# 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) |
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| • DTAB is highest statutory decision-making body on technical matters related to drugs in the country.<br>• DTAB is constituted as per the Drugs and Cosmetics Act, 1940.<br>• 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