

## Look into our issues: Medical devices industry to Health Min

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### Medical devices industry urges health ministry to look into its issues



Often identified with the pharma sector, the medical devices industry has long been fighting for recognition as a separate industry. There are said to be 14,000 different kinds of devices in India. The industry experts point out that a huge demand and supply gap of almost 92 percent exists in the market and argue that the government has so far not addressed the needs of this segment.

Lack of awareness about this industry too has been a major cause of concern. This is backed by a new report by the Advanced Medical Technology Association (AdvaMed) where the findings of a survey of 1,300 Indians from across 17 states revealed that although an overwhelming 72 percent of respondents use medical devices, 89 percent do not know enough about them.

On the sidelines of a roundtable discussion on 05 May, 2014 held at New Delhi, Ms Anuradha Das Mathur, an expert in the area told *BioSpectrum* that the medical devices industry is often confused with drugs and that there is limited understanding of the sector, leading to non-regulation and chaos. She added, "There is a need to address various issues within the bill such as spelling out medical devices in detail and clarity on the clinical trial regulations."

"Our survey suggests that people in India do not know enough about medical devices but want to know more. It is quite astounding that 60 percent of respondents think that medical devices are the same as pharmaceuticals," said Mr Sanjay Banerjee, managing director, Zimmer India, and chair of the AdvaMed India Working Group.

Interestingly, the survey also finds that although India is a price-conscious market, quality is an important consideration among the country's growing middle class. It showed that 75 percent of respondents believe that the quality of the medical device is important because the safety of the patient is paramount.

According to 72 percent of respondents, using a high-quality device would help them avoid repeated hospitalization costs. Responding to this finding, AdvaMed vice president, US-based Ms Abby Pratt said, "Unlike in the case of many other

products in India where people unequivocally choose the cheapest option, this survey suggests that when it comes to advanced medical devices, quality becomes important because of its correlation to safety. It is noteworthy that 80 percent of respondents see a correlation between brand name and quality."

However, despite the prevalence of medical devices as the survey suggests, at a macro level, the industry constitutes only 5 percent of India's \$60 billion healthcare industry. There is a major gap between medical devices currently used and what is required to address public health needs.

For example, in the case of diabetes, it is estimated that 93.75 percent of the Indian diabetic population remains undiagnosed or untreated. The situation is similar for other diseases: heart disease, cancer, glaucoma and so on remain undiagnosed and untreated because the benefits of medical devices like stents, MRI machines or intraocular lenses are not known to those suffering from them.

AdvaMed believes that the medical devices industry in India has the potential to fill these gaps. Reflecting the results of the survey, the Indian regulatory framework has also for years considered medical devices the same as drugs. To AdvaMed's relief, the Drugs and Cosmetics (Amendment) Bill 2013 which was introduced in Parliament last year, recognised medical devices as a crucial and distinct pillar of the healthcare system and created a robust regulatory framework for the medical devices sector.

Mr Banerjee said that AdvaMed was hopeful the Modi government, under the stewardship of health minister, Dr Harsh Vardhan, would provide an enabling environment for the bill to become law. "This law can help set the stage for the Indian medical devices industry to grow, innovate and ensure highest standards of quality healthcare for all Indian patients," Mr Banerjee said.

AdvaMed has submitted a letter to the new Health Minister, urging collaborative discussions that will facilitate expeditious consideration of the Bill. Ms Pratt said, "We believe that Dr Vardhan's expertise as a surgeon and health administrator will enable him to appreciate the significance of the medical device industry and its challenges. We are eager to fully participate in India's effort to improve the quality of life for patients with non-communicable diseases, and look forward to every opportunity the government might provide towards harmonised regulations for the industry."

AdvaMed is also greatly encouraged by the Health Minister's statements about stakeholder consultation and public-private collaboration. Mr Banerjee commented, "The medical device industry is excited that the new Health Ministry wants to consult stakeholders, and looks forward to discussing the Bill with the government. We are expecting greater clarity from the new regime."