Issues with USA's Policy on Drug Vigilance

Why in news?

US recently highlighted the fraud concerning generic drugs manufactured oversees, especially in India.

What are the issues with drug manufacturers?

- Allegations of widespread fraud concerning generic drugs manufactured overseas, were recently highlighted in the U.S.
- Much focus was on the contamination found in one drug made by Ranbaxy.
- For instance, the Ranbaxy saga unfolded 14 years ago, since then, several pharmaceutical companies, both foreign and local, generic and innovative, have been implicated in similar or worse behaviour.
- Notable examples include those of Martin Shkreli's Turing Pharmaceuticals, which hiked the price of a drug to 5,000%, and Purdue Pharmaceuticals, a company currently implicated for causing the opioid crisis.

What are the concerns with USA's action in this regard?

- USA's Food Safety Modernization Act (FSMA) has a provision to conduct global inspections.
- One objective in thus empowering the Food and Drug Administration (FDA) was to work with regulators of foreign countries and create a universal Current Good Manufacturing Practice (CGMP) system for drugs.
- Instead, the FDA has positioned itself as a 'global regulator'.
- For example, in a recent statement, it mentioned that it inspects all brand-name and generic manufacturing facilities around the world based on information from whistleblowers or out of concern for drug safety.
- Arguably, this amounts to regulatory overreach as there is no international instrument standardizing American CGMP practices as the

global standard.

- In 2018, out of the 4,676 human pharmaceutical sites inspections that the FDA conducted worldwide, 61% were of foreign-based facilities.
- Similarly, out of 1,365 human drug CGMP surveillance inspections conducted, 55% were conducted at facilities outside the U.S.
- The FDA's publicizing of its 'global vigilante experience' paints a picture of foreign-manufactured drugs as 'defective' or 'contaminated' while not fully acknowledging some of the regulatory failures within America.
- US doesn't have a proper scale to measure defectiveness of a drug, this provides a loophole, enabling the regulator to cherry-pick and treat all instances of non-compliance as egregious violations.

What lies ahead for India?

- USA's strategy of raising fears of 'contaminated' foreign generics has successfully prejudiced Americans against valid generic drugs, even though they have remained a viable option.
- For India, the discussion in the U.S. is notable not only because it houses generic manufacturing facilities but also because India is a nation on the verge of breaking into the innovation market.
- Thus, it is time India took a more robust role to ensure public availability of facts on both the importance of generics and their limitations.
- The country needs to create strong voices and partnerships that can highlight the benefits and pitfalls alike to create a robust space for innovation that can coexist with access to medication.

Source: The Hindu