Drug Recall

- **For Prelims: Drug Recall, Not of Standard Quality,** The Drugs and Cosmetics Act, 1940, Drugs Controller General of India, CDSCO.
- **For Mains:** Need for Drug Recall Law in India.

Why in News?

Recently, a pharmaceutical company inadvertently **shipped a Mislabeled batch of Drugs to the market**, which highlights the **issue of circulating substandard drugs** in the market and need for **Drug Recall Law in India.**

- While such recalls take place regularly in the U.S., including by Indian companies, but not seen in India.

What is a Drug Recall?

- A drug recall occurs when a prescription or over-the-counter drug is removed from the market **because of its harmful or side effects.**
- Drug recall is the process of **removing or correcting a marketed drug product** that violates the laws and regulations governing the safety, efficacy, or quality of a drug.
- Drug recalls are typically issued **when a product is found to be defective, contaminated, mislabeled, or poses a risk** to the health and safety of patients.
- The goal of a drug recall is to **protect the public from harm** by removing the affected product from the market, and to provide a remedy or refund for consumers who have already purchased the product.

What is the Need for Drug Recall Law in India?

- It is crucial for India to have a national Drug Recall Law to guarantee that once a drug is known to be **Not of Standard Quality (NSQ)**, the entire batch is withdrawn from the market.
    - Currently, **there is no such Law in India to withdraw the entire batch of substandard drugs** from the market.
- At most state **drug regulators can order a withdrawal of a particular batch** from their state but given that India is a common market, it is possible that the **same batch is dispersed across multiple states.**
- In such a case, there needs to be a central drug regulator who can execute and coordinate national recall.
- Despite flagging this as a major issue in 1976, India still lacks a **national law on recalling drugs.**
    - As a result, even after government analysts declare drugs to be NSQ, there is no system to **actually withdraw batches of drugs from across India.**

Why does India not have Regulatory Infrastructure for Substandard Drugs?

- **Apathy and Lack of Expertise:**
    - The Drug Regulation Section of government is not up to the task of **tackling complex drug regulatory issues** due to a combination of different factors including **apathy, lack of expertise in the area**, and a greater interest in enabling the growth of the pharmaceutical industry than **protecting public health.**
- **Fragmented Regulatory Structure:**
    - India has a highly fragmented regulatory structure, with **each state having its own drug regulator.**
    - But despite the fragmentation, **drugs manufactured in one state can seamlessly cross borders** to be sold in all states around the country.
- **Opposition to Centralised Regulatory:**
    - Both the pharmaceutical industry and state drug regulators **have resisted greater centralisation** of regulatory powers.
    - The incompetence of a regulator in just one state can **lead to adverse effects for patients in other states**, whose citizens have no influence or electoral power to demand accountability of that regulator.
- **No Interest within Government:**
    - There appears to be no interest within the government and **no sustained demand from civil society** for reform.
    - The government is more invested in the **growth of the pharmaceutical industry rather than public health.**
    - There is possibly a perception that **tighter regulation could slow the growth of the pharmaceutical** industry.

What are the Implications of Delay in Framing any such Law?

- When substandard drugs are not promptly recalled from the market, it can have **serious consequences for consumers**, including illness and even death. However, in India, the process of drug recall is often slow and ineffective, leading to a **dangerous situation for the public.**
- If the government does not take swift action to recall substandard drugs, it could **indicate a lack of accountability and responsibility towards the health** and safety of the people.
- Furthermore, delaying the recall of these drugs could lead to a **loss of public trust in the healthcare system** and the government.

How Drugs Are Regulated in India?

- **The Drugs and Cosmetics Act:**
    - **The Drugs and Cosmetics Act**, 1940 and Rules 1945 have entrusted various responsibilities to central and state regulators for regulation of drugs and cosmetics.
    - It provides the regulatory **guidelines for issuing licenses to manufacture Ayurvedic, Siddha, Unani medicines.**
- **Central Drugs Standard Control Organisation(CDSCO):**
    - Prescribes standards and **measures for ensuring the safety, efficacy and quality of drugs**, cosmetics, diagnostics and devices in the country.
    - Regulates the **market authorization of new drugs and clinical trials standards.**
- **Drugs Controller General of India:**
    - DCGI is the head of department of the CDSCO of the Government of India responsible for **approval of licences of specified categories of drugs** such as blood and blood products, IV fluids, vaccines and sera in India.
    - DCGI also sets **standards for manufacturing, sales, import**, and distribution of drugs in India.

Way Forward

- If health activists accept there is a problem with drug regulation and ask for systemic reform, they will **add to the medley of voices asking for reform.** Right now, there appears to be a

reluctance to even accept there is a problem with drug quality in India.

- To create an effective recall mechanism, the **responsibility of recalling drugs has to be centralised**, with one authority that has the legal power to hold companies liable for failures to recall drugs from across the country, and further, to also search and seize batches of failed medicine.

Source: TH