

Medical devices: the struggle to thrive in India

Imports still account for over 70% of the estimated ₹30,000-crore med-tech sector

PLINTH DATA

For first-generation entrepreneur GSK Velu, making and selling medical devices would have been difficult if he was operating only in India. But Tritron has a global outlook, with a limited view on India, says founder Velu, getting to the heart of the problem that domes-

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the manufacturers have to face. Willing to fight in the international arena, they seek a favourable environment back home, he says.

Regulatory supervision

Velu's is no lone voice. His despair is echoed by several domestic med-tech companies who are apprehensive, yet hopeful, as the Government is finally ready to give the sector the attention it deserves. There are about 2,000 med-

cal devices sold locally — from humble reading glasses and gloves to critical MRI machines and implants. Only 22 of them are presently under any direct regulatory supervision.

Viability factor

But, the Drugs and Cosmetics Amendment Bill, 2015, is looking to change this, bringing all medical devices into its fold.

The Bill is to be introduced in the Budget session of Parliament next month. Despite its critical nature, imports account for over 70 per cent of the products estimated ₹30,000-crore med-tech sector in other words, interestingly, much of what sells in India, is not made in India.

Against this backdrop, the Government also opened up the sector to 100 per cent foreign di-

rect investment (FDI). But, manufacturing needs to be viable, just bringing in FDI will not solve the problem, says Rajiv Nath of the Association of Indian Medical Device Industry (Aimed).

The move virtually offers Indian companies to foreign buyers on a platter, he says, adding that companies in the ₹50 crore-plus turnover bracket will be easy pickings. Like Parle sold out to Coca Cola, who will fight the local fight against Coke or Pepsi, he asks.

The competition will be between a Merck, BMW and Audi, he says, illustrating the danger of having a choice of only high-priced products.

Inverted duty structure

While opening up FDI, the Government needs to introduce a caveat that 70 per cent of the products, be made locally, he says, as this will bring down the price for consumers. Local manufacturers also deal

with an inverted duty structure, explains Velu. Import duty on finished products is less than on raw materials, which makes it easier to import a product than make it locally, he says, adding that it defeats the Make in India sentiment. India has 750 local manufacturers and over 1,000 trading companies, according to industry data.

Countering these observations, Vibhav Garg with Advanced (Advanced Medical Technology Association), a trade body for multinational companies, says that besides FDI, global companies look for a clear, predictable and globally harmo-

nised regulatory environment to invest or manufacture in a country. There is scope for more companies to manufacture in India, he agrees. And Baxter Johnson & Johnson and 3M, for instance, already do, he clarifies.

But given the nascent domestic sector and lack of recognition, importing technologically advanced high-risk devices like cardiac defibrillators or dialysis machines is the only way to ensure availability and access, he says. An appropriate regulatory framework will help companies move from import towards manufacturing, he adds.

Availability and access

On the "inverted" duty structure, he says, "we fulfil a staggering 80 per cent of our requirements for technologically advanced high-risk medical devices through imports."

Still domestic manufacturing meets the demand of Indian patients, a low duty structure for importing critical, life-saving

devices is the only way to ensure the much-needed medical care, he adds. Explaining why the med-tech regulation is important, Nath says, "No doctor will touch our product unless there is a certificate of credibility on Indian manufacturing."

Buy India' policy

Products need to be graded as low, medium and high-risk categories. And as practiced internationally, controls should be proportional to the risk of the device. So low-risk spectacles would attract less control compared to an implant, he explains.

At present, though, there are several worrisome features in the Bill on clinical trials and penalties, he says. But this being the ground reality, Velu suggests a "Buy India" policy, just as China and America give preference to their locally-made goods, the Government needs to have a "Buy India" policy, he says, to ensure that companies do in fact manufacture in India.

Industry