Law for mandatory recall of substandard drugs

Why in news?

There is rise of substandard drugs in the India due to lack of regulatory standards and no law to recall drugs.

Why the drugs failure in the Indian market is on the rise?

- **Fragmented regulatory structure** - Since each state have its own regulators and there are totally 38 drug regulators in India, so if a drug is banned from one state it can be sold in another state.
- **Jurisdictional issues** - Many regulators has led to inconsistent enforcement of the law and jurisdictional issues.
- **No focus on process** - The Indian system is still oriented towards end products (medicines sold in the market) rather than processes.
- **No transparency** - There are no transparency requirements or mandatory disclosures of medicinal requirements in the law.
- **Drug regulation being complex** - Drug regulation section of the union health ministry find it difficult to regulate since the regulation process is complex.
- **Lack of expertise** - In the drug relation section of the union health ministry.
- **Pharmaceutical industry over protecting public health** - The government has greater interest in enabling the growth of the pharmaceutical industry than protecting public health.
- **No law on drug recall** - Even though government has been mulling for a binding a law on drug recall since 1976, there exists guild lines for drug recall.

What are the measures taken for law on drug recall?

- **Drugs Consultative Committee (DCC)** - In 1976 discussed the issues of recall of bad drugs.
- The meeting resolved to have greater cooperation between various state drug controllers in order to facilitate better coordination to recall and destroy drugs that failed tests.
- **Parliamentary Standing Committee on Health & Family Welfare** - In 2012 raised the issue of recall of drugs but it didn't materialize.
- **Central Drugs Standard Control Organization (CDSCO)** - Proposed a set of draft recall guidelines, but the national regulator didn't convert the guild lines into the binding law.
- To know more about CDSCO click here.

- **Drug Controller General of India (DCGI)** - Announced that the guild lines proposed by the CDSCO will be converted into the binding law but it didn't materialize.
- **Drugs Technical Advisory Board (DTAB)** - Also discussed the issues concerning the recall on drugs but there was no resolution taken.

What is the way forward?

- To have comprehensive and clear public health policy that prioritizes public health over profit.
- To create an effective recall mechanism, the responsibility of recalling drugs has to be centralized so as to have legal responsibility over the drug companies.
- All manufacturing facilities should be licensed by a single national regulator so that it can be held accountable.
- The health activist have to work in tandem with the government to remove the substandard drugs in the Indian market.

Quick facts

Drugs Technical Advisory Board (DTAB)
• DTAB is highest statutory decision-making body on technical matters related to drugs in the country. • DTAB is constituted as per the Drugs and Cosmetics Act, 1940. • DTAB is part of Central Drugs Standard Control Organization (CDSCO) in the Ministry of Health and Family Welfare.

References

1. The Hindu | Issues Concerning Law To Recall Bad Drugs
2. Live Mint | Recall Law On Bad Drugs
3. CDSCO | About DTAB