



India's Pharmaceutical Industry

For Prelims: [India's pharmaceutical industry](#), [World Health Organization \(WHO\)](#), [Central Drugs Standard Control Organisation \(CDSCO\)](#), [Intellectual Property Rights \(IPR\) laws](#), [Production Linked Incentive \(PLI\) Scheme](#).

For Mains: Status of India's Pharmaceutical Industry, Major Challenges with India's Pharma Sector.

Why in News?

[India's pharmaceutical industry](#), renowned as the largest manufacturer of **generic medicines** globally, has faced significant challenges related to **product quality and safety**.

- **Recent incidents of contaminated medicines and substandard drugs** have raised concerns about the regulatory framework and the industry's commitment to ensuring **high-quality pharmaceutical products**.

What are the Incidents Highlighting Quality Control Failures?

- In **January 2020**, **12 children in Jammu** died after consuming contaminated **medicine**, that was found to **contain diethylene glycol**, which led to **kidney poisoning**.
 - In **March 2021**, **Nycup syrup** was found to have lower levels of active ingredients.
- In **October 2022**, the [World Health Organization \(WHO\)](#) released a medical product alert, which are said to be linked to acute kidney injury in children and [66 deaths in the small West African nation of Gambia](#).
 - Four products from India-based Maiden Pharmaceuticals had been found to be contaminated with **unacceptable amounts of diethylene glycol and ethylene glycol, both toxic to humans**.
- In **December 2022**, the [Central Drugs Standard Control Organisation \(CDSCO\)](#) initiated a probe in connection with the **death of 18 children in Uzbekistan** allegedly linked to a **cough syrup manufactured by Indian firm Marion Biotech**.
 - Recently, US Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (USFDA) [raised concerns](#) over a [drug-resistant bacteria](#) strain **allegedly linked to eye drops imported from India**.
- Recent regulatory inspections revealed that **48 drugs failed to meet quality standards**.
 - **3% of drugs used for common conditions like hypertension, allergies, and bacterial infections** were found to be substandard.

What is the Status of India's Pharmaceutical Industry?

- **About:**
 - **India is the largest manufacturer of generic medicines globally. Its pharmaceutical industry** plays a crucial role in **global healthcare**, providing **affordable generic medicines** that impact the lives of the global poor.
 - It is currently valued at **USD 50 Bn** being a major exporter of Pharmaceuticals, with over

200+ countries served by Indian pharma exports.

- It is expected to reach **USD 65 Bn by 2024 and to USD 130 Bn by 2030.**

▪ **Major Challenges with India's Pharma Sector:**

◦ **Violation of IPR Rules:**

- Indian pharmaceutical companies have faced allegations of violating [Intellectual Property Rights \(IPR\) laws](#), resulting in legal disputes with multinational pharmaceutical companies.
- One such case involved **Swiss pharmaceutical company Roche and Indian drug manufacturer Cipla in 2014.**
 - Roche accused Cipla of infringing on its patent for the cancer **drug Tarceva** by producing a generic version of the drug. The dispute escalated, leading to a court battle between the two companies.
 - In 2016, the [Delhi HC ruled in favor of Roche](#), affirming that Cipla had indeed violated Roche's patent rights. As a consequence, **Cipla was ordered to pay damages to Roche.**

◦ **Pricing and Affordability:** India is known for its **generic drug manufacturing capabilities**, which have contributed to affordable healthcare globally.

- However, the pricing of pharmaceuticals within India remains a significant concern. **Balancing the need for affordable medicines with the profitability of pharmaceutical companies is a delicate task.**

◦ **Healthcare Infrastructure and Access:** Despite India's strong pharmaceutical industry, **access to healthcare remains a challenge for a significant portion of the population.**

- Issues such as **inadequate healthcare infrastructure, uneven distribution of healthcare facilities**, and low health insurance coverage pose barriers to accessing medicines.

▪ **Related Government Initiatives:**

- [Production Linked Incentive \(PLI\) Scheme for Pharmaceuticals](#)
- [Promotion of Bulk Drug Parks Scheme](#)
- [Strengthening Pharmaceuticals Industry Scheme](#)

What Steps Can be Taken to Reform India's Pharma Sector?

▪ **Legislative Changes and Centralised Database:**

- [Drugs and Cosmetics Act \(1940\)](#) needs to be amended and the establishment of a **centralised drugs database** can enhance surveillance and ensure effective regulation across all manufacturers.
- India has **36 regional drug regulators; consolidating them into a single entity** can reduce the risk of regulatory capture and influence networks.
- Also, **implementing common quality standards** across all states is necessary to ensure consistent product quality.

▪ **Encouraging Certification:**

- Encouraging more pharmaceutical manufacturing units to **obtain WHO's Good Manufacturing Practice certification** can elevate industry-wide quality standards.

▪ **Transparency, Credibility, and Accountability:**

- The regulator and the industry must collaborate to enhance India's drug regulatory regime, making it transparent, credible, and aligned with global standards.
 - **Public disclosure of drug application reviews and inspection records, violation history** can ensure accountability.
- The cancellation of manufacturing licences for **18 pharma companies by the [Drugs Controller General of India \(DGCI\)](#) is a positive step.**
- However, more comprehensive measures are required to address the root causes of quality issues.

▪ **Focus on Sustainable Manufacturing Practices:**

- Emphasising sustainable manufacturing practices, including [green chemistry](#), **waste reduction, and energy efficiency**, can enhance the sector's environmental sustainability while reducing costs.
 - Adopting **environmentally friendly practices** can also contribute to a **positive brand image** and attract environmentally conscious consumers.

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)**

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