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**Economy and Politics**



## **Low-cost insulin pump Highlights tech transfer gaps**

**An insulin pump is a pager-like device that supplies a slow and steady insulin stream to the body of diabetics**

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Bangalore: Bipin Nair is learning.

The dean of the school of biotechnology at Amrita Vishwa Vidyapeetham in Kollam, Kerala has been in the science domain for at least 25 years. Now, he's busy learning about technology transfer as he tries to take an insulin pump to the market.

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Nair is discovering that this isn't easy. He has to reconcile research, business imperatives, and an institutional value system that insists that costs be kept low.

Nair's group at Amrita has developed an insulin pump, which could sell for one-tenth of the prices of existing devices that are currently imported in India and sold for between \$4,000 (around Rs1.94 lakh) and \$8,000.

Inspired by the sweeping adoption of mobile phones, Nair's team has designed the gadget to be more user friendly. "Most other pumps are only splash-resistant; we are close to being water-resistant," says Nair, who returned to India in 2005 after a decade-long stint in the US, to set up a biotech institute that is also one of the core biomed technology centres of the department of science and technology, or DST.

An insulin pump is a pager-like device that supplies a slow and steady insulin stream to the body of diabetics. The basic model doesn't measure the sugar level but high-end models have in-built sensors that measure the glucose level and pump insulin accordingly.

Even as Nair drives his team to develop the advanced micro-electro-mechanical system-based version of the pump, and even disposable ones, Nair is "struggling" to get a licensee who can keep the price low in bringing the device to the market. He thinks the prevailing price is high due to a monopolistic market. According to market research firm **MindBranch**, insulin pump makers Disetronic and MiniMed control 70% of the insulin pump market globally.

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Then, Nair also has to worry about the technology being bought out by multinationals which don't necessarily productize competitive technology.

"This is the story of this sector (medical devices) in this country but Nair shouldn't be rigid on pricing," says H. Vijaykumar, chief executive for **Sidd Life Sciences Pvt. Ltd** in Chennai, a company that makes three out of a pipeline of about 15 products used in open heart surgeries. "If companies get high competitive edge on the cost of manufacturing, then they would be attracted as multinationals will keep adding features on their existing products and play the superiority game as this sector has very long marketing gestation."

Vijaykumar has been there, done that. Prior to joining Sidd, he was part of the team that developed India's first artificial heart valve at Sree Chitra Tirunal Institute of Medical Sciences and Technology at Thiruvananthapuram that has been in use for about 15 years. The technology for the valve, which costs at least one-third of the imported ones, has been licensed to Bangalore-based TTK Healthcare for large-scale commercialization.

The Indian medical devices industry, worth about Rs15,000 crore according to the newly-formed Association of Indian Medical Device Industry, or AIMED, is dominated by imports. It's a territory left almost unexplored by Indian companies. One of the reasons,

also leading to the chicken-and-egg syndrome, is a lack of regulation. The revised guidelines of Central Drugs Standard Control Organization (CDSCO), which took four years in making and will govern the medical devices in a phased manner, is now open for comments. It'll probably take six to eight months to become law, says the industry.

“There is no interim guideline so the CDSCO is not issuing manufacturing licences and we are losing business,” said Rajiv Nath, principal forum coordinator of AIMED and joint managing director of Hindustan Syringes and Medical Devices. In the recent past, CDSCO has issued 700 licences for imports but only 45 for manufacturing, he added.

Nair, who developed the pump under a generous DST grant, has had to run from pillar to post before he finally discovered that the insulin pump is not covered under the lean list of products under CDSCO—the product could just be produced and marketed. But he is following the European CE marking (a European Union certifying standard) guidelines.

“We’d better be safe than sorry; in the past some insulin pumps have been recalled from the market due to functional defects,” he notes, even as some of his innovations, such as the dual microprocessor control and the complementary software, offer better control of insulin delivery in the device.

Experts say long-term view of policies is needed so that start-ups—where, traditionally, most new technologies get invented—don’t get wiped out. The current attitude of granting licences to only large entities setting up big plants will ruin this sector, says Nath.

On the other hand, there’s a danger of disruption to the distribution model as it has happened in the West, Europe particularly, says Nath, where a changing marketing landscape has led manufacturers to directly sell to large hospitals. “In a large, diversified market like India, the role of distributors is important.”

On their part, funding agencies have increased their support for research and development, including the ongoing Stanford-India Biodesign Project at the All India Institute of Medical Sciences in New Delhi, but industry will be attracted only when the regulatory environment improves.

“India will have 45 million diabetics by 2020. Even if a fraction of that population uses the insulin pump, which is increasingly being recommended not only for type I but type II diabetics as well, there’s at least Rs500 crore market out there,” says Nair.

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