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Need attention: Medical devices

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In recent years, the medical device sector has emerged as the most diverse (in terms of variety of products) and complex health care sector having the collaborative efforts of science and engineering. India, being the fourth largest health care sector in Asia with a growing economy (GDP of eight per cent) with approximately 1.1. billion people has a lot of potential for expansion and growth in the medical devices market. Currently, its market size is expected to be around $2.5 billion with an annual six per cent growth rate and a projected growth rate of 12-16 per cent within the next five years. Furthermore, Indian medical devices market rely heavily on imports (about 75 per cent) to satiate their demands.

Regulatory challenges

Though this dependency on imports must be attractive to foreign manufacturers, India's market is difficult to navigate due to the complexity of regulations. Specially, the lack of distinctive regulations between drugs/devices creates much confusion in manufacturers' mind, and those looking at the country for business.

Currently medical devices are regulated as drugs under Drugs and Cosmetics Act by the Drug Controller General of India (DCGI) of Central Drugs Standard Control Organisation (CDSCO), the central governing body of the country. The lack of a dedicated center in the country to oversee certification, approval or monitoring of medical devices would lead to a communication gap between the agency and manufacturers. Due to this, foreign manufacturers may have to wait up to one year and need to be aware about spending significant time following up with CDSCO. Apart from this, the main reason for disruption in the regulatory system has been the lack of adequate manpower, infrastructure facilities, or of knowledgeable regulatory professionals.

Though India's population is at around 1.1 billion, most Indians still cannot afford expensive medical care, given the lack of health insurance coverage. Poor medical infrastructure facilities, and low level of awareness in rural India are the other reasons. Hence, manufacturers will target the middle and upper-middle-class population; estimated at 150 million people as their potential customers. High import duties and resultant high cost of devices will also limit the number of customers, and the reimbursement opportunities for foreign manufacturers. These are the challenges manufacturers are likely to face.

Recommended changes

I will encourage foreign companies looking to enter or expand their business in India's medical markets to understand the regulatory reforms in India. The Government should work towards developing distinct regulations for devices that will eliminate confusion for manufacturers to penetrate the Indian device market. A specific medical device division should be established under the CDSCO for the proper management of approval, certification and quality. A specific division should also include a group of experts to regulate and approve clinical trials. They should also work on reducing review timelines. I would advise manufacturers to focus on the Indian Government's recent draft guidelines (August 2010) on import and registration of medical devices that came as a welcome move. The recently adopted risk-based classification based on Global Harmonisation Task Force (GHTF) model of medical devices will allow the market to grow and help patients access the best available facilities in diagnosis, monitoring. A reduction on import tariffs will work as an added incentive to foreign manufacturers. The state and central government should work closely with each other to develop world-class hospital facilities that will increase medical tourism in the country and make things easier for aspiring manufacturers. One of the most important aspects to overcome

regulatory and other hurdles is to collaborate with local trustworthy distributors, as without their networks it will be difficult to penetrate the regional markets of India.

Finally, the onus ought be on CDSCO to manage regulatory responsibilities and modalities along-with enforcement procedures, by setting up a specific division for medical devices.

Training and courses

Like other training programmes and courses, a curriculum that includes the medical devices segment and its regulatory challenges should help people understand the issues a regulator faces.

It is enough that the courses have the ability to look into regulations and specially create global awareness, providing a strong foundation with integrated knowledge and broad perspective. GHTF, an agency working for harmonising medical device regulations worldwide, has helped us address the issue regarding medical devices, medical device development, and European regulations.

Conclusion

The Indian medical devices market holds much potential and offers opportunities for foreign manufacturers. Thorough market research by manufacturers and the recent changes made by CDSCO will definitely do a world of good. Along with the proposed changes, by implementing the new rules and regulations for medical devices local Indian manufacturers can go global, leaving a strong impression of the growing Indian economy.

References:
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