Reforming India’s Pharmaceutical Sector

This editorial is based on “Making affordable generics more reliable” which was published in The Hindu on 19/12/2024. Generic medicines are crucial for affordable healthcare in India, saving ₹30,000 crore by 2024, but quality concerns persist due to fragmented regulatory oversight. Despite multiple committee recommendations, the lack of centralized regulation highlights the need for comprehensive reform to ensure both affordability and quality.

For Prelims: Generic medicines, Central Drugs Standard Control Organisation, Pharmaceutical regulation, National Pharmaceutical Pricing Authority, TRIPS (Trade-Related Aspects of Intellectual Property Rights), Patent Act, 1970, Narcotic Drugs and Psychotropic Substances Act, 1985, Antimicrobial Resistance, Ranbaxy scandal, Pradhan Mantri Jan Aushadhi Kendras.

For Mains: Current Status of Pharmaceutical Regulation in India, Major Challenges Arising from Inadequate Pharmaceutical Regulation.

Generic medicines are vital for India's healthcare accessibility, having saved consumers an estimated **₹30,000 crore through government initiatives by 2024**. While bioequivalent to branded drugs, quality concerns persist. The current regulatory framework, split between **Central Drugs Standard Control Organisation and State Drug Regulatory Authorities, allows manufacturers to exploit weaker oversight,** undermining drug quality. Despite recommendations from multiple committees since **1954, India still lacks centralized pharmaceutical regulation,** highlighting the urgent need for comprehensive reform to ensure both affordability and quality in its pharmaceutical sector.

What is the Current Status of Pharmaceutical Regulation in India?

- **Regulatory Bodies**
  - **Central Drugs Standard Control Organization (CDSCO):** Established in 1940, **CDSCO is the primary regulatory authority overseeing the pharmaceutical sector.**
    - It ensures that drugs, cosmetics, and medical devices meet safety standards.
  - **Department of Chemicals and Petrochemicals:** Founded in 1991, DCP **handles policy and planning aspects of chemicals, petrochemicals, and pharmaceuticals,** supporting the sector’s development.
  - **National Pharmaceutical Pricing Authority:** Created in 1994, NPPA is responsible for **price fixation, revision, and updating the list of drugs** under price control.
    - It ensures that the prices of essential medicines are regulated and monitored.
- **Key Policies and Regulations**
  - **Drugs Price Control:** The **Drugs Price Control Order (DPCO)**, first introduced in 1970**,** allows the government to regulate the prices of 74 bulk drugs and their formulations.

        - The **direct control over pricing,** while ensuring affordability, may discourage the production of these medicines by the industry.
    - **Product Quality and Manufacturing Standards:** **Good Manufacturing Practices (GMP)** are enforced by the CDSCO to ensure that pharmaceutical plants and materials adhere to high-quality standards.
        - The **National Pharmaceutical Policy** aims to strengthen GMP norms further.
    - **Patent and Intellectual Property Regulations:** The **Patent Act, 1970** (amended in 2005) governs the **patentability of drugs and outlines provisions for royalty, generic production immunity, patent opposition,** compulsory licensing, and export.
        - **TRIPS (Trade-Related Aspects of Intellectual Property Rights)** provides protection for undisclosed information related to clinical trials.
- **Key Regulatory Guidelines**
    - **Drugs and Cosmetics Act, 1940:** Governs the import, manufacture, distribution, and sale of drugs in India.
        - **Schedule M:** Specifies the general and specific requirements for factory premises, materials, and equipment in the manufacture of certain drugs.
        - **Schedule T :** Prescribes GMP specifications for manufacturing Ayurvedic, Siddha, and Unani medicines.
        - **Schedule Y :** Lays down the legislative requirements for clinical trials.
    - **Good Clinical Practice (GCP) Guidelines:** Drafted by the Ministry of Health, DCGI, and ICMR, based on **international standards like the Declaration of Helsinki and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use , these guidelines regulate clinical research in human subjects.**
    - **The Pharmacy Act, 1948:** Regulates the pharmacy profession in India.
    - **The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954:** Prohibits the advertising of drugs that claim to possess magical qualities.
    - **The Narcotic Drugs and Psychotropic Substances Act, 1985:** Regulates operations involving narcotic drugs and psychotropic substances.

What are the Major Challenges Arising from Inadequate Pharmaceutical Regulation?

- **Proliferation of Substandard and Counterfeit Drugs:** Weak enforcement allows low-quality and counterfeit drugs to infiltrate the market, undermining public health and patient trust.
    - This issue **disproportionately affects low-income countries,** where regulatory oversight is minimal, leading to higher morbidity and mortality rates.
    - In India**, regulatory gaps enable substandard products** to thrive in a fragmented market dominated by small manufacturers.
    - Examples include, **WHO estimates that 10% of drugs in low- and middle-income countries are substandard or falsified.**
        - WHO linked Indian-made cough syrups to the **acute kidney failure and fatalities of children in Gambia.**
- **Erosion of International Trust in Exports**: Inconsistent adherence to global standards **damages the reputation of exporting countries**, reducing competitiveness in global markets.
    - **Regulatory lapses**, including data fabrication and inadequate quality checks, erode confidence among international buyers.
        - This hinders long-term economic gains for pharmaceutical exporting nations like India.
    - Since the start of 2022, Indian drugmakers have been issued more than **9 FDA warning letters,** which may lead to a ban of new products into the US.
        - The **Ranbaxy scandal** remains a landmark case of international regulatory failure.
- **Antimicrobial Resistance (AMR) Crisis:** Unregulated production and irrational use of antibiotics contribute to rising AMR, a critical global health threat.
    - **AMR weakens healthcare systems**, as common infections become untreatable, leading to prolonged illnesses and higher mortality.
    - Lack of stringent oversight allows pharmaceutical companies to produce fixed-dose antibiotic combinations without adequate clinical trials.

    - A recent survey reveals that a high number of Indian inpatients are prescribed multiple antibiotics, leading to antibiotic resistance.
        - **Nearly 64% of antibiotics sold in India are unapproved,** fueling resistance.
- **Adverse Drug Reactions and Lack of Pharmacovigilance:** Inadequate monitoring systems **fail to track and mitigate adverse drug reactions (ADRs),** posing long-term health risks.
    - Regulatory authorities often lack resources and mechanisms to evaluate drug safety in real time, leading to avoidable complications.
    - This also reflects poor post-marketing surveillance systems in developing countries.
    - Despite 895 Adverse drug reaction monitoring Centre's India contribution to global ADR database is **only 2%**
        - In 2019, the recall of ranitidine due to **N-nitrosodimethylamine** contamination underscored the gaps in pharmacovigilance systems.
- **Barriers to Global Market Entry:** Inconsistent regulatory frameworks and lack of transparency in **standard-setting** hinder access to international markets for emerging pharmaceutical firms.
    - These barriers prevent smaller manufacturers from scaling operations and competing globally.
        - **Non-compliance with Good Manufacturing Practices (GMPs)** is a significant limitation.
    - With **only 19% of the 10,500 pharmaceutical manufacturing units** in India currently boasting **WHO-GMP certification.**
        - This significantly affects India’s ability to penetrate regulated markets like the US and EU .
- **Environmental Damage from Pharmaceutical Waste: Unregulated pharmaceutical waste disposal** leads to severe environmental contamination, affecting ecosystems and public health.
    - **Effluent discharge from manufacturing units,** especially in emerging economies, contributes to pollution in rivers and groundwater.
        - This issue is **compounded by weak enforcement** of environmental regulations.
    - A recent study **identified pharmaceutical pollutants in 43.5% of global rivers**, with the Yamuna River among the most polluted.
        - **India is a major contributor to global antibiotic pollution,** exacerbating the AMR crisis.
- **Disparities in Access to Essential Medicines:** Inadequate price regulation and **monopolistic practices** make essential medicines unaffordable for marginalized populations.
    - **Weak implementation of drug price** controls allows companies to charge exorbitant prices, worsening health inequities.
        - Lack of availability further exacerbates the issue in remote and rural areas
    - Accessibility to affordable medicine at government medical stores is a challenge for the rural population.
        - As per a recent report, **only 12.2% respondents have access (within commutable distance from their villages)** to subsidised medicines at **Pradhan Mantri Jan Aushadhi Kendras.**
- **Ineffectiveness of Compliance Standards**: **Fragmented and complex regulatory systems** confuse manufacturers, reducing compliance rates and increasing product rejections in global markets.
    - Different standards across agencies like **FSSAI, BIS, and APEDA** create redundancies and inefficiencies. This leads to low international acceptance of Indian pharmaceutical products.

What Measures can be Adopted to Enhance Drug Regulation in India?

- **Streamlining Regulatory Frameworks:** India needs a unified and transparent **regulatory structure to eliminate overlaps and ensure accountability.**
    - Merging agencies like CDSCO and state-level bodies into a **Centralized Drug Authority** can improve coordination and compliance.
    - This will standardize the **approval, testing, and monitoring processes, reducing inefficiencies.**
    - Countries like the **US have centralized systems like the FDA,** which ensures consistency in drug regulation and enforcement across states.

- **Strengthening Pharmacovigilance and Post-Marketing Surveillance:** Establishing robust pharmacovigilance systems is crucial to monitor **adverse drug reactions (ADRs)** and improve public safety.
    - Expanding the **Pharmacovigilance Programme of India (PvPI)** to include private hospitals, rural health centers, and e-pharmacies can increase ADR reporting.
    - Advanced data analytics and AI can predict potential drug risks early.
- **Enforcing Compliance with Good Manufacturing Practices (GMP):** Periodic audits and real-time monitoring of manufacturing facilities can ensure adherence to GMP standards.
    - Implementing **stricter penalties for violations and incentives for compliance will foster accountability.**
    - Introducing QR codes on drug packaging can help trace and verify compliance across the supply chain.
- **Creating a National Drug Database for Transparency:** A centralized, publicly accessible database listing **approved drugs, manufacturers, and regulatory statuses** can enhance transparency.
    - This will allow healthcare providers and consumers to verify drug authenticity and prevent the sale of unapproved or counterfeit products.
        - Integrating blockchain technology can further secure data integrity.
- **Improving Regulatory Capacity and Infrastructure:** Investing in a**dvanced testing laboratories, skilled workforce, and digital tools** will strengthen India's regulatory capacity.
    - **Allocating funds under the National Health Mission** for regulatory infrastructure can bridge gaps in rural and semi-urban areas.
    - Regulatory staff must undergo regular training in international standards and practices.
- **Harmonizing Domestic and International Standards:** India must align its drug standards with internationally accepted benchmarks like those of the **US FDA and European Medicines Agency (EMA).**
    - Bilateral agreements for mutual recognition of standards can reduce export rejections and enhance market access.
    - Introducing a **"Single Window Clearance System"** for export certifications can streamline approvals.
- **Encouraging Ethical Clinical Trials and R&D Oversight:** Strict guidelines for clinical trials, along with real-time monitoring, can ensure ethical practices and patient safety.
    - Establishing a **national oversight committee with AI-enabled monitoring** tools can track trial compliance effectively. Incentives like tax breaks for ethical R&D can foster innovation while maintaining ethical standards.
- **Regulating Online Pharmacies and Digital Platforms:** Digital platforms must be brought under **strict regulatory oversight to curb the sale of counterfeit and unlicensed drugs.**
    - **Mandatory registration of e-pharmacie**s and linking them to Aadhaar-enabled verification systems can improve accountability.
        - AI tools can monitor online transactions for irregularities.
- **Incentivizing Sustainable Pharmaceutical Practices:** Introducing **green manufacturing practices** can minimize environmental damage caused by pharmaceutical waste.
    - **Strict enforcement of effluent treatment norms** and subsidies for cleaner technologies can promote compliance.
    - Collaborating with agencies like **CPCB and MoEFCC** can ensure adherence to environmental guidelines.
- **Building Public Awareness and Consumer Empowerment:** Educating consumers about **safe drug usage, identifying counterfeit medicines, and reporting adverse effects is vital.**
    - Public campaigns through mass media, schools, and community programs can raise awareness. A **toll-free helpline and mobile app for drug-related grievances** can empower consumers.
    - **"Be Aware, Report Counterfeit" campaign** can be introduced in India, ensuring greater public participation.
- **Developing Regional Drug Regulation Hubs:** Regional hubs with **advanced laboratories and regulatory offices** can decentralize oversight and improve efficiency.
    - These hubs can cater to specific needs like drug testing, inspections, and monitoring in underserved areas.
        - This will ensure timely enforcement and reduce the burden on central agencies.
- **Adopting Blockchain for Supply Chain Transparency:** Blockchain technology can

ensure **end-to-end visibility of the pharmaceutical supply chain,** preventing counterfeit drugs from entering the market.
    - This technology can also **enhance product traceability, ensuring quality and compliance at every stage.**
        - A government-backed blockchain system can boost stakeholder confidence.
- **Creating a Real-Time Drug Recall Mechanism:** India needs a robust, **technology-enabled drug recall system** to quickly remove substandard or harmful drugs from circulation.
    - A centralized alert system linked to **manufacturers, wholesalers, and retailers can ensure immediate action.** Regular mock drills can enhance readiness for large-scale recalls.
- **Introducing Performance-Based Manufacturer Accreditation:** A **performance-based accreditation system** can incentivize manufacturers to comply with high-quality standards.
    - **Rankings based on adherence to GMPs**, environmental standards, and innovation can encourage healthy competition.
    - Regular updates to accreditation criteria will align practices with global advancements.

Conclusion

Strengthening pharmaceutical regulation in India is crucial to ensuring both **affordability and quality in healthcare**. A unified regulatory framework, improved **pharmacovigilance, and stricter compliance with manufacturing standards** will enhance drug safety and international credibility. Emphasizing transparency, technological advancements, and sustainability can further elevate India's pharmaceutical sector. With proactive reforms**, India can better meet domestic healthcare needs and strengthen its position in the global market.**

Drishti Mains Question:

Examine the role of regulatory bodies and policies in ensuring the quality, pricing, and accessibility of drugs in India. Discuss the challenges faced by the pharmaceutical industry in light of the existing regulatory framework.

UPSC Civil Services Examination, Previous Year Question (PYQ):

Mains:

Q. How is the Government of India protecting traditional knowledge of medicine from patenting by pharmaceutical companies? **(2019)**