India as a Net Exporter of Medical Consumables

For Prelims: Good Manufacturing Practices, **Pharmaceutical quality system**, **Pharmaceutical Companies**, **Drugs Manufacturing Standards**, **PTUAS Scheme**, **PMPDS**, **PLI scheme for Pharmaceuticals**, **Schedule M and WHO-GMP Standards**, Central Drugs Standard Control Organization**,** Drugs and Cosmetics Act, 1940**,**

For Mains: Revised Good Manufacturing Practices Standards, **Indian pharmaceutical industry**, **health, Government policies and interventions**, Consequences of ineffective drug regulations

Source: ET

Why in News?

- India has achieved a **significant milestone** in the medical goods business, becoming a **net exporter** of **medical consumables and disposables** for the **first time** in the **fiscal year 2022-23.**
- This marks a **reversal of an old trend** where imports of such products outweighed exports.

What is the Status of India's Pharmaceutical Industry?

- **About:**
  - India has historically been **dependent on imports** for medical consumables and disposables. India has now reversed this trend, indicating a shift towards self-sufficiency in this sector.
  - India is the **largest manufacturer of generic** medicines globally. Its pharmaceutical industry plays a crucial role in global healthcare, providing affordable **generic medicines.**
  - It is currently valued at **USD 50 billion** as a major pharmaceutical exporter, with over 200+ countries served by Indian pharma exports.
  - It is expected to reach USD 65 Billion by 2024 and to USD 130 Billion by 2030.
  - **Export and Import Statistics:**
    - **Exports:** India exported medical consumables and disposables worth USD 1.6 billion, showing a 16% surge over the previous fiscal year (2021-22).
    - **Imports:** Imports amounted to approximately USD 1.1 billion, indicating a 33% decline.
- **Major Challenges with India’s Pharma Sector:**
  - **Lagging Research and Development (R&D):** India's R&D spending in pharma is lower compared to developed nations. This hinders the creation of new drugs.
  - **Limited Innovation Ecosystem:** Collaboration between academia, research institutions, and pharmaceutical companies is weak, **slowing down development of high qualtity drugs and medical devices.**
  - **Price Controls and Profit Margins:** Government price controls on some drugs can limit profits, making it less attractive for companies to invest heavily in R&D for new drugs.
  - **Complex Regulatory Framework:** Navigating the approval process for new drugs can be lengthy and complex which **leads to red tapism.**

- **Skilled Workforce Shortage:** There's a lack of highly qualified scientists and researchers in the pharma sector, which leads to **overburdened staff affecting efficiency.**
- **Intellectual Property (IP) Concerns:** Uncertainties around IP protection, due to provisions like **compulsory licensing (Indian Patents Act 1970),** can discourage large pharma investment in India.
- **Import Dependency:** Despite progress, India remains largely dependent on imports for medical devices, with around 70% sourced from other nations.
    - India's heavy dependence on **Active Pharmaceutical Ingredients (APIs) imports,** particularly from countries like China.
- **Substandard Drugs:** One significant issue in the Indian pharmaceutical sector is the occurrence of deaths linked to the consumption of substandard or counterfeit drugs.
    - Indian-origin **medicines leads to** multiple deaths of children in Africa **and Central Asia.**

Government Initiatives in the Pharma Sector

- **Production Linked Incentive (PLI) Scheme for Pharmaceuticals**
- **Promotion of Bulk Drug Parks Scheme**
- **Strengthening Pharmaceuticals Industry Scheme**
- **National Policy on Research and Development and Innovation in Pharma-MedTech Sector in India**
- **Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP)**
- **Pharmaceuticals Technology Upgradation Assistance (PTUAS) Scheme**
- **Revised Good Manufacturing Practices (GMP)**

What Further 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.
    - Also, implementing common quality standards across all states is necessary to ensure consistent product quality.
- **Encouraging Certification:**
    - Encouraging more pharmaceutical manufacturing units to obtain **World Health Organization (WHO)** 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.
- **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.
- **Moving Beyond Generics:** India excels in producing affordable generic medicines but faces **challenges in developing novel drugs.**
    - Government support through initiatives like PLI and facilitating clinical trial funding can accelerate research and development efforts.
- **Boosting R&D and Innovation:** India's lower expenditure on research and development compared to global leaders can be improved.
    - Focus should be to foster public-private partnerships and provide tax incentives for innovation.

Note

Recently, the Union government has assumed sole authority over the **issuance of manufacturing**

licences for new drugs intended for export, thereby transferring this responsibility from state governments.

- This decision was prompted by heightened global scrutiny of Indian-made drugs.
- Consequently, the Central Drugs Standard Control Organisation **(CDSCO)** has been designated as the exclusive licensing authority for drugs in India.
    - Manufacturers are now required to obtain a **No Objection Certificate (NOC)** from the CDSCO's respective zonal office.
- CDSCO is the **Central Drug Authority** for discharging functions assigned to the Central Government under the **Drugs and Cosmetics Act, 1940.**
    - The **Drug Controller General of India (DCGI)** heads the CDSCO.

Drishti Mains Question:

Q. India's recent achievement as a net exporter of medical consumables and disposables marks a significant milestone. How can this achievement be leveraged to strengthen India's position in the global medical goods market?

UPSC Civil Services Examination, Previous Year Question (PYQ):

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)