Abbott India's Digene Gel Antacid Syrup Recalled

Source: TH

Why in News?

Abbott India's popular antacid syrup, **Digene Gel,** manufactured at its **Goa facility,** is being **voluntarily recalled** due to isolated customer complaints regarding **taste and odor.**

- The **Drugs Controller General of India (DCGI)**, who leads the **Central Drugs Standard Control Organisation (CDSCO)**, further recommended that healthcare practitioners exercise caution when prescribing Digene Gel.

What is Digene Gel?

- Digene Gel is a popular **antacid syrup** known for **relieving acidity and its associated symptoms,** including heartburn, stomach discomfort, abdominal pain, and gas.
    - The antacid's primary mechanism of action involves the **use of basic compounds like magnesium hydroxide** to neutralize stomach acid.

What is a Drug Recall?

- A drug recall is a **process in which a pharmaceutical company or regulatory authority removes a specific medication from the market** due to safety concerns, defects, or other issues that may harm patients or consumers.
- Presently, **India does not possess legislation that empowers the recall of complete batches of substandard drugs.**
    - The establishment of a comprehensive Drug Recall Law in India is imperative. Such a law would ensure that **when a drug is identified as being of substandard quality (NSQ), the entire batch is promptly removed from circulation in the market.**

Central Drugs Standard Control Organization:

- The **Central Drugs Standard Control Organization (CDSCO)** is the Central Drug Authority for discharging functions assigned to the Central Government under the **Drugs and Cosmetics Act, 1940.**
    - CDSCO has **6 zonal offices, 4 sub-zonal offices, 13 port offices** and laboratories under its control.
- **Major functions of CDSCO:**
    - Regulatory control over the import of drugs
    - Approval of new drugs and clinical trials
    - Meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB)
    - Approval of certain licenses as **Central License Approving Authority** is exercised by the CDSCO headquarters.

Drugs Controller General of India

- DCGI is the head of the CDSCO. The DCGI is responsible for approving licenses of specified categories of drugs such as **blood and blood products, IV fluids, vaccines, and sera in India.**

The DCGI also sets standards and **quality of manufacturing, selling, import and distribution of drugs in India.**