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USFDA opens door to drug import

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The import of the drugs would be limited to the drugs that are off-patent and have no exclusivity remaining

US Department of Health & Human Services (HHS) said that the Donald Trump administration is working on ways to import drugs from other countries. US President Trump has been vocal about the administration's concern over the soaring novel drug prices and lower competition.

In order to overcome the shortcoming and lower the price of prescription drugs, the Trump administration is now exploring ways to safely import certain drugs from foreign countries.

As per HHS Secretary, Alex Azar, USFDA is forming a working group to examine how to safely import prescription drugs from other countries in an event of a dramatic price increase for a drug produced by one manufacturer and not protected by patents or exclusivities.

This working group will examine the potential to promote competition for drugs that are off-patent or off-exclusivity and produced by one manufacturer. This stands in contrast to proposals to import a broader range of drugs, which raise additional questions about how to protect American patients.

The working group will consider drugs unprotected by patents or exclusivities, which will allow other manufacturers to introduce new competition. Importation will be limited to cases where drugs can be imported with adequate assurances of safety and effectiveness.

Because the drugs being considered for importation are off-patent and have no exclusivity remaining, the proposals contemplated by the working group would not dilute intellectual property rights or affect incentives for innovation. Rather, they would provide a new avenue for competition to drive down prices for American patients.

This is positive for Indian pharma industry as India is having highest number of USFDA approved drug manufacturing plants outside the US. If this opportunity comes, Indian companies are likely to benefit.