Cuddle for Imports, Hurdles for Exports

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At a time when every country on this planet is pushing and facilitating their exports and encouraging domestic industry, Ministry of Health and Family Welfare's strange reluctance to issue 'Free Sale Certificate' to domestically manufactured medical devices for the purpose of exports despite competent certifications being held by bonafide exporters and recommendations by Ministry of Commerce and DGFT has created a major roadblock for the Indian exports and domestic medical device industry.

MoH&FW's stance and attitude is even more perplexing and inexplicable when imports are being given a free run even as PM Modi is un relentlessly pursuing the 'Make in India' dream to encourage domestic manufacturing and increasing India's exports of hi-value products.

"It is very unfortunate that our own MoH&FW has become India's biggest non-tariff barrier for Indian exports while laying zero non-tariff barrier for market access by importers and foreign manufacturers," lamented Mr Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Manufacturers.

"Lack of availability of Free Sales Certification has resulted in lost opportunity and lost of face as manufacturers are losing their face after evoking the interest and expectations of the overseas distributors wishing to procure Indian medical devices. This is embarrassing .The myopic stance of MoH&FW is all the more perplexing at a time when PM Modi in unrelentlessely pursuing 'Make in India' dream and trying to galvanize Indian exports of high value products," added Rajiv Nath.

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It may be known that to export medical devices manufacturers need to take registration with foreign countries and seek approval from their regulatory authorities for permitting import of medical devices into that Country. The regulatory authorities usually ask for a 'Free Sales Certificate' from the country of origin. The intent being that if a product is freely sold within the country of origin and safe for the people of that country, then it would also be acceptable for the importing country.

Typically, medical devices regulatory authorities desire this Free Sales Certificate to be issued by Ministry of Health or the Regulatory Authority of the exporting country.

However, due to legacy regulatory and policy overhang, to which AiMeD has been constantly been drawing attention to, medical devices are categorized as drugs and the Free Sale Certificate in India is issued only for the 15 medical devices notified as Drugs by the State Drug Authorities with a validity of two Years.

But for the rest of thousands of medical devices which are not yet covered in Regulations , the Free Sales Certificate is currently issued by DGFT (Directorate General of Foreign Trade) as in the case of consumer goods and engineering items. Many countries especially China, South & Central America are not satisfied with the certification issued by DGFT and insist on certification by MoH if it's a medical device. In the absence of such certification, they do not permit registration to enable the Indian Manufacturers to enter and sell in their domestic market.

A proposal to overcome this issue (considering absence of independent Medical Device Regulation) was made to MoH&FW / CDSCO to endorse the Certificate of DGFT which may satisfy the importing countries registration approving authorities on the basis of submission of an IS/ISO: 13485 certification by the manufacturer. In a meeting taken by the Jt Secy, MOH on 05.12.2015, it was mooted by AiMeD to MoH&FW to create an online registration for all manufacturers of medical devices (even if not regulated) which will enable Government of India to have a registry of all Indian manufacturers of medical devices whether regulated or not to enable MoH to have a dialogue with the manufacturers which is necessary for capacity building considering the inevitable regulatory framework, sooner or later.

Based on the registration in database and on request of the manufacturers and exporters the Free Sales Certificate of DGFT could be endorsed by MoH at least for those manufacturers who have an IS / ISO 13485 Certification. But till date, MoH &FW/DGHS/CDSCO haves shown remarkable reluctance to endorse this simple and workable idea.

India exports $1.2 Billion of Medical Devices and Imports $3.5 billion of medical devices.

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