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.

Source: BS

Why in News?

Recently, around 36% of **pharmaceutical manufacturing** units inspected by the **Indian drug regulator** were **shut down for non-compliance with quality standards** following risk-based inspections by the **Central Drug Standards Control Organisation (CDSCO)** since December 2022.

What are the Incidents Highlighting Quality Control Failures?

- **According to a report by Indian Pharmaceutical Alliance and McKinsey & Company in 2023, the** US Food and Drug Administration (FDA) **classified 13% of its 145 inspections of Indian facilities as Official Action Indication (OAI), which is lower than the global average of 15% OAIs.**
    - Data integrity issues were prevalent, including falsified data, improper cohort distribution, questionable sample reanalysis practices, and poor systemic quality management.
- In October 2022, the World Health Organisation (WHO) issued an alert linking four products from India's Maiden Pharmaceuticals to acute kidney injury and 66 child deaths in Gambia, due to contamination with toxic chemicals diethylene glycol and ethylene glycol.
- In December 2022, the 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.
- In January 2020, 12 children in Jammu died after consuming contaminated medicine, that was found to contain diethylene glycol, which led to kidney poisoning.

How Drugs Are Regulated in India?

- The Drugs and Cosmetics Act,1940:
  - The Drugs and Cosmetics Act, 1940 and Rules 1945 have **entrusted various responsibilities** to central and state regulators for regulation of drugs and cosmetics.
  - It provides the regulatory guidelines for issuing licenses to manufacture Ayurvedic, Siddha, Unani medicines.
- **Central Drugs Standard Control Organisation (CDSCO):**
  - **Prescribes standards and measures** for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country.
  - Regulates the **market authorisation** of new drugs and clinical trials standards.
- Drugs Controller General of India:
  - DCGI is the **head of the department of the CDSCO** of the Government of India responsible for the approval of licences of specified categories of drugs such as blood and blood products, IV fluids, vaccines and sera in India.
  - DCGI also **sets standards for manufacturing**, sales, import, and distribution of drugs in India.

What is the Status of the Indian Pharmaceutical Industry?

- **Current Scenario:**
  - India is one of the biggest suppliers of low-cost vaccines in the world and is the largest provider of generic medicines globally, occupying a 20% share in global supply by volume.
    - India accounts for **60% of global vaccine production** making it the largest vaccine producer in the world.
  - The Pharmaceutical industry in India is the **3rd largest in the world** in terms of volume and **14th largest in terms of value.**
    - The Pharma sector currently contributes to around 1.72% of the country's **Gross Domestic Product (GDP).**
- **Market Size & Investments: India is among the top 12 destinations for biotechnology worldwide and 3rd largest destination for biotechnology in** Asia Pacific.
  - The Indian pharmaceutical industry has seen a massive expansion over the last few years and is expected to reach about 13% of the size of the global pharma market while **enhancing its quality, affordability, and innovation.**
  - **Up to 100%,** Foreign Direct Investment (FDI) **has been allowed through automatic routes for Greenfield pharmaceuticals projects.**
    - For Brownfield Pharmaceuticals projects, FDI allowed is up to 74% through automatic route and beyond that through government approval.
  - Indian pharmaceutical market is estimated to touch **USD 130 billion in value by the end of 2030**.
- **Exports: Pharmaceutical is one of the top ten attractive sectors for** foreign investment in India**. The pharmaceutical exports reached more than 200 nations around the world, including highly regulated markets of the USA, West Europe, Japan, and Australia.**
  - India's drugs and pharmaceuticals exports stood at USD 22.51 billion in FY24 (April-January) r**ecording a strong year-on-year growth** of 8.12% during the period.

Greenfield vs Brownfield Investment

- **Greenfield Project:** It refers to **investment in a manufacturing,** office, or other physical company-related structure or group of structures in an area **where no previous facilities exist.**
- **Brownfield investment:** The projects which are modified or upgraded are called brownfield projects. The term is used for purchasing or leasing **existing production facilities to launch a**

new production activity.

What are the 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 claimed Cipla copied its cancer drug Tarceva, leading to a **legal fight** where Cipla was found guilty and ordered to compensate Roche.
- **Pricing and Affordability:** India is known for its **generic drug manufacturing capabilities**, which have contributed to affordable healthcare globally.
    - However, ensuring medicines in India are **affordable** while maintaining pharmaceutical companies' **profitability** is **challenging.**
    - Additionally, quality problems in generic drugs could harm the reputation of the industry, which supplies **more than 90% of US prescriptions.**
- **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.
- **Overdependence on Imports:** The Indian pharma sector relies heavily on imports for **Active Pharmaceutical Ingredients (APIs)**, the raw materials for drugs. Disruptions in the global supply chain can lead to shortages and price hikes.

Related Government Initiatives

- Production Linked Incentive (PLI) Scheme for Pharmaceuticals
- Promotion of Bulk Drug Parks Scheme
- Strengthening Pharmaceuticals Industry Scheme
- National Medical Devices Policy, 2023

Way Forward

- **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.
- **Promote Continuous Improvement Programs: Motivate pharmaceutical companies to implement voluntary quality management systems and self-improvement initiatives. This can be fostered through industry associations and government incentives.**
- **Transparency and Public Reporting:** Increase **transparency in regulatory actions** and public reporting of quality control failures. This can be achieved through designated government portals for sharing inspection reports and drug recalls.
- **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.
- **Digital Drug Regulatory System (DDRS)**: A request for proposal has been floated for the DDRS, which will be an **umbrella portal for pharmaceutical regulations.**
    - The **SUGAM portal** is being enhanced to create an improved version. This new version will **integrate all the activities and functions of the CDSCO**. Eventually, it will also include the state drug controllers and other relevant agencies under its purview.
- **Streamlining and Rationalising the Drug Regulatory Structure and Functions: The government should create a single, central authority with adequate powers, resources, expertise and autonomy to regulate the entire pharma sector and ensure effective enforcement and compliance of the drug laws and norms.**
- **Strengthen Pharmacovigilance:** Enhance **surveillance of drugs post-marketing** to identify and address adverse effects promptly. This aligns with recommendations for stricter quality control measures.

Drishti Mains Question:

Q. Critically analyze the current challenges faced by the Indian pharmaceutical sector. Discuss the implications of these challenges on public health and the economy.

UPSC Civil Services Examination Previous Year's Questions (PYQs)

Prelims:

Q. Which of the following are the reasons for the occurrence of multi-drug resistance in microbial pathogens in India? (2019)

1. Genetic predisposition of some people
2. Taking incorrect doses of antibiotics to cure diseases
3. Using antibiotics in livestock farming
4. Multiple chronic diseases in some people

Select the correct answer using the code given below.

(a) 1 and 2
(b) 2 and 3 only
(c) 1, 3 and 4
(d) 2, 3 and 4

Ans: (b)

Mains:

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

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