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## Regulatory reform stuck in a loop in Health Ministry

(The Hindu, 10-09-24)

Earlier in 2024, three policy initiatives were announced by the Drugs Controller General of India (DCGI)

- Recall guidelines for drugs that fail testing
- Guidelines on good distribution practices (storage of drugs during transit)
- Measures against confusing brand names for drugs

### What are the main issues regarding the above initiatives?

- Bureaucratic delays and repeated consultations (lack of recall guidelines was first highlighted way back in 1976 & again by Parliamentary Standing Committee in 2012)
- The DCGI lacks legal power to make binding rules (Only the Ministry of Health has that power).
  - Therefore, India continues to have these guidelines which cannot be legally enforced and the breach of which have no legal consequences.
- Good distribution practice guidelines may be “difficult to implement” across the estimated six lakh retail outlets in the country
- Pushback from trade associations and the pharmaceutical industry
- Confusing brand names problem addressed through self-declaration doesn't solve the problem. Instead, such names should be vetted by the regulator itself as done in other countries.
- Lack of domain expertise and institutional knowledge in the Ministry of Health leadership
- Constant rotation of joint secretaries heading the Drug Regulation Section

### What can be the consequences arising due to above issues?

- Public health risks:
  - Substandard or contaminated drugs remaining in the market due to lack of effective recall mechanisms → Loss of consumer confidence
  - Degradation of drug quality during storage and transit, leading to reduced efficacy or harmful effects
  - Increased medication errors due to confusing brand names, potentially causing harm
- Economic impact:
  - Potential decrease in pharmaceutical exports if international markets lose trust in Indian drug quality
  - Increased healthcare costs due to treatment of adverse effects from substandard medications
- Legal and ethical issues:
  - Increased litigation due to drug-related injuries or deaths
  - Potential violation of the right to health, which is implicit in the fundamental right to life under Article 21 of the Indian Constitution
- International reputation:
  - Damage to India's reputation as a global leader in generic drug manufacturing
  - Potential scrutiny from international health organizations like WHO
- Innovation and investment:
  - Deterrence of investment in the pharmaceutical sector due to regulatory uncertainty

- Potential brain drain of pharmaceutical talent to countries with more robust regulatory frameworks

### What is the way forward?

- **Empower the DCGI:** Grant legal authority to the Drugs Controller General of India to make and enforce binding rules, reducing dependency on the Ministry of Health for regulatory decisions.
- **Implement binding GDP guidelines:** Enact and strictly enforce Good Distribution Practices as law, with clear penalties for non-compliance, to ensure proper drug storage and distribution.
- **Centralize brand name approval:** Establish a centralized system for vetting and approving pharmaceutical brand names, prioritizing public health and safety over industry self-regulation.
- **Strengthen recall mechanisms:** Develop and implement a robust, legally enforceable drug recall system that operates seamlessly across all states.
- **Enhance bureaucratic expertise:** Create a specialized cadre of drug regulation experts within the Ministry of Health to ensure consistent, knowledgeable leadership in policy formulation and implementation.

*Can you answer the following question?*

*Examine the challenges faced by India's drug regulatory system in implementing effective reform and suggest measures to overcome these obstacles.*

## On the challenges to road safety in India

(The Hindu, 10-09-24)

The “India Status Report on Road Safety 2024,” prepared by the TRIP Centre at IIT Delhi, only highlights India’s slow progress toward meeting international goals of reducing road accident fatalities.

- This report analyses road safety in India, using data from First Information Reports (FIRs) from six States and audits of State compliance with Supreme Court directives on road safety governance.

### What are the main findings of the report on road safety in India?

- Road traffic injuries remain a major public health challenge in India
- Most Indian States are unlikely to meet the UN goal to halve traffic deaths by 2030
- In 2021, road traffic injuries were the 13th leading cause of death in India
- Six states account for nearly half of all traffic fatalities in India (Haryana, Jammu and Kashmir and Ladakh, Punjab, Rajasthan, Uttarakhand, Uttar Pradesh).
- Pedestrians, cyclists, and motorized two-wheeler riders are the most common victims

### What are the issues with India's current road safety data systems?

- No national crash-level database exists
- Current statistics allow only basic analyses, preventing effective intervention
- Data often contains inaccuracies on key variables like victim's mode of transport
- Lack of a comprehensive crash surveillance system
- Road safety vary across Indian states
  - Per capita death rates differ more than threefold between states
  - Tamil Nadu, Telangana, and Chhattisgarh have the highest death rates
  - Only seven states have over 50% helmet usage among motorized two-wheeler riders

- Only few states have audited their highways for safety
- India fares poorly in terms of road safety when compared at global levels
  - In 1990, an Indian was 40% more likely to die in a road accident than someone in Scandinavian countries. By 2021, this figure had increased to 600%

**What is the way forward?**

- Establish a national crash surveillance system:
  - Develop a centralized, real-time database for all road crashes
  - Ensure accurate data collection on key variables like victim's mode of transport
  - Make this data publicly accessible for research and policy analysis
- Strengthen state-specific interventions:
  - Tailor road safety strategies to address unique challenges in each state
  - Prioritize high-risk states for immediate action and resource allocation
  - Implement targeted programs for vulnerable road users (pedestrians, cyclists, two-wheeler riders)
- Enhance road infrastructure and safety audits:
  - Mandate safety audits for all National and State Highways
  - Implement traffic calming measures, proper markings, and signage across all roads
  - Design roads with dedicated spaces for pedestrians and cyclists
- Improve vehicle safety standards:
  - Enforce stricter safety norms for all vehicles, especially trucks and two-wheelers
  - Promote the adoption of advanced safety features in vehicles
- Strengthen law enforcement and awareness:
  - Increase penalties for traffic violations and ensure consistent enforcement
  - Launch nationwide awareness campaigns on road safety, focusing on helmet use and drunk driving
  - Incorporate road safety education in school curricula

*Can you answer the following question?*

*Analyze the challenges in India's road safety management system and suggest comprehensive measures to improve road safety across the country, considering the disparities between states and global best practices.*

