Medical gear makers up in arms against zero-duty imports under EU FTA

SOHINI DAS
Mumbai, 23 September

The medical devices lobby has written to the Department of Pharmaceuticals (DoP), opposing the import of medical devices at zero duty under the EU-India FTA. The trade talks are underway.

At the moment, India is 70 per cent import-dependent and Germany and the Netherlands are among the top five countries from where the country imports. The main reason for the opposition from the local industry is that, they claim, the EU regulatory system permits organizations to label themselves as legal manufacturers even if they are not making the product themselves, which has led to "pseudo manufacturing" in the EU as country of origin is not listed on labelling of med-devices in the EU and the UK (unlike in the US and India). In a letter, dated September 21, to Arunish Chawla, pharma secretary, and Nitin Yadav, joint secretary, the Department of Commerce (medical devices), and others, Rajiv Nath, forum coordinator, Association of Indian Medical Device Industry (AiMeD) said that they "strongly" oppose the zero-duty import proposal under the EU-India FTA, for which talks are underway.

AiMeD is an umbrella organisation representing the domestic medical devices-makers.

From countries like Germany and the Netherlands, India's imports of medical devices have grown over the years. From ₹4,742 crore in FY20, imports from Germany grew to ₹7,490 crore in FY24, and from ₹2,329 crore in FY20, imports from the Netherlands rose to ₹3,815 crore in FY24. Nath claimed that the regulatory system for medical devices in the EU has a provision of permitting organizations to label themselves as "legal manufacturer" even if they are not making the product themselves.

"This was done to allow EU regulators to make market authorised holder to be responsible & accountable from the patient-safety perspective, but this facility has been abused and it led to pseudo manufacturing to thrive in the EU as 'country of origin' is not insisted upon on the labelling of medical devices in Europe and the UK, unlike the case of the US and India, which seek labelling of country of origin on unit of sale," he mentioned in the letter. Therefore, legal manufacturers should be kept out of the FTA, the AiMeD claimed.

"We have been given assurance in the past for UK-India FTA that 'legal manufacturer' labelled packages will not enjoy zero-duty FTA benefits if the manufacturer or exporter is not an actual manufacturer and not able to prove that he assembles and manufactures the medical device in the UK with at least 40 per cent value addition," the letter said.

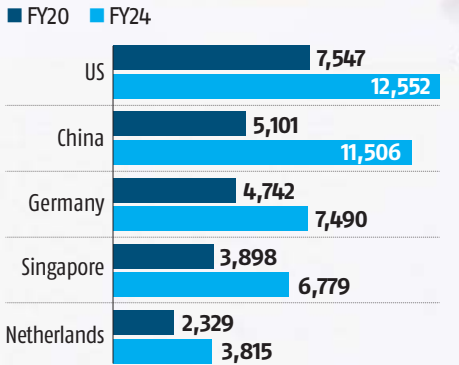
The medical devices lobby here felt that medical devices made in China and Taiwan would end up landing in India through this loophole under the EU-India FTA.

Nath further claimed that India needs to focus on Mutual Recognition Agreement of Regulatory Approval, or QMS (Quality Management System) Certification like Indian Certification for Medical Devices (ICMED).

More on business-standard.com

IMPORT DYNAMICS

Countries from where India imports medical devices (₹cr)



India's medical device imports (₹cr)

	FY20	FY24
Consumables	4,943	7,430
Disposables	2,716	4,090
Electronics and equipment	26,075	44,132
Implants	2,940	5,087
IVD reagent	3,761	6,477

Source: AiMeD