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Are strict regulatory compliances responsible for supply shortage and manufacturers' withdrawal from injectables?

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Every governmental regulation has benefits and cost. The same applies to Food and Drug Administration (FDA) regulations as well. Drug regulators ensure that harmful drugs do not reach consumer hands, while also holding responsibility for the cost of delays. At times, they do prevent beneficial and much needed drugs from reaching consumers as well. Several studies in the past have quantified Type I errors (FDA allowing harmful drugs) and Type II errors (FDA disallowing beneficial drugs) and the results indicate that the harm caused from Type II errors, far exceeds those from Type I errors.

The beginning of 2010 experienced sudden spike in shortage of generic injectables due to FDA's intensified inspection and compliance efforts. This made four of America's largest manufacturers of generic injectable products to cut down on their production volume and even temporarily suspend some of their production facilities.

The FDA desired that, all injectable manufacturers take necessitated action promptly, thus resulting in shortage of injectables in the market.

Drug companies receive strong incentive to maintain quality from an ongoing quality concern perspective. Else they run the risk of being out of business due to regulatory penalties like import alerts, fines imposed, product recalls or close of manufacturing facilities. The question then arises, if there is over regulation such as, to an extent of not striking balance between benefits of continuous remediation efforts of FDA inspection observations versus creating shortage of medicines to consumers. Maybe, a balanced approach by FDA could have avoided some of the injectable drug shortages.

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Over the last couple of years, vast product shortages were reported in the US and most of them were related to the sterile injectable drugs. There were many reasons for these shortages, which included – quality/manufacturing issues, discontinuation of products by manufacturers, limited number of Active Pharmaceutical Ingredients (API) suppliers for older injectable drugs and small number of manufacturers with limited production capacities. However, the situation has improved considerably this year, with many manufacturers regaining FDA approvals for their facilities and thus, resuming supplies of injectable drugs to the US.

Strict regulatory compliances are necessary for every pharmaceutical product and the quality standards are expected to be even higher in the case of sterile injectable drugs. Such strictures would help in ensuring that the product manufactured in these facilities would be of highest quality standards and absolutely safe for consumption by critically ill patients.

Therefore, we believe that the FDA's enforcement of stricter Good Manufacturing Practice (GMP) standards will positively impact the industry. Furthermore, the recent introduction of Generic Drug User Fee Amendment (GDUFA) by FDA is expected to approve generic drugs at a much faster pace. This will lead to increase in the availability of injectable drugs in the US market.

Business is always about rising to meet shortages and improve gains. Companies known for their excellence in managing sterile facilities have taken cognizance of the supply shortages and set up new injectable facilities. Hence, according to my opinion stricter FDA regulations have not deterred companies from creating newer injectable facilities.

FDA's strict regulatory norms on injectables and frequent inspection drive has forced manufacturers to reconsider injectables production. Will the drive cause shortage for much needed drugs to consumers or further strengthen the drug supply value chain? Our experts analyse the various aspects of it and opine on the issue.