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Regulatory reform stuck in a loop in Health Ministry

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Paper - II (Governance)

Earlier this year, the Drugs Controller General of India (DCGI), working under the direct control of the Ministry of Health and Family Welfare, announced policy initiatives on three issues: recall guidelines, guidelines on good distribution practices and the use of similar brand-names by pharmaceutical companies for their drugs.

All three measures have a direct impact on public health. Recall guidelines are meant to swiftly remove drugs that fail testing in government laboratories from the market. The guidelines on good distribution practices are meant to regulate how drugs are stored and distributed during transit and sale. The measure against confusing brand names is aimed at preventing prescription errors, wherein wrong drugs are dispensed to patients causing them harm. Unfortunately, these measures either lack the force of law or are poorly thought through.

What Are the Key Issues with Drug Regulation in India?

- **Drug Recalls:** Guidelines for recalling drugs are not legally enforceable. Despite being identified as necessary since 1976, there is no legal consequence for not adhering to these guidelines.
- **Distribution Practices:** The guidelines for how drugs should be stored and transported are not mandatory. A 2013 proposal to adopt World Health Organization standards for drug distribution was considered too difficult to implement across India's numerous retail outlets.
- **Confusing Drug Names:** Efforts to prevent pharmaceutical companies from using similar brand names for different drugs have been ineffective. A legal rule introduced requires companies to declare that their brand names are distinct, but this self-regulation is flawed and doesn't address public health concerns.

What Historical Context and Legal Precedents Exist?

- **Drug Recalls (1976):** The Drugs Consultative Committee flagged the absence of drug recall guidelines when state drug controllers noticed banned drugs were still being sold in other states.
- **Storage Standards (1974):** The Supreme Court, in Swantraj & Ors vs State Of Maharashtra, recognized the need for proper standards in drug storage, especially during transit, to prevent drug degradation.
- **Brand Name Confusion (2001):** The Supreme Court, in Cadila Healthcare Limited vs Cadila Pharmaceuticals Limited, highlighted the issue of confusing drug brand names and its impact on public health.
- **Parliamentary Standing Committee Report (2012):** The 59th report of the PSC further emphasized the need for drug recall guidelines, proper drug storage standards, and regulations on confusing brand names, creating pressure for reform, but these issues remain unresolved.

What Actions Have Been Taken?

- **Drug Recall Guidelines:** Introduced in 2012, 2017, and again in 2023 by the Drugs Controller General of India (DCGI), but they lack legal enforceability. The Ministry of Health has not made them binding, despite being flagged since 1976.
- **Distribution Practices:** In 2013, the World Health Organization's good distribution practices were discussed but not implemented due to concerns over feasibility. The proposal was revisited in 2019 after poor storage conditions were found in New Delhi, but no binding law followed.

- **Confusing Brand Names:** In 2019, after a court ruling, the Ministry of Health introduced a rule requiring pharmaceutical companies to self-certify brand name uniqueness. However, this rule has proven ineffective in addressing public health concerns.

How Effective Have These Measures Been?

- The measures have been criticized as ineffective and lacking legal force.
- A report from the Parliamentary Standing Committee in 2012 and subsequent actions have not resulted in substantial improvements.
- The bureaucracy's reluctance to implement stringent regulations continues to hinder progress.

Way Forward:

- To break the cycle of ineffective policymaking, direct intervention from the Prime Minister's Office may be necessary
- Continuous stakeholder consultations have delayed essential reforms, highlighting a leadership gap within the Ministry of Health.
- Stronger, decisive action at the highest level is needed to implement binding regulations on drug recalls, distribution practices, and brand name clarity.
- Ensuring accountability and cutting through bureaucratic delays could lead to more effective and enforceable policies that prioritize public health.

Expected Question for Prelims

Que. Consider the following statements with reference to regulation of drugs in India.

1. Central Drugs Standard Control Organization is the primary regulatory body in India.
2. Drug Controller General of India (DCGI) is responsible for approving new drugs for marketing in India.

Which of the statements given above is/are correct?

(a) Only 1 (b) Only 2
(c) Both 1 and 2 (d) Neither 1 nor 2

Answer : C

Mains Expected Question & Format

Que.: What are the major issues related to drug regulation in India? Discuss.

Answer's Approach:

- Explain drug regulation in India in the first part of the answer.
- In the second part, discuss the issues related to drug regulation in India.
- Finally give a way forward.

Note: - The question of the main examination given for practice is designed keeping in mind the upcoming UPSC mains examination. Therefore, to get an answer to this question, you can take the help of this source as well as other sources related to this topic.