

SURPRISE US FDA INSPECTIONS: CAUSE FOR ALARM?

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What is the surprise inspection project?

The USFDA will conduct unannounced inspections of manufacturing plants in India and China in an attempt to uphold the quality standards of drugs that are supplied to the US market. Under the current practice, the USFDA gives advance notice to foreign manufacturers before it begins its regulatory inspections. The current pilot, however, is an attempt to ensure that domestic drug makers in the US get a level-playing field with their foreign counterparts. The House of Representatives has granted the USFDA \$5 million to implement this pilot programme, starting from India.

What's bothering Indian generic firms?

Due to the pandemic, the USFDA had suspended all its foreign inspections over the last two years—no Indian drug maker had to deal with the regulatory uncertainty of a warning letter or supply ban. This is set to change. In 2014, a similar 'surprise' inspection pilot was started by the FDA. The move led to a 60% increase in regulatory action against generic companies. Between 2014 and 2015, India's top five generic companies collectively lost a market cap of 15 billion. The whole episode left a bitter taste and subsequently, many companies made the hard choice of diversifying from the lucrative US drug market.

What happened to the 2014 pilot?

The unannounced visits stopped in 2015. In a representation to the US congress, the FDA said it had to discontinue as it lacked protocols and evaluation criteria. Since then, it has shifted its focus towards 'risk-based inspections' that helped the body prioritize resources. Yet, the House of Representatives has asked the FDA to pursue this initiative again.

Is there a political motive to the move?

Around 40% of the finished drugs sold in the US are made outside the country. The clamour to safeguard the drug supply chain and bring manufacturing closer to the US has grown since the Trump era. Two Republican senators now want to amend an FDA regulation that would give FDA inspectors powers to inspect foreign plants without prior notification. Though the senators appear to be targeting China, Indian firms will face the scrutiny first—the current covid-19 travel curbs are less stringent in India compared to China.

What can Indian drug companies do?

Generic companies that have a large US business are evaluating the impact that these visits could have. The Indian Pharmaceutical Alliance, the lobby group of large Indian generic manufacturers, is seeking inputs from member firms. Large drug makers such as Sun Pharma, Dr. Reddy's, and Lupin have already started diversifying their business beyond the US market. This would continue. There is also a possibility of firms asking the Indian government to intervene and initiate dialogue with the Joe Biden administration.

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