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'Indian regulatory system very hierarchical'

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Singapore: In an effort to smoothen out the understanding of global regulations amongst Indian companies, Ms Carolyn Beeden, General Manager and Mr Ash Ramzan, Principal Consultant, Woodley BioReg have been working very closely with many firms.

In the light of global regulatory patterns leading towards harmonization, the FDA has initiating many programs like the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, Pharmaceutical Inspection Cooperation Scheme and the Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee.

However, the understanding of all these regulations and the changes in it, often gets misinterpreted or completely ignored by firms across the world. This is where UK based healthcare consulting firm, Woodley BioReg gets into the picture, Mr Ramzan explained.

"We deal with generics and have been helping companies file documents that are aligned with the regulations," he added.

"Some of the main problems that we have encountered amongst Indian firms when it comes to regulations is recalls, shutdowns and import alerts being issues - which are most prevalent problems. We look at analyzing the problem, fixing it and then even preventing it in the future," explained Mr Beeden.

She added that though the number of manufacturers in India is huge, documental evidence suggests that many do not really understand the nuances behind the current Good Manufacturing Practices.

"Further, there is a need for non-biased assessment based on not just understanding of FDA's regulations, but also the regulations in place in other geographies. Each individual market is different," she explained.

Further, Mr Ramzan added that while overall regulatory harmonization is a great idea, it is not practically possible. "The mindset in the US is of having one single body taking care of everything. As per the recent talk on harmonization, what will happen is that the EU will probably hand over the audits and FDA will implement," he said.

Speaking of India, they said that while India has been able to grab the bulls by the horns in the case of generic manufacturing, it has been proactive in BioSimilars too, even though they suggested that there is still a long way to go.

"India is struggling in establishing its own regulatory framework. The system is very hierarchical, you can't tell the higher ups that something is wrong. The Indian board has no teeth. The Indian Patents Act 1970 did away with protection of product patent process. There was no monopoly on product," he explained.

That said, they specified that as per their estimates, India is third largest when it comes to volume and eight largest when it comes to price. One out of five formulations are from India. The potential of need for help with understanding regulations is amongst the highest here, they opined.

FDA's efforts towards harmonization
FDA's role in harmonization and multilateral relations is to coordinate and collaborate on activities with various international organizations and governments on international standards and harmonization of regulatory requirements.

Recognizing the considerable synergy between its domestic policy and its international policy priorities, FDA is sharpening and focusing its planning for enhanced alignment of FDA and international standards. In recent decades, great changes in the world economy, together with expanded working relationships of regulatory agencies around the globe, have resulted in increased interest in international harmonization of regulatory requirements. Increased international commerce, opportunities to enhance public health through cooperative endeavors, and scarcity of government resources for regulation have resulted in efforts by the regulatory agencies of different nations to work together on standards and harmonize their regulatory requirements. Such harmonization enhances public health protection and improves government efficiencies by reducing both unwarranted contradictory regulatory requirements and redundant applications of similar requirements by multiple regulatory bodies. FDA's goals in participating in international harmonization are:

â€¢ To safeguard global public health,
â€¢ To assure that consumer protection standards and requirements are met
â€¢ To facilitate the availability of safe and effective products
â€¢ To develop and utilize product standards and other requirements more effectively
â€¢ To minimize or eliminate inconsistent standards internationally

FDA's harmonization efforts are intended to pool regulators' resources in developing standards for public health protection; reduce industry's compliance costs in the global market, and minimize impediments to bringing safe food and safe and effective treatments to consumers and patients around the world.
Source: FDA Website