INDIA AND PHARMA SECTOR - GS III MAINS

Q. The Indian Pharma industry has turned to a net exporter but still it is suffering with hurdles and challenges. Discuss (15 marks, 250 words)

News: *India reverses old trend in medical consumables business, is now a net exporter*

What's in the news?

- In the fiscal year 2022-23, India reached a notable milestone in the medical goods sector by becoming a net exporter of medical consumables and disposables for the first time.

Status of India's Pharmaceutical Industry:

Manufacturing:

- India, historically reliant on medical imports, has transitioned to self-sufficiency in medical consumables and disposables, becoming the largest global manufacturer of generic medicines.
- The industry is valued at USD 50 billion and serves over 200 countries, with projections to reach USD 65 billion by 2024 and USD 130 billion by 2030.

Export and Import Statistics:

- Exports of medical consumables and disposables surged by 16% to USD 1.6 billion, while imports declined by 33% to approximately USD 1.1 billion.

Challenges of India's Pharma Sector:

1. Lagging R&D:

- India's pharmaceutical R&D expenditure is lower compared to developed nations, hindering new drug development.

2. Limited Innovation Ecosystem:

- Weak collaboration between academia, research institutions, and pharmaceutical companies slows down high-quality drug and medical device development.

3. Price Controls and Profit Margins:

- Government price controls on some drugs can limit profits and deter heavy R&D investment.

4. Complex Regulatory Framework:

- Lengthy and complex approval processes for new drugs lead to bureaucratic hurdles.

5. Skilled Workforce Shortage:

- Shortage of highly qualified scientists and researchers affects efficiency.

6. Intellectual Property Concerns:

- Uncertainty around IP protection discourages large pharma investment.

7. Import Dependency:

- India heavily relies on imports for medical devices and APIs, particularly from China.

8. Substandard Drugs:

- Occurrence of deaths linked to substandard or counterfeit drugs tarnishes the sector's reputation.

Way Forward:

1. Legislative Changes and Centralised Database:

- Amend the Drugs and Cosmetics Act (1940) and establish a centralised drugs database for enhanced regulation.

2. Encouraging Certification:

- Encourage more units to obtain WHO Good Manufacturing Practice certification to elevate industry-wide quality standards.

3. Transparency, Credibility, and Accountability:

- Enhance India's drug regulatory regime for transparency and alignment with global standards.

4. Focus on Sustainable Manufacturing Practices:

- Emphasise green chemistry, waste reduction, and energy efficiency for environmental sustainability.

5. Moving Beyond Generics:

- Government support and initiatives like PLI can facilitate the development of novel drugs.

6. Boosting R&D and Innovation:

- Foster public-private partnerships and provide tax incentives for innovation to improve R&D expenditure.