Streamlining the Pharma Sector

Why in news?

India's drug regulator CDSCO has withdrawn powers delegated to State licensing authorities to issue NOCs (no objection certificates) for manufacture of unapproved, banned or new drugs for export purposes.

Picture of India's Pharma Industry

• From being import-dependent in the 1960s to now meeting 20% of global generics demand, the Indian pharmaceutical industry has rightfully earned India the title of ***'Pharmacy of the World'***.
• The Indian Pharmaceutical industry is currently ranked
  - 3rd in pharmaceutical production by volume
  - Largest producer of generic drugs globally
• According to a recent report by Asian Lite, India accounts for 13 % of the global pharma market.
• **Global vaccine supply**- It meets 62% of the overall demand, at least 70% of WHO's vaccines are sourced from India.
• **Essential vaccines**- It provides vaccines such as DPT, BCG (primarily used against tuberculosis) and measles vaccine.
• The Pharma sector currently contributes to around 1.72% of the country's GDP.
• **Market size**- It is expected to reach US$ 65 billion by 2024, and US$ 130 billion by 2030.



• **Export-** India is the 12th largest exporter of medical goods in the world.

What will be the impact of CDSCO's move?

- **Aim-** To create a more standardized and efficient process for manufacturers and exporters.
- **Improve exports**- The move aligns with India's broader vision of the pharmaceutical sector, which includes ambitious targets such as reaching exports of 450 dollar billion by 2047.

- **Global player**- By improving regulatory oversight and ensuring compliance with quality standards, the government aims to enhance the reputation of Indian pharmaceutical products in international markets.
- **Uniform protocol**- By bringing uniformity in protocols, India can enhance its reputation as a reliable supplier.
- **Foster efficiency**- It can help reduce delays and administrative burdens for industry players, enabling them to focus more on innovation, research, and development.
- **Self-reliance-** It would make India a more competitive player in the global pharmaceutical market, driving economic growth and supporting the country's aspirations for self-reliance in this crucial sector.
- **Entry of generic drugs-** As several drugs are expected to go off-patent, this presents an opportunity for the entry of generic products.

What are the challenges faced by the pharma sector in India?

- **Concern with IPR**- India has faced scrutiny and legal challenges related to its patent laws and intellectual property rights regulations, particularly regarding the production and export of generic drugs.
- **Lack of research**- India is a major player in generic drug manufacturer but still it lags behind in original research and development.
- **Regulatory compliance**- Compliance with regulations can be challenging and may require significant resources and expertise.
- **Ambiguity**- Changes in domestic and international laws, trade agreements, and political landscapes can impact the pharmaceutical industry.
- **Price-controls**- Government-imposed price controls ensure affordable healthcare but can impact the profit margins of pharmaceutical companies.
- **Import dependency**- India relies heavily on foreign nations for intermediates and active pharmaceutical ingredients (APIs), making it vulnerable to price fluctuations and supply disruptions.
- **Quality concerns**- India has faced issues such as WHO investigation into contaminated cough syrups linked to child fatalities in Gambia.

What lies ahead?

- Investing in R&D is crucial for the long-term competitiveness of the industry and for fostering innovation in drug discovery and development.
- The need of the hour is meeting stringent regulatory standards, both domestically and in international markets which is essential for ensuring the safety, efficacy, and quality of pharmaceutical products.
- The challenges must be addressed effectively by collaboration between industry stakeholders, government bodies, regulatory agencies, and research institutions.
- Aligning strategies with the evolving needs of the global pharmaceutical market is essential for success.

Quick facts

Central Drug Standard Control Organisation (CDCSO)

• **About-**It is the apex drug regulatory framework.
• **Governed by**- Drugs and Cosmetics Act, 1945.
• **Ministry**- *Directorate General of Health Services* under Ministry of Health and Family Welfare
• **Role**-
- Ensures safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.
- Regulates the market authorization of new drugs and clinical trials standards.
- Supervises drug imports and approves licenses to manufacture the products.
• **Drug Controller General of India (DCGI)-** It is within CDSCO that regulates pharmaceutical and medical devices

References

1. The Hindu- Streamline pharma sector
2. IBEF- Pharmaceutical sector in India

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