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## Exclude medical devices from the list of India-EU Free Trade Agreement (FTA) items: AiMeD

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In view of the steep growth in imports of medical devices from Europe and other countries into India, the domestic manufacturers of these devices have demanded the exclusion of medical equipment and consumables from the list of EU Free Trade Agreement (FTA) items.

Amidst the ongoing India-EU FTA talks, in a letter written to the Commerce Ministry, the Association of Indian Medical Device Industry (AiMeD) has highlighted that the imports of these items in India has grown at a staggering rate of 68% in the last four years, making India dependent on imports to the tune of 70% currently.

At a time when India's existing import duty on medical devices is already very low (0.0%-7.5%), bolstering imports further by including these medical items in the EU-FTA list would not only jeopardise the medical security of India but also prove to be highly detrimental to the domestic manufacturing industry, according to Rajiv Nath, Forum Coordinator, AiMeD.

Whenever India has signed any FTA with another country, the imports of medical devices into India have only grown. India signed the Japan-India Comprehensive Economic Partnership Agreement (JICEPA) but the imports of medical equipment from Japan has risen from Rs 1826 crore in FY20 to Rs 3085 crore in FY24, a jump of 19%. Similarly, India inked India-Singapore Comprehensive Economic Cooperation Agreement (ISCECA) but the imports from Singapore have jumped from Rs 4294 crore in FY20 to Rs 6779 crore in FY24.

Germany and Netherlands, both EU countries, are already among the top five exporters of medical devices into India. "EU has many non-tariff barriers for Indian imports into any EU nation. We need a Tit-for-Tat policy from India's side. Indian manufacturers require CE Certification to sell to EU nations which is not only an expensive affair but also leads to a lot of time wasted in getting the certification - approximately 2 years. EU nations get our factories inspected rigorously before buying from here. We need a similar policy from India where inspection of EU factories and verification of compliance to Indian Medical Device Rules (MDR) and also of Domestic Content in EU factories is done by Indian regulators," said Nath in AiMeD's letter to the Commerce Ministry.

AiMeD has also highlighted that the regulatory system for medical devices in the EU permits organisations to label themselves as a 'Legal Manufacturer' even if they are not making the product themselves. This was done to allow EU regulators to make Market Authorisation Holder to be responsible and accountable from the patient safety perspective but this facility has been abused and lead to pseudo manufacturing to thrive in EU as Country of Origin is not insisted upon on the labeling of medical devices in Europe & UK, unlike the case of USA & India, which seek labeling of 'Country of Origin' on medical items. There's a huge risk of 3rd country exports to be routed via EU to India under this legal manufacturing route whereby a marketing company can pass itself off as a legal manufacturer.

The Indian medical device manufacturing industry has been given assurance in past for UK-India FTA that 'Legal Manufacturer' labeled packages will not enjoy 'ZERO Duty' FTA benefits if the manufacturer/ exporter is not an actual manufacturer and not able to prove that he assembles and manufacture the medical device in the UK with at least 40% value addition. AiMeD has sought to know how this assurance will be enforced.

"When there is inspection is done by Bureau of Indian Standards (BIS) for items like steel and plastics when imports are involved, then why not make it mandatory for factories if Medical Devices in foreign countries to be inspected by BIS and CDSCO in case of medical devices which are far more crucial than simple plastic items," said Nath.

China, Singapore, Malaysia, Japan, South Korea, Thailand, Argentina, Vietnam, Indonesia, Philippines, New Zealand, etc. have gained much more than India after FTAs were signed by Indians with them.