

# 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 <u>Drugs Controller General of India (DCGI)</u>, who leads the <u>Central Drugs Standard</u> <u>Control Organisation (CDSCO)</u>, 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.

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