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MedTech industry welcomes govt's segregation efforts

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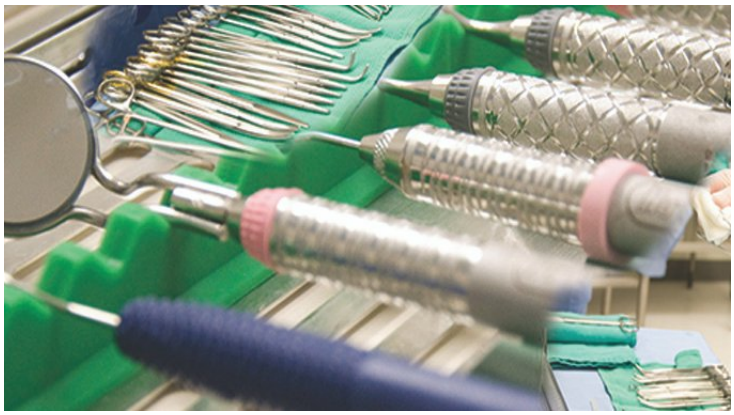
Medical device industry welcomes govt's renewed efforts to segregate it from drugs



In response to widespread media reports regarding medical devices, AdvaMed, an association of medical device manufacturers, recently discussed some of the regulatory hurdles the industry faces in India. It welcomed the government's efforts to create a distinction between medical devices and drugs through a separate chapter in the Drugs & Cosmetics (Amendment) Bill, and its commitment to tackling non-communicable diseases. It believes that in the long run, a separate Act would better facilitate the industry's ability to address India's healthcare challenges.

Mr Sanjay Banerjee, Chair of AdvaMed India said, "For decades in India, the medical device industry has gone unrecognized as a distinct pillar of the healthcare sector. Of the 14,000 types of medical devices, only 22 are on the regulator's list and even these are treated as drugs. There is a misconception here that medical devices and drugs are the same because they are both used to treat diseases. The obfuscation of the two categories in India has limited the ability of the sector to address India's healthcare needs. There is a major gap between devices used and what is needed."

There are dramatic differences between the two categories. While medical devices interact with the body in multiple ways, drugs have well-defined physiological characteristics and effects. Devices are based on mechanical/electrical/materials engineering whereas drugs are based on pharmacology, chemistry and biochemistry. As far as failure is concerned, medical device failure occurs due to mechanical/electrical component failure and biocomparability problems whereas drug-related injuries or deaths are caused by overdose, incorrect drug administration or side effects.

AdvaMed is heartened that the D&C Bill 2013, which was introduced in Parliament last year, has recognized these differences and created a separate chapter for medical devices. "The medical device industry believes that in the short to medium term, the Bill has tremendous potential to remove the impediments that have limited the medical device industry from addressing India's healthcare needs in a safe, effective and timely manner. This is a great first step towards more investment, innovation and manufacture," said Ms Abby Pratt, Vice President of AdvaMed.

However, the distinction between drugs and devices - for example, with respect to clinical trials - is yet to be taken to the last mile. To ensure an appropriate regulatory framework, for instance, a separate cadre of regulators trained in biomedical engineering will be needed. Pricing authorities would have to be cognizant of the variations between devices and drugs - in pharmaceuticals, pricing is a function of the product supplied while for medical devices, pricing is a function of the product

and services provided. To reflect the true quality of care provided, there would have to be public reporting of quality information along with cost information.

AdvaMed believes that while in the short term, the Bill can go part of the way in fixing regulatory issues, in preparing for the future, a new and separate Act (as is in place in other emerging economies like South Korea and Malaysia) would pave the way towards supporting the exponential growth of the industry and its ability to tackle India's growing non-communicable disease (NCD) burden.

Medical devices play a critical role in diagnosing and managing these NCDs. For example, the evolution of coronary stents has already halved the number of patients dying from heart attacks; implantable cardiac defibrillators have increased the chances of surviving a cardiac arrest from 5 to 98 percent and diabetics now have access to accurate glucose monitoring technologies that can prevent hypoglycemia, blindness and peripheral nerve damage triggered by diabetes.

"We are greatly encouraged by the Health Minister's intention to focus on non-communicable diseases. We are committed to partnering with the government in moving beyond simply removing existing regulatory problems and instead creating a healthcare system that meets the needs of Indian citizens," said Mr Banerjee.