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20% of US import alerts were for Indian products last year

INTERVIEW

MARGARET A HAMBURG

USFDA COMMISSIONER

With many Indian pharma companies being red-flagged, the issue of compliance and regulatory standards set by FDA is creating an image problem for the country. In an interview with ***Soumonty Kanungo****, FDA's* ***Margaret A Hamburg*** *says training will help. Excerpts:*

■ Going by the present regulatory hurdles faced by some major Indian drugmakers, how do you feel most Indian companies can meet the issue of compliance, quality and regulatory standards set by FDA before it becomes a growing problem across the sector?

Many Indian firms understand good manufacturing practices and use them. The problems we've seen with companies are why we have chosen to make quality one of our highest priorities this year. Whether innovator or generic, building quality is how companies must build their reputation and why patients and healthcare professionals will build trust in their products. Quality is the basis of public confidence in pharmaceuticals and confidence in the high quality of products being produced at American facilities is what has helped to make the US pharmaceutical industry the gold standard for the world.

■ Why do you think it is so difficult for Indian companies to be compliant with good manufacturing practices in the first place?

Ensuring that the products distributed in the United States meet our requirements for product safety and quality is among my top priorities as commissioner. Unfortunately, the many Indian companies that understand good manufacturing and quality processes have been overshadowed by recent lapses in quality at a handful of pharmaceutical firms. While the FDA will take appropriate action against any company that doesn't meet our requirements, we are also willing to work with them to address their issues. All consumers deserve access to safe and affordable drugs and should not have to sacrifice quality to get that. Officials at India's ministry of health and family welfare share this goal. In the spirit of continued collaboration and a commitment to quality, our agencies signed the first-ever

statement of intent. Our organisations plan to collectively work together to improve the lines of communication between our agencies and work diligently to ensure that the products being exported from India are safe and of high quality.

■ The USFDA is to conduct training sessions with the pharma industry here to bridge the gaps in manufacturing practices. Is this a regular practice of the FDA to conduct such training or is it especially for countries, which fail to live up to the regulatory standards and compliance issues?

The establishment of an FDA India office has allowed us to collaborate more effectively with our Indian regulatory counterparts and enables us to leverage our combined resources, ensure standards consistency and increase regulatory capacity, which includes information sharing, exchange programmes and specialty training. Through our India office, the FDA also works to ensure that Indian manufacturers shipping to the United States understand the risks associated with their product's processes and that they remain compliant with the FDA's requirements for product quality, safety and, as applicable, efficacy. And our presence in India allows us to better collaborate with our Indian regulatory counterparts and enables us to leverage our combined resources, harmonise science-based standards and increase regulatory capacity. In doing so, the FDA continues to help ensure that products intended for US consumers moving in international commerce are safe, effective and of high quality.

Safety concerns

483s issued during human drug pre-approval and good manufacturing practice inspections in FY13

Category	no issued
483s issued in India	78
All foreign 483s issued	384
All domestic 483s issued	655

* Does not include inspections for the President's emergency plan for Aids relief (PEPFAR), bioresearch monitoring (BIMO) inspections such as clinical trial sites and adverse drug experience inspections.
Note: Data extracted from FACTS on 2/3/2014

■ How exactly does FDA ensure that the product manufacturers comply with the set standards and regulations?

Through a variety of methods, including scientific reviews, inspections of facilities and post-market surveillance, FDA strives to ensure that regulated product manufacturers, wherever they may be located, comply with standards and regulations for their products provided to the US consumers. FDA seeks to ensure that Indian manufacturing facilities importing to the United States understand the risks associated with their product's processes and assure they remain compliant with FDA regulations.

■ While Ranbaxy, Wockhardt and Strides Arcolab have received an import alert from FDA in the recent times, receiving Form 483s seems a rather common phenomenon in India. Is it really such a commonplace thing? How frequent is this phenomenon in the case of other countries?

In FY13 (which ended September 30, 2013), FDA issued 78 Form 483s in India, and a total of 384 foreign inspectional findings. So Form 483s issued in India comprised 20 per cent of all foreign 483s issued in FY13.

■ With the current regulatory issues, will FDA now be more careful before giving approvals to Indian companies manufacturing drugs to the US market?

FDA must, by regulation, conduct a formal standard review of applications submitted by companies worldwide before granting an approval. Indian companies, like all others around the world, must continue to focus on quality in the development and manufacturing of drug products. As I said earlier, whether innovator or generic, building quality is how companies must build their reputation and why patients and healthcare professionals will build trust in their products.

soumonty.kanungo
@mydigitalfc.com

Regulatory