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GENERAL STUDIES 2: SOCIAL JUSTICE **TOPIC:** HEALTH

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STATES AND THE DANGER OF POORLY MANUFACTURED DRUGS

Recent Concerns Over NSQ Drugs

• Recent incidents of Not of Standard Quality (NSQ) drugs have raised serious concerns, with five young mothers in Ballari, Karnataka, allegedly dying due to contaminated drugs manufactured by a pharmaceutical company in West Bengal. These cases highlight the pressing need for stricter regulatory measures to ensure drug quality and public safety.

Regulatory Challenges Under the Drugs and Cosmetics Act, 1940

• The Drugs and Cosmetics Act, 1940, permits pharmaceutical companies to distribute their products nationwide, even if they are licensed and inspected only in the state where the manufacturing facility is located. This creates a regulatory loophole, making it difficult for states like Karnataka to prevent substandard drugs from entering local pharmacies, posing significant public health risks.

Problems States Face in Addressing NSQ Drugs

- Jurisdictional Issues: States face challenges in regulating drugs manufactured outside their borders.
- Limited Authority: Drug inspectors can only prosecute pharmaceutical companies, a process that is lengthy and ineffective.
- Unrestricted Sales: Manufacturers from other states can continue selling products during trials, as only their home-state drug inspectors can suspend or cancel licenses.

Proposed Solutions for Effective Regulation

- 1. **Information Sharing:** Establish systems to promote data exchange between drug control departments across states and public procurement agencies.
- 2. **Centralized Database:** Create a comprehensive repository of test results from central and state drug testing laboratories. This database can track drug failures and enable risk-based enforcement and procurement decisions.
- 3. **Centralized Licensing Information:** Include inspection reports and licensing details to help procurement agencies verify pharmaceutical manufacturers' credentials and avoid low-quality suppliers.

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Benefits of a Centralized Database

- Facilitates verification of pharmaceutical manufacturers' quality before procurement.
- Helps prevent incidents like the Maharashtra scandal, where spurious antibiotics were sold to public hospitals.
- Tracks manufacturers with poor inspection records, allowing procurement officers to prioritize suppliers from states with rigorous inspection protocols, thereby improving public health outcomes.

Additional Recommendations for Strengthened Regulation

- **Blacklist Register:** The Union Ministry of Health should maintain a central register of pharmaceutical manufacturers blacklisted for supplying NSQ drugs, ensuring such players are eliminated from the market.
- **Empowering States:** States should have legal authority to block the sale of drugs causing adverse effects, such as deaths, until the manufacturers address the issue.

Conclusion

• The recurring issue of NSQ drugs in India underscores significant regulatory shortcomings and public health risks. Implementing centralized databases and empowering states with greater authority can improve drug quality control and monitoring. Legislative reforms and strengthened enforcement mechanisms will be critical to ensuring drug safety and protecting public health nationwide.