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ASIA EDITION

Robust regulations needed

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Singapore:Ã?Â The Asia Pacific (APAC) medical device market touched an estimated $54.5 billion at the beginning of 2012. This growth was primarily led by the population size, an ageing population and increasing awareness of better healthcare services, according to an industry report by market analyst firm, Epsicom. Industry analysts predict that the medical device market in Asia is likely to grow at a compound annual growth rate (CAGR) of 10 percent in the years to come, and would likely touch the scale of $70 billion by 2015. However, the regulatory norms, which are governing the medical device sector in Asia, have cast a shadow and are posing several hindrances to the streamlined growth of the sector. Moreover, the lack of clarity in the regulatory frameworks is preventing foreign companies from setting up operations in Asia.

Various diseases including cardiovascular, orthopedic and diabetes, along with infectious diseases are propelling the integration of medical devices in healthcare management. Analysts opine that the outlook for medical devices segment over the next few years would be strong, with the increase of healthcare services in developing countries. With such a promising growth projection in medical devices segment, Asia needs to build a streamlined, well-defined and guided regulatory framework that supports and encourages development and availability of medical technology in the market.
According to the BioSpectrum Asia Smart Healthcare Survey findings, Asian markets lack clarity in their regulatory framework and the policies are not updated in line with the evolution in technologies and devices. Regulatory pathways for medical device approvals are an ongoing work-in-progress across many countries. For instance, India had no regulatory procedures for medical devices until 2005. However, certain classes of medical devices are now regulated under the provisions of the Drugs and Cosmetics Rules.

Dr Niraj Shende, R&D head at the analytical chemistry development lab of Pune-headquartered Serum Institute of India says, "Despite increasing emphasis on strengthening infrastructure for healthcare, the Indian government has overlooked the need to chalk out a well-defined regulatory pathway for diagnostic products, leaving the upcoming companies in the segment lurching in the dark. There is no clear pathway by the government on what and how exactly should the validation process be carried out. Companies and research institutes have to scout around for institutes or hospitals to test and validate their tools."
Authorities in China are in the process of reviewing and amending regulatory norms for medical devices. ASEAN (Association

of South East Asian Nations) countries are, in particular, working towards convergence of standards and a combined regulatory practice that promotes technological innovation and paves way for the Asian medical device developers to venture into global markets.

The World Health Organization (WHO) guidance says that regulations should be used to enable patient access to high quality, safe and effective medical devices and restrict access to those products that are unsafe or have limited clinical use. The WHO established the International Medical Devices Regulatory Forum (IMDRF) in 2011, which is a voluntary group of medical device regulators from around the world, to build on a strong foundation for Global Harmonization Task Force on Medical Devices (GHTF) and to accelerate international medical device regulatory harmonization and convergence.
IMDRF aims to develop training materials with professional organizations in order to assist national regulatory agencies with staffing of qualified biomedical engineers, technicians and regulatory professionals. This helps them to perform evaluation, registration, conduct pre-market approval and post-market surveillance activities for medical devices.

Recent regulatory strides across Asia
The medical device market in China was valued at $19.4 billion in 2010 and is estimated to grow exponentially in the years to come. China Food and Drug Administration (CFDA) recently introduced initiatives in the medical device sector for review and approval of medical device clinical studies, with the intention to tighten its approval processes related to high risk medical devices. It has amended the policy for manufacturers to apply for Clinical Trial Authorization (CTA) with the CFDA. Furthermore, a supplementary CTA application is mandatory in the event of substantive changes in the study protocol or resuming a study that was previously suspended or terminated.

The CFDA intends to impose a pre-approval requirement for certain high-risk medical devices that include implantable pacemakers, implantable blood pumps, nano-orthopedic implants, and 3D-printed orthopedic implants, among others. China is also planning to improve its infrastructure for monitoring of adverse events associated with medical devices and enhancing its technical evaluation capabilities.
The Indian medical device and equipment market is also witnessing a substantial growth. Currently valued at $4.4 billion, the Indian medical device and equipment market is expected to grow to around $5.8 billion by 2014 and $7.8 billion by 2016, growing at a CAGR of 15.5 percent, according to estimates by Grant Thornton India in its report on the medical technology sector.

The Indian Semiconductor Association mentions that India's medical device market is currently the fourth largest in Asia with 700 medical device makers, and ranks among the top 20 in the world. However, there is still a lack of guided medical device regulatory policies in India, and this is posing to be a hurdle to innovations and technological developments and implementation of the technology in healthcare services.
India has proposed a bill, aimed at regulating the medical equipment industry in the county, which largely remains unregulated. Speaking at 'Harnessing medical technology for inclusive healthcare in India', this year, Mr Arun Kumar Panda, joint secretary, health ministry, India, emphasized that regulation of the medical devices industry has been a major challenge for the Indian government, and presently, thousands of such equipments are being used in an unregulated manner.

The new bill, which is yet to be approved by the Indian legislative body, is aimed at monitoring and setting standards for medical devices that strengthens domestic manufacturing industry and makes medical devices more accessible and affordable.
Asia needs to recognize the contribution made by the medical device industry in the growth of its economy and understand that a robust regulatory platform encourages local device manufacturers to bring innovation and also helps them position themselves in the global market.

South Korea's medical device market size is over $3.6 billion and is growing strongly followed by Japan and China. In order to channel quality and high standard medical devices into Korea within a short and transparent processing time, the Korean Food and Drug Administration (KFDA) recently redefined its Medical Device Act. The revision is done to ease the registration and approval process of medical devices and to help them to expand the medical device market in the country.
Korea's Ministry of Food and Drug Safety (MFDS) made amendments to the regulations regarding classification and grades of medical devices and on general requirements for basic safety and essential performance of medical electrical equipment.

MFDS on its announcement of the amendment stated, "Technical developments have led to more complicated structures and functions with electrical and medical equipments and have made it harder to understand the potential risks. Therefore, MFDS is set to establish a standard for essential performance and an organized management system to analyze, evaluate and control potential risks that are directly related with safety. MFDS is going to lay down new safety standards for medical

electrical equipment with software as they have become popular. These standards will be effective for class III and IV medical devices by 2014, for class II medical devices as of 2015 and for class I medical devices by 2016."

The amendments suggested by MFDS will change the length and complexity of the approval procedures of pre-market medical devices in South Korea. Registration of low risk level medical devices has been eased and a third party is now being involved to review some of the medical devices.
Strengthening its medical device regulatory norms, the Malaysian Medical Device Authority (MMDA) recently issued guidance on good distribution practices for medical devices that specify the scope of supply chain movement of medical devices in Malaysia. This will help address quality, safety and performance provisions for foreign device makers, importers and distributors. Malaysia also appointed global standard assessment companies, responsible for independently assessing medical device manufacturers, importers and distributors and they will help ensure compliance with the Medical Devices Act 2012.

Similarly Singapore, with a medical device market of around $500 million, has formulated stringent guidelines for high-risk products and has moderate regulations for low-risk products to enter into market. With an objective to accelerate availability of the medical devices market in the country, the Health Sciences Authority (HSA) of Singapore enhanced its regulatory framework for low-risk medical devices by lowering regulatory fees and facilitating quicker access in market. The HSA rolled out its medical device regulatory framework in various phases, beginning 2007, and fully implemented it by January 2012.
An HSA spokesperson, elaborating about this, says, "HSA is mindful to ensure that the cost of medical device regulation does not significantly impact the overall healthcare cost even as the regulations continue to ensure patient safety. HSA will continue to refine regulatory framework and further stratify its fee structure, especially for certain low cost medical devices with a low volume demand."

Commenting on the strategy of implementing and reviewing regulatory norms in Singapore, Dr Raymond Chua, group director, HSA, told BioSpectrum that, "HSA has judiciously adapted good international regulatory principles and practices to meet Singapore's unique situation, without compromising public safety, imposing over-regulations or blindly approving products that are already approved in the international market. We aim to make wise use of the regulatory tools and risk-based regulation for our key areas that include medical devices, generics, pharmaceutical, biologics and advanced therapies."
In order to speed up the approval process for medical devices, Japan is also planning to introduce some changes in the accreditation procedures. According to reports, Japan's Health, Labor and Welfare Ministry, is proposing a new bill that enables speedy approval for regenerative medical products made from induced pluripotent stem cells.

ASEAN harmonized effort

One-of-the-biggest challenges for foreign players entering into South East Asia is the unclear regulatory environment for medical devices, fragmented market, and individual and unique policies for border sharing countries. The policies for distribution and post-market surveillance vary in each country and this acts as hurdles in entering the local market. Realizing the bottleneck, the ASEAN community decided to design a harmonized set of standards for medical device registration and post-market surveillance throughout the region. The regulation draft, known as ASEAN Medical Device Directive (AMDD), was released in 2012, and is scheduled for implementation by December 2014.

ASEAN countries are co-working on their strategy to adopt the harmonized regulatory system. They are seeking to position themselves in the global market and attract international players to identify opportunities and help them get a smooth access to the Asian market. Malaysia is playing the lead role among ASEAN countries. It is spearheading the development of a harmonized system, including the development of a common submission dossier template for medical devices market approval and formalization of a post-market alert system for ASEAN and Asian nations.
Furthermore, there is a dire need for medical device regulatory bodies to keep abreast with the latest technological advances and novel products and advanced therapies like stem cell therapies or biologics development. Also, with the emergence of complex healthcare products in a healthcare market that includes drugs, medical devices and dose counts, regulators will have to develop expertise and build regulations for emerging domains.