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AiMeD & BCIL address comprehensive regulation of Medical Devices

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AiMeD & BCIL Conference supported by DoP asks for ending confusion by regulating all medical devices by an incredible regulatory framework

First joint conference "Comprehensive Regulation of Medical Devices" was organized by Association of Indian Medical Device Industry (AiMeD) & Biotech Consortium India Limited (BCIL) supported by Department of Pharmaceuticals (DoP) was recently organized in New Delhi.

1st Govt. & Indian Manufacturers Conference on Comprehensive Regulation of Medical Devices Calls for a Separate Medical Device Patient Safety Law Separate from Drugs

Rajiv Nath, Forum Coordinator, AiMeD & Dr. Purnima Sharma, MD, BCIL along with other dignitaries of the Government, Industry, Academia & Indian Medical Device Industry Associations were part of this conference.

Dr. Vinod Paul, Member, NITI Aayog during his inaugural emphasized on the need for integrated efforts to promote innovations and development of indigenous medical devices for having a vibrant domestic medical devices industry for the society. He assured full support of NITI Aayog to ensure that the intent of domestic industry to provide access to safe, effective and quality medical device to the patients are kept in all Govt. policies.

Dr. V.G Somani, DCGI, CDSCO said "Regulations need to encourage – Make in India & Made in India. To improve Brand value, credibility and acceptance of Made in India Medical devices, all Medical Devices need to be regulated at one go and not item by item."

Dr. Vinod Paul & Dr. V.G Somani allayed apprehensions of the medical device industry and assured to regulate all medical devices in a phased manner rather than item by item in a stipulated time frame starting with voluntary registration for manufacturers & importers and voluntary compliance to Medical Devices rules while an eco-system is built up with infrastructure along with adequate team of competent officers.

The opening session threw light on the Need for Comprehensive Regulation of Medical Devices in India. Rajiv Nath pointed out the need to regulate all Medical Devices under a Patients' Safety Medical Devices Law to protect patients and aid responsible manufacturing.

Gurmit Chugh, Jt. Coordinator (AiMeD) said, "The Manufacturers have been confused with informally choosing of Products and notifying them as Drugs. They seek a predictable and comprehensive regulatory framework that allows for adequate

transition and is predictable. Only then will investments speed up as they get discouraged to be regulated as Drugs."

The first technical session on Comprehensive Regulation of Medical Devices highlighted the current state of the beleaguered Indian Medical Devices domestic industry. The urgent need for the Government to expedite steps to end the 80-90% import dependence forced upon us and an ever increasing import bill of over Rs 38,837 Crore, expedite steps for patients' protection, stronger quality & Safety regulations, price controls to make medical devices and quality treatment accessible and affordable and ethical indigenous manufacturing viable .

MSME dominated medical domestic manufacturing took a hit post GST as imports become 11% cheaper and shoot up 24%. Imports of medical devices are up by record 24 % at 7450 Cr ? from ?31386 Cr in 2017-2018 to 38,837 Cr ? in 2018-2019.

GST on medical devices is in favour of imports and is detrimental to Make in India. MSME sector has been worst hit with huge job losses

Voicing the concerns of Domestic Medical Devices Industry, Rajiv Nath said "Medical Devices are not Drugs though both are medical products but differ in approach in marketing. We have been specifically seeking Trade Margin Caps on Devices notified as Drugs but from 1st point of sale in Supply Chain, which as per us is when 1st sale takes place and GST is applied 1st time e.g. when goods enter country (on the CIF import landed price for imported and Ex-factory price for Indian). This will maintain parity between Indian & overseas manufacturers. GoI needs to take policy decisions to give at least a level playing field, if not a strategic advantage to domestic manufacturers while safeguarding consumers."

Priority issues raised during the conference are:

- Need to regulate all Medical Devices under a Patients' Safety Medical Devices Law to protect patients and aid responsible manufacturing
- Need to protect Consumers from exploitatively high MRP in Medical Devices by rationalized price controls and aid ethical marketing
- Need to encourage employment and Make in India of Medical Devices and address 80-90% import dependency by a predictive nominal tariff protection policy as done for mobile phones to ensure a vibrant domestic industry & competitiveness and price stability driven by competing domestic players
- Need to incentivize Quality in Healthcare Products in public healthcare procurements by preferential pricing for Q1 e.g. ICMED (QCI's Indian Certification for Medical Devices) instead of L1 (lowest price) to ensure patients access acceptable quality
- must ensure importers of Medical Devices are not kept out of the move to cap Trade Margins