Indian Drug Makers under Lens

Why in news?

Recently, Gambia declared that from July 1, 2023, it is running strict quality control checks on all pharma products imported from India due to contaminated drugs.

What is the position of India in pharma Industry?

- India is known as the ***"pharmacy of the world"*** due to the low cost and high quality of its medicines.
- The Pharmaceutical industry in India is the ***third 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 GDP.***
- India is the ***world's largest provider of generic medicines*** by volume, with a 20% share of total global pharmaceutical exports.
- It is also ***largest vaccine supplier*** in the world by volume, accounting for more than 50% of all vaccines manufactured in the world.
- India is the ***12th largest exporter of medical goods*** in the world.
- According to Economic Survey 2023, the turnover in the domestic pharmaceutical market is estimated to be at $41 billion in 2021.
- 100% (Foreign Direct Investment FDI) is allowed under automatic route for Greenfield pharmaceuticals.

What is the issue with Indian Pharma products?

- In Gambia and Uzbekistan it's reported that children died due to consumption of contaminated cough syrup.
- In Sri Lanka patients reported to have died after being administered with anaesthetic drug.
- So Indian drug makers were brought under international scrutiny due to alleged contaminated drugs.
- India has at least 5 major poisoning drug events since 1972.

What is the regulatory process in pharma industry?

- **Central Drug Standard Control Organisation (CDSCO) -** It is the apex drug regulatory framework. It also
  - 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.

- **Drugs and Cosmetics Act, 1945 -** CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials. It
  - Lays down the standards for Drugs, control over the quality of imported Drugs in the country.
  - Coordinates the activities of State Drug Control Organizations by providing expert advice.

- **Indian Council of Medical Research (ICMR) -** Formulates, coordinates, and promotes biomedical research and Ethical principles.
- **Power of the Central Government-** It is responsible for imports and approving new drugs based on safety and efficacy data.
- **Power of the State Government-** Deals with Licensing and prosecutions of pharma companies.
- **Legislation-** Under Drugs and Cosmetics Act 1945, manufacturers not adhering to good manufacturing practices can be subjected to a maximum punishment of imprisonment for life death.

What are the challenges ahead of Indian pharma industry?

- **Loss of international market value** -Due to international scrutiny, globally India may lose its pharma value market.
- **Poor track record-** Irregular management over drug contamination and there is no mandatory provision to disclose inspection reports.
- **Poor conviction rate-** Due to errors committed by drug inspectors including
  - Shoddy paperwork,
  - Failure to seize , record its condition of storage and label the samples properly,
  - Failure to complete the testing process of samples before its expiry date.

- **Less manpower-** CDSCO is under shortage of drug inspectors, which results in poor monitoring of drug regulations.

  For example: Karnataka is working at nearly half its sanctioned capacity for drug inspectors.

- **Lack of Accountability-** Mere cancellation or suspension of license allows the owner to manufacture under new name.

What lies ahead?

- **Robust management of pharma industry-** Make mandatory provision to disclose inspection reports.
- **Increase the expenditure in R&D-** Need to ramp up investments in research which would result in safe drugs and increase efficacy of drugs.
- **Increase the penalty over violation-** In case of threat to life or alleged death criminal prosecution can be executed against those responsible for manufacturing and

marketing of drugs.
- Enhance accountability and transparency over regulatory framework.
- **Increase manpower -** Proper track record in regulating and monitoring the drug regulatory framework.

References

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