BioSpectrum the business of Bio & Health Sciences

â€œYearning for attention!â€?

28 October 2013 | News | By Rahul Koul Koul

â€œYearning for attention!â€?

Meanwhile, catching up latest global trends, the technologies in India too are fast moving from labs to the patient's bedside. BioSpectrum tries to find out the latest in this segment.

Access to quality healthcare in India needs to be expanded, and that is not possible without increasing access to medical technology which is a crucial pillar in the healthcare sector. Broadly categorized into two categories, capital equipment, and implantables or what few may call consumables, India's close to $3 billion strong medical devices market is growing at a rate of 15 percent per annum, promising immense potential. As healthcare is also a top priority for government, the industry has also been making many efforts to better explain the medical devices industry and the value of medical technology to patients and the population in general.

We are different please!

Industry insiders feel that with regards to pricing and reimbursement, there is a need to treat medical devices separately. "Compared to pharmaceuticals, medical devices (that include invitro diagnostics) are an extremely diverse group of products. Some are as simple as adhesive bandages, tongue depressors, and plastic tubing. Others are complex, for example, implanted cardiac, cardiovascular, and neurological devices, stair-walking wheelchairs, robotic surgical systems, and magnetic resonance imaging devices, opinions Ms Abby Pratt, associate vice president, Global Strategy & Analysis, AdvaMed, "In contrast to single-molecule drugs, many complex devices involve a number of components that, together, form a system. Given the diversity and complexity of medical devices as compared to pharmaceuticals, outcomes of the use of medical devices often depend directly on the skill or experience of the user."

Another point that is highlighted by experts is in terms of the industry composition, over 80% of the medical devices industry is comprised of small and medium sized companies (SMEs) whereas the pharmaceutical industry is dominated by a few very large multinationals.

The active components of medical devices are generally based on mechanical, electrical, and materials engineering. Many medical devices incorporate and are driven by software. In contrast, pharmaceuticals are based on pharmacology and chemistry, and increasingly encompass biotechnology and genetic engineering. In recognition of these dramatic differences, pharmaceuticals and medical devices are regulated separately in all major markets across the world.

Medical devices typically have a short product life cycle, about 18 to 24 months, and investment recovery period. Market competition from similar devices is often intense, even in the early stages of a new technology. In contrast, pharmaceuticals typically have a long commercial life-cycle (10-20+ years), during which they do not undergo significant changes. Therefore, pharmaceuticals require intensive patent protection including data exclusively due to the extensive product life cycle and long investment recovery period.

Says Gautam Khanna, executive director, Health Care Business, 3M India, "Drugs and devices need to be considered separately also in terms of their product lifecycle. In the pharmaceutical world, companies undertake extensive research and development of a specific compound or molecule. It typically takes several years for a new drug to enter the pipeline. Medical devices in contrast are developed through continuous innovation and iterative improvements based on new clinical practices, new science, new technology and new materials."

Due to the wide variety of structures and technologies embodied in medical devices, many different patents typically cover a single medical device. For example, a pacemaker will typically have separate patents (often several) covering the housing, battery, capacitor, electrical circuit, communication system, software programs for therapy delivery, sensing and detection, lead structure, and electrical system (electrodes and sensors) on the lead. By comparison, there are typically very few patents for individual pharmaceutical products. Since there are a finite number of molecules that may be used to elicit a desired biological response and clinical outcome, competitors may be effectively excluded from making the pharmaceutical product by a single patent covering the class of molecules that comprise the pharmaceutical product. Once the patent expires, or is no longer applicable, it is possible for competitors to produce "generic" versions. Therefore, unlike pharmaceuticals, the basis for competition in the medical device field is generally not patents and patents generally do not confer market exclusivity as they do for medicines.

Plugging policy loopholes

Another aspect where we need to differentiate between drugs and devices are in the rules for clinical trials. The way drugs and devices affect your body are very different. For instance, drugs get assimilated into the blood stream and can have an impact on your entire body, which means that in case of adverse reactions they can have damaging effects on multiple parts. On the other hand, devices interact with body parts in a limited way - for instance, stents with the heart and knee implants with the knee. So they have a very limited negative impact in case of adverse reactions during trials.

The industry over the years has been making efforts to introduce separate and appropriate regulations for medical devices. The new Drugs and Cosmetics Amendment Bill will hopefully bring right differentiation between drug and device. Says Ms Abby Pratt, "As policy goes through a lifecycle of regulations, it is important to differentiate between rules made for drugs and rules made for devices at every stage and these regulations should be harmonized with global regulations so that we get best of class devices available in India without hassle.

According to Gautam Khanna, the guidance documents developed by the global harmonization task force (now the IMDRF) would be an excellent starting point for India's new regulatory regime for medical devices. Gautam explains, "In 2011 India was invited to join the International Medical Device Regulators Forum (IMDRF). This would be a huge opportunity for the India Govt to work with foreign regulators side by side towards a harmonized system for medical devices regulations that benefit India's patients by improving the quality of India's device regulations, enhance the environment for innovation and benefit regulators who would be able to exchange views with regulators across the world."

Sanjeev Johar, CEO, Alere India opines that the though Indian regulators understand the need and they are not properly staffed to carry out their tasks. Under the circumstances, he says that it would be best for them to remain abreast on devices and the trends in Europe and US. "Normal tendency should be not be that this imported technology is new and now we therefore can't allow it due to unawareness. That would be unfortunate. So it is advisable for them to remain aware on such new technologies and innovations," he says.

Market unpredictable though future bright

Despite the small market size, the industry is growing at strong pace. The reports suggest that in next 3-5 years, this industry

is expected to go upto $ 4-5 billion. Abby Pratt feels that the unpredictability of the market leads companies to be cautious about investing in and expanding into this market. "The trajectory of the new regulations as well as pricing and reimbursement policies will likely affect how companies judge the attractiveness of the India market," she says.

Amitabh Roy Chowdhury, executive director and COO of Prisma Global is of the opinion that the technology is making healthcare more accessible and popular. He mentions, "We also need to spread awareness about the benefits of medical technology. Exploring public private partnership solutions can further strengthen healthcare access and tap into the potential of the sector."

Traditionally India has been focused on laboratory research. But latest trends point towards the fact that the technology will move out of the lab and get closer to point of care. There is an overall consensus that much attention is needed for the smarter devices that are closer to patients and help in early prevention and treatment. The policymakers, regulators and industry stakeholders will have to engage in repeated discussions over the period of time to ensure the clear roadmap for the segment.