

New Medical Device Rules to be notified at the earliest

New Delhi, 12 July 2016: The Prime Minister's Office (PMO) convened a meeting on promoting Make in India in the Medical devices sector in India on Monday. Office bearers of the top industry associations in medical device industry including FICCI, Association of Indian Medical Device Manufacturers, CII and Medical Technology Association of India presented to the PMO a series of issues relating to Ease of doing Business, regulation, fiscal imperatives, scaling manufacturing, promoting exports and encouraging Innovations, to make India an attractive destination for investment in Medical device sector.

A detailed discussion on streamlining regulatory issues was held on which the government assured an early action. The uniqueness of medical devices, as different from pharmaceuticals was acknowledged and the participating associations were informed that the new Medical Device Rules would be notified at the earliest.

The Ministry of Health & Family Welfare also announced that the new Medical Device Act would be tabled in the forthcoming winter session of the Parliament. No new medical devices would be notified till this new Act is passed.

Industry has appreciated the proactive, progressive approach of the Government and welcomed the engagement of consultation with the industry.

Mr. Probir Das, Chairman FICCI Medical Device Forum said "an attractive fiscal package coupled with the streamlining of regulation will help attract global investment and greenfield & brownfield expansion in India".

"We thank the Government for this opportunity to engage and enable quick resolution of Regulatory issues. This will certainly help the industry", added Mr. Pavan Choudary, Medical Technology Association of India.

"An added focus on promoting exports will add value. On the other hand, continued investment in healthcare will help expand the market of medical devices increasing India's attractiveness as a manufacturing destination", said Mr. Himanshu Baid, Chairman - CII Medical Technology Division.

The meeting was chaired by Principal Secretary to the Prime Minister and held in presence of senior officials from PMO, NITI Ayog, Ministry of Health & Family Welfare, and Department of Pharmaceuticals. Department of Revenue.

Medical Devices sector has emerged as a focus sector in Make in India aspirations of the country. It has a tremendous potential to grow with a huge demographic dividend on demand side and India's R&D innovation capabilities on the supply side. Despite the immense opportunity it remains shackled in an unpredictable regulatory environment, which is expected to change very soon and is also impeded by concerns around pharma style price control and an abysmally low market penetration, which shall need a gradual increase in public spend and awareness campaigns.

FICCI MEDIA DIVISION