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DAILY EDITORIAL ANALYSIS

TOPIC

REGULATORY NEGLIGENCE IN INDIA'S PHARMA INDUSTRY

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REGULATORY NEGLIGENCE IN INDIA'S PHARMA INDUSTRY

Context

- Recent tragic incidents involving contaminated cough syrup and the resulting deaths of several children have placed India's reputation as the 'pharmacy to the world' under scrutiny.

About India's Pharmaceutical Industry

- India's pharmaceutical industry stands as a global powerhouse — renowned for its scale, affordability, and innovation.
- India supplies affordable medicines to over 200 countries and contributes significantly to domestic and international public health.
  - India's pharmaceutical exports are vital to low- and middle-income countries.

Scale and Reach

- According to the **Department of Pharmaceuticals,** India ranks:
  - 3rd globally by volume of pharmaceutical production;
  - 14th by value, reflecting its cost-efficiency and mass-scale manufacturing;
- As of **FY 2023–24:**
  - The industry is valued at USD 50 billion;
  - Domestic consumption accounts for USD 23.5 billion;
  - Exports contribute USD 26.5 billion, with major markets including the U.S., Europe, and Africa;
- **Future Projection:**
  - Industry growth to USD 130 billion by 2030;
  - A potential USD 450 billion valuation by 2047, aligning with India's centennial independence goals;
- **Global Leadership:** India supplies:
  - Over 50% of global vaccine demand;
  - Around 40% of U.S. generic drug consumption;
  - A significant share of Active Pharmaceutical Ingredients (APIs) and biosimilars;

Key Issues & Challenges Around India's Pharma Industry

- **Issues of Safety:** It includes the contamination of **cough syrups with toxic industrial solvents** to the seizure of **counterfeit cancer drugs** in Telangana.
  - In one incident, **diethylene glycol (DEG)** and **ethylene glycol (EG)** — toxic industrial chemicals used in paints and brake fluids — were found in **pediatric medicine**, leading to the **deaths of several children**.
  - These incidents are not isolated; they **point to systemic failures** in **oversight, quality control, and enforcement.**
- **Recurrent and Preventable Crisis:** Similar incidents in **The Gambia (2022)** and **Uzbekistan (2022)**, which killed nearly 90 children combined, were **traced back to Indian-made cough syrups**.
  - Investigations by the **World Health Organization (WHO)** revealed 'unacceptable levels' of these toxins.
  - India introduced **mandatory pre-export testing** for cough syrups in 2023 — but **only for export-bound batches**, which **left domestic products largely unchecked.**
- **Fragmented Oversight and Weak Enforcement:** India's drug regulation is governed by the Drugs and Cosmetics Act of 1940, with **responsibilities split between centre and state-level authorities**. This **dual structure** has led to:
  - Jurisdictional confusion, with unclear accountability.
  - Inconsistent inspections and licensing standards across states.
  - Reactive governance, where enforcement follows public outcry rather than proactive monitoring.

- **Threat to India's Pharmaceutical Credibility:** India supplies about **40% of generic medicines in the US; 25% in the UK; and 90% in Africa.**
  - The combination of **lax oversight**, **fake drug markets**, and **profit-driven shortcuts** risks undermining India's hard-won global standing in pharmaceuticals.

Regulatory Framework in India

- **Central Drugs Standard Control Organisation (CDSCO):** It is a national regulatory authority **responsible for** drug approvals, clinical trials, import control, and coordination with state regulators under the MoH&FW.
  - It oversees compliance with the Drugs and Cosmetics Act, 1940 and Rules, 1945.
- **State Drug Control Authorities:** Handle licensing, inspections, and enforcement at the state level;
  - Work in tandem with CDSCO to ensure uniform implementation of drug laws;
- **National Pharmaceutical Pricing Authority (NPPA):** Regulates prices of essential medicines under the **Drug Price Control Order (DPCO);**
  - Ensures affordability and accessibility of key drugs

Legal Framework

- **Drugs and Cosmetics Act, 1940**: Governs manufacture, sale, and distribution of drugs and cosmetics;
  - Includes provisions for Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP);
- **New Drugs and Clinical Trials Rules, 2019:** Streamlines clinical trial approvals and compensation mechanisms;
  - Introduces timelines for regulatory decisions and waivers for certain drug categories
- **Schedule M & Schedule Y:**
  - **Schedule M:** Standards for manufacturing practices;
  - **Schedule Y:** Guidelines for clinical trial conduct and ethics;

Reforms and Policy Initiatives

- **National Pharmaceutical Policy (Draft 2023):** It focuses on regulatory efficiency, innovation, and global competitiveness;
  - Emphasizes self-reliance in Active Pharmaceutical Ingredients (APIs) and biosimilars;
- **Production Linked Incentive (PLI) Scheme:** It encourages domestic manufacturing of critical drugs and raw materials
- **Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS):** It supports SMEs in upgrading to WHO-GMP standards
- **Promotion of Research and Innovation in Pharma-MedTech (PRIP):** It aims to build a robust R&D ecosystem.

Innovation & R&D

- Establishment of National Institutes of Pharmaceutical Education and Research (NIPERs);
- Launch of the National Policy on R&D and Innovation in Pharma-MedTech (2023);

Global Alignment

- India is increasingly aligning its regulatory practices with international standards:
  - Collaboration with WHO, US FDA, and EMA;
  - Adoption of ICH guidelines for drug development and safety;
  - Participation in global pharmacovigilance networks;

Way Forward

- Rebuilding trust requires more than punitive action after each tragedy. India needs to:

- **Enforce uniform quality standards** for both domestic and export markets.
- **Empower and reform the CDSCO** to function independently of political and industrial pressures.
- **Mandate transparency** in drug testing and recall data.
- **Establish accountability chains** linking manufacturers, distributors, and regulators.

- India's claim to being the world's reliable medicine supplier will continue to ring hollow, without such reforms.

Source: BS

Daily Mains Practice Question

[Q] Critically examine the impact of regulatory negligence on the credibility and global standing of India's pharmaceutical industry. Discuss recent incidents, structural challenges in oversight, and suggest reforms to strengthen regulatory governance.

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