MED DEVICE ONLINE

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India Introduces Sweeping — And Welcome — Device Regulations

By Gunjan Bagla and Rajnish Rohatgi, Amritt, Inc.

Since 2002, American companies have lobbied for clearer oversight of medical device sales and manufacturing in India. As of January 2018, they will have their wish. Under a mandate to improve patient safety while improving the ease of doing business, Prime Minister Narendra Modi's Ministry of Health published a 108-page notification covering the regulation of the manufacture, sale, and possible recall of virtually all kinds of medical devices, whether imported or domestic.

Current Situation

In India, 15 medical device categories have been regulated as if they were a kind of pharmaceutical drug; all other categories have been virtually unregulated. The regulators' staff have lacked the training to deal with novel devices, and approval processes can take from a year to two or three years. Every three years, companies must re-apply for approval. The regulations stipulate that, if there is a "change in constitution" of the selling company, a new approval must be sought before sales can continue; this often causes product to be unavailable during the transition.

In such an environment, some companies have been able to freely sell unsafe or obsolete devices in India, devices that would likely not pass muster in any major economy. This is, of course, unsafe for patients, and also puts medical providers at risk. At the same time, European and American companies have been reluctant to take the market risk of introducing many of their products into India due to regulatory uncertainty, denying Indian patients of the best medical care available in other markets.

Innovation also has suffered, since investors, designers, and manufacturers have felt uncomfortable about approval timelines and about unscrupulous competitors (who may cut costs, for example, by not using clean room manufacturing or global quality standards).

Major Changes

Device Licenses now will be granted in perpetuity, not just for three-year terms. The manufacturer simply has to pay a renewal fee every five years if the product still is being marketed. For imported devices, the approval or rejection will take a predictable maximum of nine months; device registration will automatically imply an import license, without the need to wait an additional three months for the import license. Multiple devices produced at the same factory can now be included in a single application, and the application must be filed completely online. There is a proactive time commitment in the regulations. If the regulatory authority fails to complete the process within the specified time, a license shall be "deemed" to have been approved; this is a novel concept in Indian bureaucracy.

These improvements will enable foreign and Indian companies to embrace market opportunities more aggressively, and will benefit millions of Indian patients, doctors, and hospitals.

All devices must be designed, produced, sold, and serviced according to standards: either those published by the Bureau of Indian Standards, the International Standards Organization (such as ISO 13485, ISO 14971, ISO 10993), the International Electro-technical Commission (IEC), or the manufacturer's own standards (in case none of the preceding is applicable to an innovative device). Since these standards apply to all devices, errant manufacturers will now be called to task for violations and risks to patient safety. Western companies that have largely been compliant with such standards for decades will have a temporary advantage while less sophisticated players from India and emerging countries update their processes.

All devices now are covered in a four-class system consistent with International Medical Device Regulators Forum (IMDRF, formerly known as the Global Harmonization Task Force) guidelines. Class A devices are deemed to have the lowest risk (typically, non-invasive products), while Class B may be invasive for short-term use (e.g., syringes and catheters). Class C and D devices will be those considered moderately high-risk or high-risk. The regulator, not the designer or manufacturer, will classify devices into appropriate risk categories.

Imported devices where the manufacturer possesses a "Certificate of Free Sale" in Australia, Canada, the European Union, or the United States will not be subject to clinical trials (clinical investigations). On the other hand, prior to Indian manufacture of Class C and Class D devices, the government will conduct a mandatory inspection of the facility (this applies whether the manufacturer is Indian or foreign). In addition, the new regulations require that devices must be labeled, and instructions for use must be provided. Manufacturers are required to report major adverse events anywhere in the world to the Indian regulator within 15 days.

Whether from India or the West professional companies overall welcome the implementation of standards-based design and manufacture. Grey market operators from emerging countries may find themselves at some risk and subject to higher regulatory review, especially if they don't have free sale certificates in Australia, Canada, the European Union, or the United States.

Bloomington, Indiana-based Cook Medical operates a unit in Chennai, in India's southern state of Tamil Nadu. General Manager Vijayan Govindaraman calls the new rules "a positive step by the government to a long-standing demand by industry to frame separate regulations for medical devices."

India plans to train 200 of its 3,000 drug inspectors immediately in the operation of the device regulations. Govindaraman goes on, "This will positively impact the industry. Implementation and training the officers, coordination between central and state governments and setting up an online portal are key" to rollout of the new regulations in 2018. He feels that multinational corporations will be encouraged to introduce more devices into the Indian market with the implementation of these new regulations.

Conclusions And Next Steps

While the devil will lie in the detailed implementation of these new regulations (after India's parliament approves them), we think that device companies and patient advocates have much to celebrate. We expect that the Indian government will encourage foreign companies to leverage local manufacturing opportunities. To that end, it may make sense for Western companies to start looking at greenfield manufacturing in India; others may wish to buy and bolster small and medium-sized Indian companies, who will appreciate the global expertise in building up their own capabilities.

Note: This brief article is not meant to provide regulatory advice; it also excludes many salient details about the role of state versus federal authorities and the processes relating to manufacturing in India. For a copy of the complete regulations and for specific insights into a particular situation, email usa@amritt.com.

About The Authors

Based in Los Angeles, Gunjan Bagla is managing director of Amritt Inc., a California-based consulting firm focused on helping American companies to succeed in India. His clients include Covidien (now Medtronic), Roche Diagnostics, BD, Lifenet Health, Johnson & Johnson, Gojo, and many more. Gunjan spoke three times at the MD&M West Conference in Anaheim, and was on the keynote panels at MEDevice San Diego and IMDI in Ahmedabad, India.

For his India expertise, he has appeared in The New York Times, the Los Angeles Times, and the Washington Post, and on Bloomberg TV, BBC Television, and Fox Business News. He also writes about India for the Harvard Business Review and the Huffington Post. Gunjan has an MBA from Southern Illinois University and a mechanical engineering degree from the Indian Institute of Technology (IIT) Kanpur in India.

Based in New Delhi, India, Rajnish Rohatgi is a senior advisor for Amritt's Medical Technology Practice. He spent over seven years building BD's medical surgical business in South Asia. Rajnish has over 25 years of marketing, sales, and leadership experience in India and Africa in the healthcare, medical device, and consumer sectors. This includes a stint as VP of marketing for Max Healthcare, a leading hospital chain in North India.

Among his key accomplishments at BD was pioneering a customer-centric segmentation strategy, followed by tight tactical execution, to win against low-cost local competitors. At Max Healthcare, Rajnish developed one of the first branding strategies for a healthcare provider in a market where the only brand had been the physicians themselves. Rajnish has an MBA from the Indian Institute of Management Calcutta (which was established by MIT's Sloan School) and a bachelor's degree in metallurgical engineering from IIT Kanpur.