



# IAS PARLIAMENT

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## Indian Drug Makers under Lens

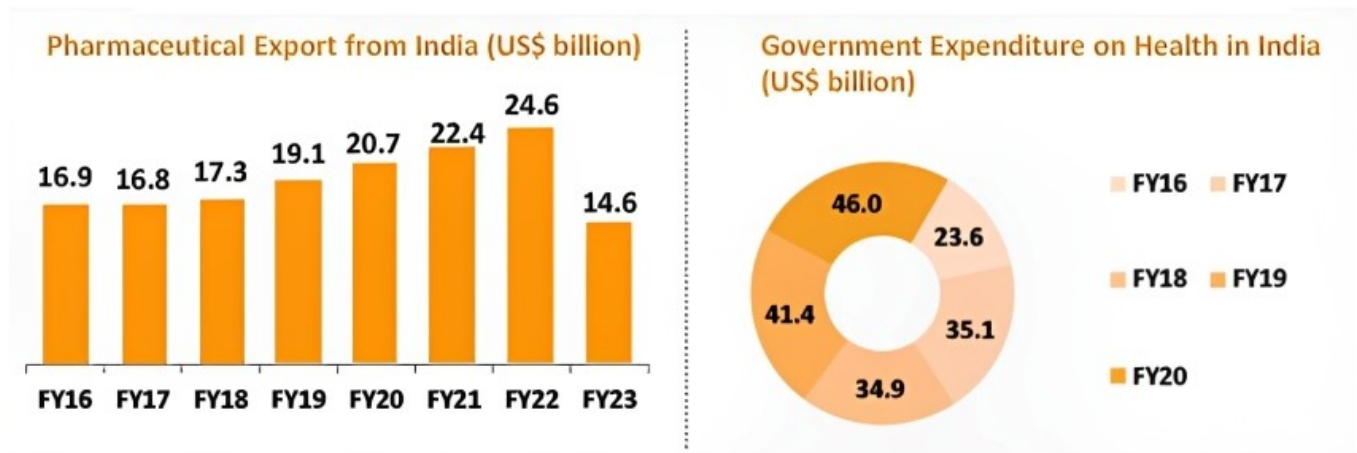
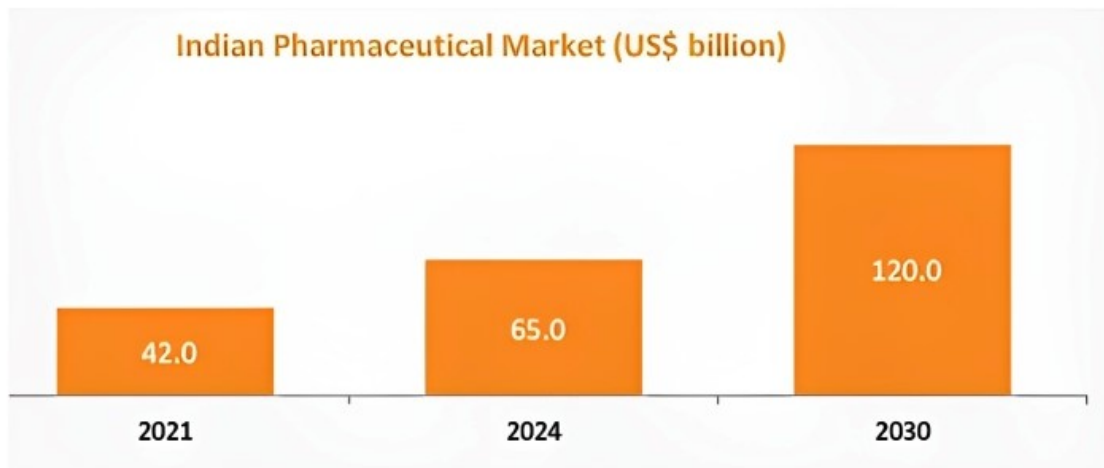
### Why in news?

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.

## INDIAN PHARMA SECTOR



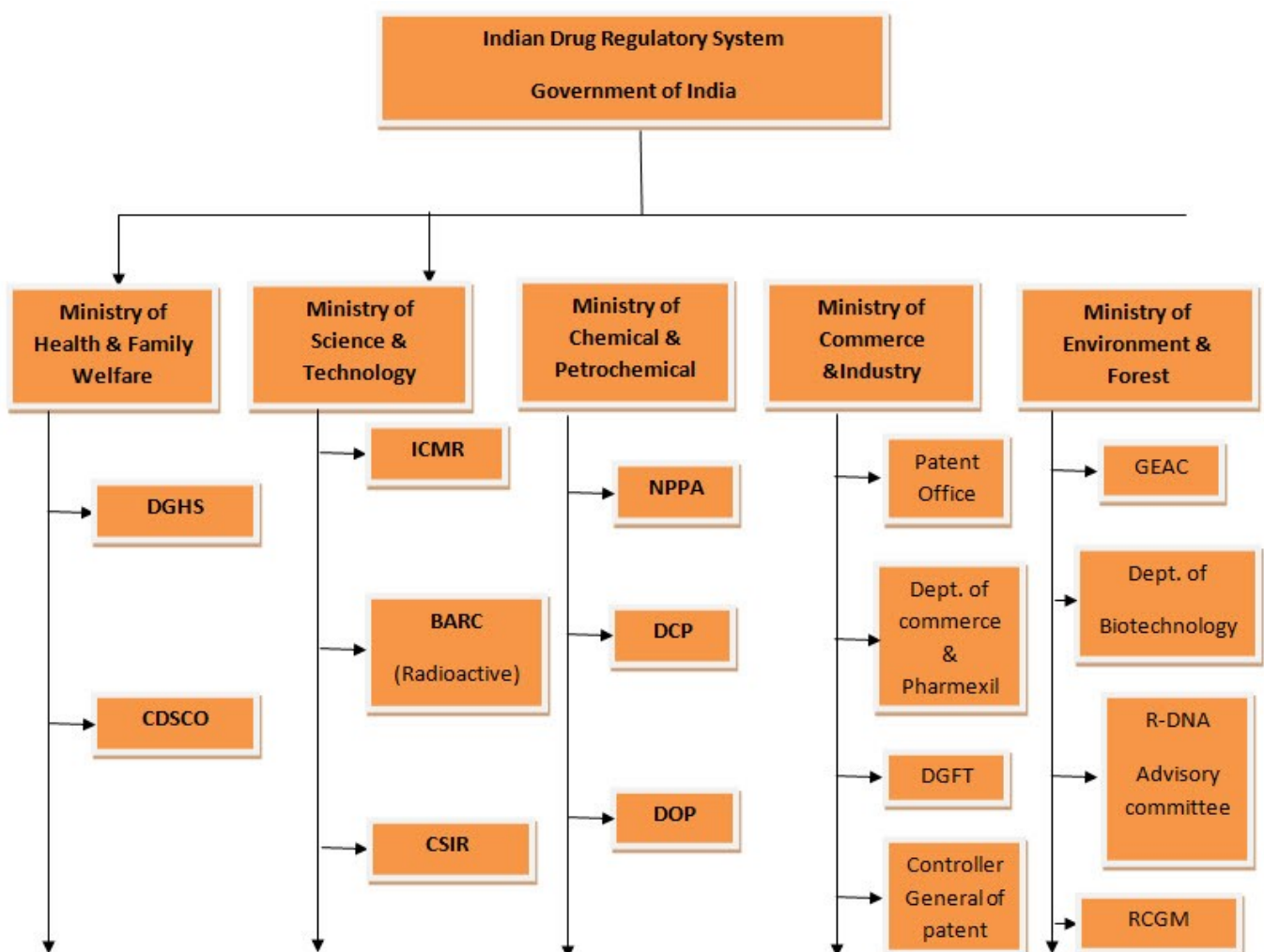
### What is the issue with Indian Pharma products?

- 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

1. [The Hindu| Indian Pharma industry under lens](#)
2. [CDSCO| About](#)
3. [IPEF| stats](#)



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