Pharmaceutical recommends a Preferential Market Access Policy but ironically here Indian Medical Devices manufacturers are still grappling against a Preferential Exclusionary Buy American Policy by Indian Healthcare Institutes.