ISSUES IN INDIAN PHARMA SECTOR - GS III MAINS

Q. Indian pharma companies have been under constant international scrutiny at the present market scenario. Critically examine the challenges faced by the Indian pharma sector in the global market and steps taken by the government to overcome the same. (15 marks, 250 words)

News: *Why are Indian drugmakers under the lens*

What's in the news?

- Since October last year, Indian pharma companies have been under constant international scrutiny for exporting allegedly contaminated drugs, which have led to deaths of children.

Key takeaways:

- Nigeria raised the red flag on two oral drugs; Cameroon too sounded an alarm over another cough syrup reportedly made in India when several children died.
- Sri Lanka called out two drugs manufactured in India linking them to adverse reactions in several patients.
- In the latest move, Gambia has declared that from July 1, it is running strict quality control checks on all pharma products shipped into the country, before they leave Indian shores.

Market Size of Indian Pharma Sector:

1. Foreign Direct Investment (FDI):

- 100% FDI in the Pharmaceutical sector is allowed under the automatic route for greenfield pharmaceuticals.
- 100% FDI in the pharmaceutical sector is allowed in brownfield pharmaceuticals; wherein 74% is allowed under the automatic route and thereafter through the government approval route.

2. Market Size:

- The pharmaceutical industry in India is valued at $50 bn in 2022-23 and exports accounting for 50% of the production.
- It is expected to reach $65 bn by 2024 and to $130 bn by 2030.

3. Export:

- India is a major exporter of Pharmaceuticals, with over 200+ countries served by Indian pharma exports.
- India supplies over 50% of Africa's requirement for generics, ~40% of generic demand in the US and ~25% of all medicine in the UK.
- For the period 2021-22, export of drugs and pharma products stood at $24.6 bn compared to $24.44 bn as of 2020-21.
- The Indian pharma industry witnessed exponential growth of 103% during 2014-22 from $11.6 bn to $24.6 bn.

Challenges in Pharma Sector in India:

1. Safety of Drugs:

- Except for some customary inspections, the Indian drug regulator has so far failed to institute measures to make sure drugs produced in India for export and domestic use are safe.

2. Failing the Quality Tests:

- According to a Central Drugs Standard Control Organization (CDSCO) survey in 2014-2016, about five per cent of Indian drugs, several of them manufactured by large pharma companies, failed the quality test.
- Independent studies suggest that this figure could be much higher.
- The country's pharma industry has largely been in denial over quality-related concerns expressed by national and international observers.

3. Costs of Production:

- The cost of production in India is 50 percent less than in developed nations, but it is still around 18 percent higher than China.
- This is attributable to raw materials being 25-30 percent costlier, electricity being 20 percent more expensive, and other costs such as financing, logistics, transportation, etc., being 30 percent more expensive.

4. 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.

Regulation of Drug Manufacturing in India:

1. Drugs and Cosmetics Act, 1940:

- The Act regulates the import, manufacture, and distribution of drugs in India.
- The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to state quality standards.
- The Drugs and Cosmetics Act, 1940 was amended by the Drugs & Cosmetics (Amendment) Act, 2008 to provide for more stringent penalties for manufacture and trade of spurious and adulterated drugs.

2. New Drugs, Medical Devices and Cosmetics Bill, 2022:

- To accommodate changing requirements and encourage the adoption of new technology, the Ministry of Health and Family Welfare released a draft bill in July 2022 to replace the existing Drugs and Cosmetics Act 1940.
- This act governs drug importation, production, and distribution across the country.

3. Central Drugs Standard Control Organization:

- It is the apex department of the Central Drugs Standard Control Organization (CDSCO) of the Government of India.
- CDSCO is a regulatory body for Indian pharmaceuticals and medical devices.
- It comes under the Ministry of Health and Family Welfare.

4. Drugs Controller General of India:

- Drugs Controller General of India (DCGI) is the head of department of the Central Drugs Standard Control Organization of the Government of India
- It is responsible for 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.

5. Vision Pharma 2047:

- Make India a global leader in the manufacturing of affordable, innovative & quality pharmaceuticals & medical devices for the goal of Vasudhaiva Kutumbakam.

6. National Pharmaceutical Policy (2023):

- The policy is being drafted to serve as a comprehensive framework to address the challenges faced by Indian Pharmaceutical industries.
- The draft policy encompasses five key pillars:
    - Fostering Global Pharmaceutical Leadership, Promoting Self-Reliance, Advancing Health Equity and accessibility, Enhancing Regulatory Efficiency in the Indian Pharmaceutical Sector and Attracting investments.

WAY FORWARD:

1. Statutory Changes:

- Drugs and Cosmetics Act (1940) needs to be amended. Which should cater to the present conditions.

2. Centralized Database:

- The establishment of a centralized drugs database can enhance surveillance and ensure effective regulation across all manufacturers.

3. 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.

4. Strengthen Pharmacovigilance:

- Enhance surveillance of drugs post-marketing to identify and address adverse effects promptly. This aligns with recommendations for stricter quality control measures.