Contamination Concerns over Indian Eye drops in US

Why in News?

US Centers for **Disease Control and Prevention (CDC)** and the **Food and Drug Administration (USFDA)** have raised concerns over a **drug-resistant bacteria strain allegedly linked to eye drops imported from India.**

- **Drugs Controller General of India (DCGI)** has written to the USFDA seeking details about the issue.
- Global Pharma Healthcare is recalling EzriCare eye drops from the US market and has halted the Production of ophthalmic (connected with the eye and diseases that affect it) products until the investigation is completed.
- Preliminary Reports by the Healthy ministry in India suggest contamination in the US came from opened bottles; as samples collected from the company were not contaminated.

What is the Status of Indian Pharmaceutical Sector?

- The **Indian Pharmaceuticals industry** plays a prominent role globally. **India ranks 3rd worldwide for production by volume and 14th by value.**
- The nation is the **largest provider of generic medicines** globally, occupying a **20% share in global supply by volume,** and is the **leading vaccine manufacturer** globally.
- India is **home to more than 3,000 pharma companies** with a strong network of over 10,500 manufacturing facilities as well as a highly skilled resource pool.

Note

- Previously in 2022, the **World Health Organisation (WHO)** had issued an alert about four **Indian-manufactured cough syrups**, which are said to be linked to acute kidney injury in children and 66 deaths in the small West African nation of The Gambia.

Drugs Controller General of India (DCGI)

- The **Drugs Controller General of India (DCGI) is the head of the** Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare.
    - The **CDSCO is responsible for approving licenses for specified categories of drugs,** such as blood and blood products, IV fluids, vaccines, and sera in India.
- The DCGI is also responsible for setting standards for manufacturing, sales, import, and distribution of drugs and medical devices in India, as well as ensuring uniformity in the enforcement of the **Drugs and Cosmetics Act,1940.**
- In addition to these responsibilities, the **DCGI acts as an appellate authority in case of disputes regarding the quality of drugs and prepares and maintains the national reference standard for drugs.** Furthermore, DCGI is the **central licensing authority** for medical devices that fall under the **Medical Device Rules 2017.**

Source: TH