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Medtech Industry on the right path?

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India is currently growing as a key market for medical devices and diagnostics. According to reports, emerging markets will play an essential role in the global medical device industry and India as an emerging market will continue to be important for the global Medtech industry. Current scenario: the untapped market?

India has seen growth in terms of the increase of hospitals as well as the medical devices market. According to a white paper by EEPC (Engineering Export Promotion Council) India , Medical device Industry in India, the Indian Medical industry is currently the fourth largest market in Asia and valued at `30, 000 crore. It is expected to grow at a Compounded Annual growth Rate (CAGR) of 15 percent.

The Indian medical device is currently fragmented with close to 1,000 domestic firms primarily manufacturing low tech products, whereas importers dominate the costly and high end medical equipment with extensive service networks.

However, domestic companies seem to be transitioning from producing devices in the low technology segment to the medium technology segment.

According to the CII-BCG report, currently the sector is import driven with more than 70 percent of the devices are exported and the sector remains highly underpenetrated contributing 7-8 percent of the healthcare spends compared to pharmaceuticals at 18 percent. The challenges: Perhaps the biggest drawback of the industry is the lack of recognition as a separate sector. It is currently included in the Drugs and Cosmetics Act 1940 and comes under pharmaceuticals. The passage of the drugs and amendments bill might be for the better.

Earlier this year, AdvaMed, the medical devices association had written a letter to the health minister asking for early passage of the Drugs and Cosmetics (Amendment) Bill 2013.

A study titled "Access to Healthcare: Indian Perspective", released by The Associated Chambers of Commerce and Industry of India (Assocham) highlighted that India's medical device industry is facing severe challenges because of inadequate quality standards, coupled with huge reliance on imports, time delays, and other related hassles. This is causing a major hindrance.

"Unfavourable Duty structure for imports and exports is another significant impediment in the growth of domestic medical devices' industry as higher import duties for raw materials than finished goods has established an 'import-export anomaly' whereby devices manufactured in India become expensive owing to high raw material costs making them uncompetitive against low priced Chinese goods," noted the study.

"Besides, unlike China, our country does not provide any incentive on setting up medical device production bases to encourage medical device manufacturing, as such significant steps to overcome these anomalies are imperative to boost the domestic medical device industry thereby reducing our high dependence on exports," said Mr DS Rawat, secretary general, ASSOCHAM while releasing the findings of the chamber's study.

"There is an urgent need for a single window clearance system to spur growth in new product development as the limitation of medical devices, falling under preview of the Drugs and Cosmetics Act, 1940 has been a major deterrent in the medical devices' sector growth," said Mr Rawat. "Low research and development (R&D) spends, lack of innovation and promotion including low medical device funding from Department of Science and Technology (DST) or the Department of Biotechnology (DBT), inadequate quality standards and others are significant challenges faced by the industry."

Further, the CII - BCG report states that the industry is faced with significant lack of clarity in terms of regulation and predictable access to the market. This has limited investments into the market which in turn has led to lower investments in building up the component ecosystem and the technology skills base to support it.

Without a vibrant component manufacturing system, domestic capabilities in innovation and manufacturing are not built, leaving it to the critical enablers to address the market not being in place. This leads to fewer market appropriate products being introduced as the local capability does not exist and therefore, a reliance on imported products.

As imported products typically address a small part of the market, they have a lower relevance in the government's agenda and hence, a limited focus on clear and tangible policy and regulation which can shape the core of the industry. Roadmap to $50 billion industry In order for India to become a significant force in the medical technology industry, the country has to revise its policies and all the stakeholders should come together on the same page to foster the growth of the industry.

It should be excluded from the Drugs and Cosmetics Act and be recognized as a separate sector. "We need relevant regulation, a proper system that enables and rewards innovation, streamlining of the process to invest in manufacturing infrastructure and investment in training to produce skilled manpower," said industry observers.

There is a need for review of policies through inter-minister coordination for providing appropriate fiscal and support environment. This will help manufacturing to thrive and consistency in its implementation over a 5-10 year time frame.

Also we should review FDI policy which allows 100 percent equity to set up manufacturing units. There needs to be stipulation to ensure at least 60 percent of the turnover would be from manufacturing operations in India, suggested EEPC in its white paper.

Also, infrastructure would be needed for establishment of regional or zonal specialised test labs to provide low cost external testing by accredited labs.

CII along with Boston Consulting Group (BCG) in the vision document, entitled 'Revitalising Manufacturing and Innovation to realise the $50 billion Potential' proposes that the regulatory reforms need to be accompanied by appropriate reimbursement policies. Price controls serve as a major deterrent to stimulating innovation as research based companies are unable to generate a fair return on their investments. At extremely low price points, companies are not able to import their products into India, thereby denying patients access to the latest lifesaving technologies.

The industry is nascent, accounting for less than 8 percent of the total healthcare spending in India. To continue to attract investments, this nascent industry which has long gestation periods should be allowed to let market forces regulate prices and should not be clubbed with the pharmaceutical industry for price control. Also, what is required is a unified regulatory body that can approve bringing new products to the market quickly.