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Pharma companies see need for tighter compliance procedures

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Worried about the increasing global enforcements faced by domestic manufacturing facilities, leading Indian pharmaceutical companies say the industry needs to tighten its compliance procedures and raise investment in quality to ensure its share in the global market remains intact.

"There are concerns as well as awareness due to the stringency in regulations. Quality and compliance is a continuous process. It is certainly important for the industry to focus on ensuring there are robust systems in place for compliance," says Biocon Chairman and Managing Director Kiran Mazumdar-Shaw. She said the sudden rise in enforcements was because of the growing market share of Indian drug manufacturers globally. "Domestic companies represent a significant part of the global drug industry and, therefore, there is an increase in the scrutiny of these companies. Also, with the presence of US FDA (Food and Drug Administration) in India, now, there are frequent audits compared to periodic reviews earlier," she added.

Kiran Mazumdar-Shaw, Biocon chief, says the sudden rise in global enforcements is due to growing market share of Indian drug manufacturers

The total number of US import alerts imposed on domestic manufacturing facilities increased significantly this year. Of late, some facilities of major drug makers such as Ranbaxy, Wockhardt and RPG Life Sciences were barred from supplying products to the world's largest pharmaceuticals market. Wockhardt's Waluj facility received enforcements from the UK drug regulator and has, subsequently, been barred from supplying medicines to the whole of Europe. So far this year, Indian manufacturing facilities have received a total of 13 import alerts, compared with seven in China and two each in Australia, Canada and Japan.

However, drug makers, analysts and other stakeholders *Business Standard* spoke to brushed aside arguments the enforcements were targeted at Indian drug makers. "The bottom line is compliance, and there are no short cuts to ensuring quality. I don't think recent regulatory actions by the US FDA are directed against Indian pharmaceutical companies alone. I have seen the warning letters issued to the US and other companies globally and all the FDA is trying to do is differentiate the good manufacturers from the not-so-good ones globally," said Vinita Gupta, chief executive, Lupin Pharmaceuticals.

Industry officials and experts emphasised while some violations had recently been highlighted by international regulators, this didn't imply all Indian manufacturing facilities were non-compliant.

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