Drive towards accessible, affordable medical devices

Finance Minister Arun Jaitley, while presenting the Budget 2017-18, announced that the government will soon formulate new rules for regulating medical devices, a sunrise sector. These rules will be internationally harmonised and attract investment into this sector. This will reduce the cost of such devices.

The Ministry of Health and Family Welfare notified Medical Devices Rules, 2017, on a month before the presentation of the Budget. The new rules have been framed in conformity with the Global Harmonisation Task Force (GHTF) framework and conform to best international practices. The Government of India has identified medical devices as one of the four focus sectors under the 'Brand India Engineering'.

The 'Brand India Engineering' is an initiative being implemented by India Brand Equity Foundation (IBEF) and the Engineering Export Promotion Council (EEPC) of India, under the aegis of the Ministry of Commerce and Industry, in close cooperation with the
industry to enhance Indian engineering exports, by highlighting and showcasing Made in India products and their capabilities in the global market. The initiative involves a 360° approach in promoting the branding of Indian engineering products.

According to IBF and EEPC India, the Indian medical devices industry is currently valued at around $5 billion. The overall healthcare industry in India is valued at $90 billion, which is expected to reach $220 billion by 2020. Thus, India's medical devices, surgical equipment and pharmaceutical industry is poised to grow significantly in the coming years and emerge as a cost-effective supplier globally.

The Indian surgical equipment, medical device and pharmaceutical machinery industry is fragmented with close to 1,800 domestic firms, who are predominantly MSMEs, primarily competing in the range of low-to-medium technology products. However, in recent years, there has been a paradigm shift in the manufacturing landscape, and which now has expanded to producing more cost-effectively, to high-end products including hi-tech R&D and testing in the sector. The domestic market caters to low-value disposables and supplies space, whereas importers dominate the costly and high-end medical equipment with extensive service networks.

Even as it is deemed as a sunrise sector in the healthcare space, with a focus on technology, innovation and a conducive regulatory framework, the Indian medical devices industry will attract investments from the private sector. This would help Indian companies become originators rather than traders. International companies in this field are also using India as a manufacturing base by either setting up facilities of their own or by acquiring domestic manufacturers.

India provides a lot of opportunities for the medical devices players as the country has a growing and ageing population, income base and associated disposable income, increasing socio-economic inclusion of rural and deprived in the mainstream economy, hightened manufacturing innovation to create customised products to meet the needs of all income segments, changing disease prevalence pattern (eg. early onset of diabetes and heart disease) and growing awareness among the middle class to focus on early detection and disease prevention.
New Medical Devices Rules, 2017

As per the new Medical Devices Rules, 2017, only 15 categories of medical devices are, at present, regulated as drugs and to that extent, the current regulatory practices in India were not fully geared to meet the requirements of the medical devices sector. The new Rules seek to remove regulatory bottlenecks to Make in India, and facilitate ease of doing business while ensuring availability of better medical devices for patient care and safety.

Medical devices will, under the new Rules, be classified as per GHTF practice, based on associated risks, into Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk). The manufacturers of medical devices will be required to meet risk proportionate regulatory requirements that have been specified in the Rules and are based on best international practices.

With a view to bring in the highest degree of professionalism in regulation of medical devices, a system of 'Third Party Conformity Assessment and Certification' through Notified Bodies is envisaged. The Notified Bodies will be accredited by the National Accreditation Board for Certification Bodies (NABCB), which, before accrediting Notified Bodies, will assess their competence in terms of required human resources and other requirements. These bodies will undertake verification and assessment of Quality Management System of Medical Device Manufacturers of Class A and Class B categories and may, on as required basis, be called upon to render assistance for regulation of Class C and D medical devices too.

The Rules also seek to evolve a culture of self-compliance by manufacturers of medical devices. A network of NABL-accredited laboratories will be set up both, by the government and by other entities, for testing medical devices. Separate provisions for regulation of clinical trials of investigational medical devices (i.e. new devices) have also been made at par with international practices and, like clinical trials, these will be regulated by CDSCO. The trials will be conducted to ensure realisation of the twin objectives of patient safety and welfare and discovery of new medical devices.
Under the new Rules, for the first time, there will be no requirement of periodic renewal of licences. Accordingly, manufacturing and import licences will remain valid till these are suspended or cancelled or surrendered. These Rules envisage creation of a robust ecosystem for all stakeholders including innovators, manufacturers, providers, consumers, buyers and regulators.

The Rules will provide a conducive environment for fostering India specific innovation and improving accessibility and affordability of medical devices across the globe by leveraging comparative cost advantage of manufacturing in India. The new Rules will help in developing a quality standardisation framework in India at par with international standards.

The implementation of these Rules will provide the assurance of the best quality, safety and performance of medical devices. These Rules coupled with other measures, taken by the government in the recent past, are expected to sharpen the competitive edge and provide incentives to firms to become more efficient, innovative, and competitive. All this will support entrepreneurship, market entry and economic growth that in turn, would produce high-quality jobs.

Promotional initiatives
The government has launched voluntary scheme 'ICMED' or Indian Certification of Medical Devices to bring international respect to medical devices which are made in India.

With effect from January 1, 2016, the government has scrapped the requirements of obtaining a 'No Objection Certificate' from the Ministry of Health for exports meant to developed countries. It has allowed 100% FDI to promote world-class manufacturing and enhance competencies in the local manufacturing. Existing companies or setting up of new companies are allowed to bring FDI under automatic route into the sector. To stimulate domestic manufacturing, the Centre announced (on January 19, 2016) withdrawal of earlier concessional import duty.

In order to boost self-sustaining industry oriented R&D mechanism, the Ministry of
Commerce and Industry has undertaken an initiative for technological upgradation for boosting engineering exports.

With the support and push from the Prime Minister’s Office, the Department of Pharmaceuticals is making efforts to fast-track formulation of the medical devices policy that will give the sector a leg-up and attract FDI, to see growth in the coming years.