

Addapedia Editorial Analysis PDF 10 September 2024

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)

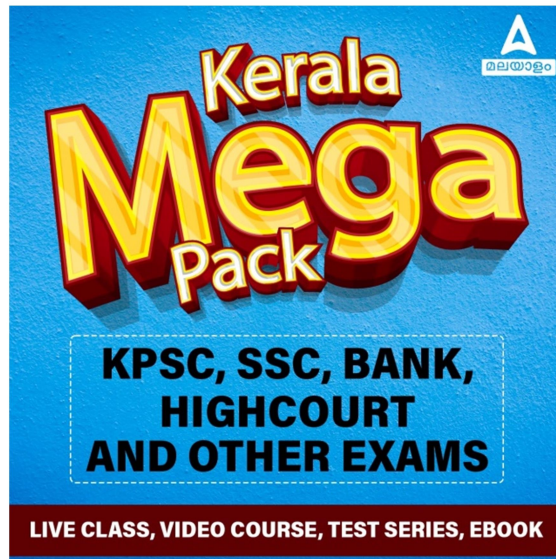
- Recall guidelines for drugs that fail testing
- Guidelines on good distribution practices (storage of drugs during transit)
- Measures against confusing brand names for drugs

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



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