Govt. to Create a Separate Ministry for Medical Devices: Union Minister Mr. Ananth Kumar

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The Indian Medical Device Industry is enthused to learn of huge opportunities coming up through the Government’s envisaged programme ‘Modicare’ aimed at providing Universal Healthcare Coverage to 500 million people. Inaugurating the 3rd Global Conference on Pharma Industry and Medical Devices today at Bengaluru, Union Minister for Chemicals & Fertilizers, Mr. Ananth Kumar reiterated that the government’s flagship programme, “Modicare” will unleash huge growth opportunities and challenges for the Indian pharma sector through explosive demand.

“We appreciate that the government is thinking of creating a separate Ministry of Pharmaceuticals & Medical Devices sector to serve the sector in a more integrated manner. This has been long overdue and we have been demanding this for a long time to focus on issues and regulations pertaining to our sector judiciously and expeditiously,” said Mr. Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AiMed).

“We are enthused to hear the Honourable Minister’s announcements. Yes, there is a huge growth opportunity but, if this growth is fuelled and demand met by imports to the order of 70-90%, it will be a shame. We await a coherent Medical Device policy to enable manufacturing in India”, added Mr. Nath.

Mr. Nath also said that AiMed would be tabling a Strategic Road Map for Promoting Indigenous manufacturing of Medical Devices to the Government, based on following key Strategic ‘Make In India’ enablers, which include:

(a) Predictable tariff strategy for investors: We have been asking for a Phased Manufacturing Plan and predictable tariff structure linked with manufacturing capacity and international competitive capabilities as evidenced by exports performance. This would include:

Basic customs duty (BCD) on Medical Devices having an export turnover of more than:

- Rs. 100 crore (in any one of last three financial years), should be at least 15 percent, (WTO bound rate is 40 percent).
- Rs. 10 crores to Rs. 100 crore, BCD should be 7.5 percent, and
• For less than Rs. 5 crores, BCD could be at 5 percent or higher instead of NIL.

The linkage of growing exports is to demonstrate growing capability and international competitiveness of these Devices to silence critics or India will forever remain import dependent on unaffordable Medical Devices, Mr. Nath added.

(b) MOH & FW to expedite a Buy Indian Policy of Preferential Pricing for Indian Medical Device and have weightage for ICMED / ISO Certification and Design India Certification for promoting quality and indigenous development.

(c) Make IS / ISO 13485 Standard mandatory for Medical Devices under BIS Act as an interim Regulatory Measure for Patient Safety till we get a Medical Device Law.

(d) Till we have Regulations Enforce Restrictions on Refurbished Medical Equipment for over 3 years for ensuring Patient Safety.

(e) Department of Pharmaceuticals should accelerate trade margin capping proposal in the range of 50-100 percent, depending on the value of the Devices or ask Dept. of Revenue to introduce a Tax Based Disincentive to discourage Importer / Manufacturer from labelling High MRP.

The inaugural session witnessed the launch of two major initiatives for medical device industry – the world’s first unique e-Auction Tech Transfer Portal exclusively dedicated for Medical Technologies and world’s first Med Tech Enterprise Resource Planning (ERP) software for Medical Device Manufacturers which is free and developed on open source. These initiatives will showcase to the world that the ‘Make in India’ dream is coming true to reduce the healthcare cost in the country and world over, the Minister said.

We welcome these new initiatives. But, these are a small part of the whole well defined, integrated, conducive policy and regulatory framework that we are looking forward to, without which the ‘Make in India’ dream will remain on paper, Mr. Nath said.

Medical devices can be equally if not more as a critical part of overall healthcare cost as medicines and diagnostics. If the government had focused on giving a major boost to medical device manufacturing in the country and also ensured a robust MRP regime, then it would have served many purposes with one shot – i.e. (a) lower the overall healthcare cost and (b) lead to a sharp reduction on import dependency.

The additional benefit would have been quality job creation within the country.