India US - Import Alert

Why in news?

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The stock of Divi's Laboratories dropped over 20% following the announcement that one its facility has received an import alert from the US drug regulator U S Food and Drug Administration (FDA).

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What is import alert?

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- Companies that sell medicines in the US market are required to comply with the regulations mandated by the FDA.
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- Manufacturing units that supply drugs to the US are inspected by the FDA periodically.
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- If they find any lapses in the adherence to the mandated regulations, the same is notified by the FDA in Form 483 as observations.
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- This is the first level of action by the FDA in case of deviation from the **good manufacturing practices (GMP).**
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- The company is given time to respond to the observations.
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- If the reply is not convincing the FDA may issue a warning letter.
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- This letter restricts the ability of that manufacturing unit to supply drugs to the US from that facility.
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- Then the company has to appoint consultants to advice on corrective actions and its monitor implementation.
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- After this, it approaches the FDA for re-inspection.
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- If the FDA is not satisfied again, it issues an **import alert**.
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- This implies a ban on the facility from supplying drugs to the US.
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- However, there have been instances where the FDA has directly issued an import alert even without an initial warning letter.
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Why is it important?

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- The US is the largest pharmaceutical market in the world.
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- The share of Indian pharma companies in the US market has risen significantly over the past few years, catering nearly 40% of its pharma drug requirement.
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- Many patents are expected to expire in the upcoming years, opening a huge market for generic drugs from India.
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- So to an investor in pharma stocks, it is important to keep a close tab on the regulatory action by the FDA as they can pose growth risks.
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- The progression of observations into import alerts and warning letters has been increasing of late.
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- So investors need to focus on the speed with which a company resolves these issues.
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Source: Business Line

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