

## 100 Percent FDI in medical devices: A step in the right direction?

08 July 2015 | Features

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In a bid to boost the indigenous manufacturing of medical devices in the country, the union cabinet has approved the amendments in the existing Foreign Direct Investment (FDI) policy to allow 100 percent foreign investments into medical devices.

According to Mr Sanjay Banerjee, chair - AdvaMed India Working Group, "We believe that the decision is a step in the right direction and will enable the medical device industry to significantly increase investment, innovation and manufacturing in the long run. This decision will also act as a catalyst for the development of indigenous MedTech industry and will also have spillover effects in several ancillary industries. "

He added, "We are encouraged by the government's efforts to delineate medical devices from drugs through the FDI policy. In India, the medical devices sector currently constitutes only 6percent of total healthcare spending, and its ability to address the country's growing disease (particularly non-communicable disease) burden has historically been limited by the fact that medical devices are treated as drugs. The recognition of the sector as a distinct and crucial pillar of the medical device industry in the policymaker's mind is the first step towards creating a conducive environment."

While FDI for green-field projects is under automatic route, brown-field projects are placed under government route.

"Permitting 100 percent FDI in brownfield projects will not only kill the existing domestic manufacturers by making them easy target for takeovers but will also defeat the very purpose of reducing import dependency or encouraging manufacturing of medical devices within the country. By permitting 100 percent FDI in brownfield projects, we are only encouraging cherry-picking by foreign companies. Our reasons are not aimed at scaremongering but based on past experience and ground realities," said Mr Rajiv Nath, forum coordinator, AIMED.

He further added that even for Greenfield projects, there has to be a condition that at least 60 percent of overall goods being sold by a foreign company in India have to be manufactured within the country.

"Unless, this is done, I firmly believe that manufacturing of medical devices within the country will never take off and India will continue to be heavily import dependent," he said.

American Chamber of Commerce (AMCHAM) in India has said that 100 percent foreign direct investment (FDI) in the medical devices sector will attract US firms to invest and manufacture in India.

Mr Banerjee agreed, "Yes, we believe that this move will spur investment, innovation and manufacturing in the long run. Our member companies have a long-term commitment to India and actively contribute to improving public health and strengthening the health system in India. These companies recognize that in order to be successful in India, they must build lasting partnerships, undertake capacity-building initiatives, and develop programs outside of their traditional business models to address India's health and health care delivery challenges. They are eager to invest in India's economy, and bring with them technical expertise, investment tools, and research and development capabilities and believe that the medical device industry in India is poised for spectacular growth and innovation if a supportive policy environment can be established and maintained in India."

However, well that might seem like a good way to increase investment, it is not really a question of capital, to boost the sector, opined Mr Nath, "Question is not really of 'investment' but of creating conducive healthy environment for domestic manufacturing to flourish. One cannot have a decade of myopic and derailing policy regime and investment climate leading to near demise of Indian manufacturers and then top it up with another myopic demoralizing policy - just to show that we are doing something. FDI is not panacea for all ills plaguing the medical device industry. This kind of announcement - we are permitting 100 per cent FDI - is the easiest, almost lazy way out to grab some headlines. But it leaves the problem where it was. You want the manufacturing to flourish here, then one needs to sit with the industry captains, listen to their problems and take corrective measures. One needs to learn from countries like China or US as to how they protect and encourage their domestic companies. Investments may come but it will be for cherry picking and will not really help achieve PM Modi's objective of 'Make in India'.

#### **A right policy and regulatory framework is need of the hour.**

"At this stage though, the 100 percent FDI announcement is only an indication of the government's eagerness to promote the medical device industry as an essential segment of the healthcare industry. In order for intent to translate into concrete action, other critical factors, such as a predictable, globally harmonized regulatory framework, availability of an adequate ecosystem together with an appropriately skilled workforce also need to fall into place," said Mr Banerjee.

Together with appropriate regulations, what is also needed is a suitable legislations for the protection of intellectual property. He added, "Medical devices feature a wide variety of different types of technologies, often in combination. Regulations providing robust protection to intellectual property will significantly boost investor confidence."

#### **"Make in India": A boon for Medtech sector?**

Medical device industry has been recognized by the Government of India as one of the five key sectors which can play a catalyst's role in shaping Prime Minister Mr Narendra Modi's vision of 'Make in India'.

This campaign throws up opportunities for growth of domestic medical devices industry, which is not only underinvested but heavily import-oriented at present, says WHO.

"We are very encouraged by the Prime Minister's call to medical device manufacturers to 'Make in India'. Several of our member companies have already established manufacturing units in India and India is being increasingly seen as an R&D base. The medical device industry sees itself contributing significantly to India's healthcare ecosystem including patients' issues of availability and access. Like in the case of 100 percent FDI, "Make in India", will become a reality only if an appropriate regulatory framework is first created, said Mr Banerjee.

"Nonetheless, I would like to emphasize that the growth potential can be realized only if government puts in place a forward looking and long-term enabling policies and regulatory framework which encourages manufacturing within India and helps Indian companies compete with major competitors from China and US. The right policy push and regulatory framework, as of now, is not in place. We do hope, the situation is corrected soon," said Mr Nath.

According to Mr Nath, Rationalization of Tax Structure, An Incentivized Export Substitution Policy, Preferential Public Procurement Policy and De-clubbing of Medical Device industry from Drug & Cosmetics Sector can immensely help the

medical device industry.