

## Pharmaceuticals Import into India

### Why in news?

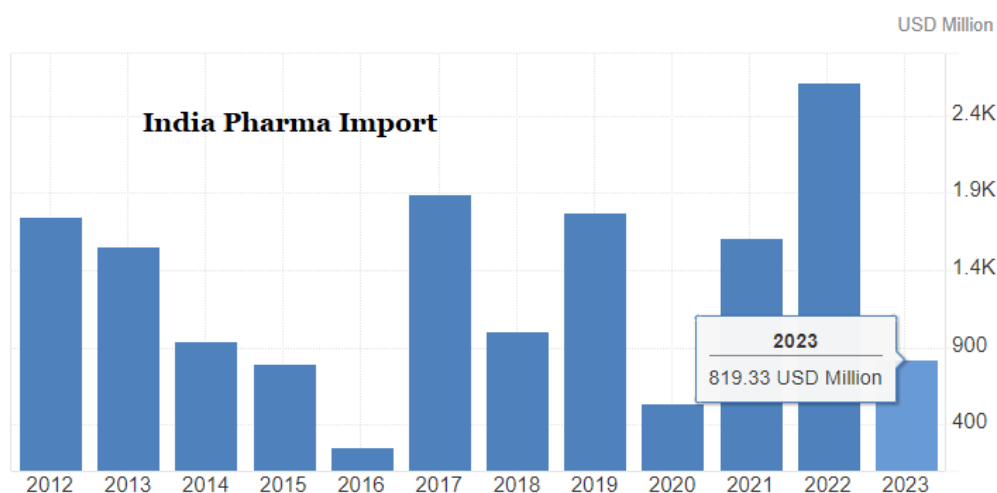
Recently, Union Budget 2024-25 has proposed removing the 10-12% customs duty on three cancer medicines marketed by AstraZeneca.

### What are the impacts of pharmaceutical imports?

#### Status of Indian Pharma Industry

- India **ranks third** in production of drugs and pharmaceuticals by volume, exporting to around 200 countries/territories.
- The Indian pharmaceutical industry supplies **62%** of the global demand for vaccines.
- India is the leading supplier of DPT (diphtheria, pertussis and tetanus), BCG (Bacillus Calmette-Guérin, used primarily against tuberculosis), and measles vaccines.
- At least **70% of WHO's vaccines** (as per the essential immunisation schedule) are sourced from India.

- **Imports of Pharmaceutical Products in India** - It averaged 850.28 USD Million from 1996 until 2023, reaching an all-time high of 2616.87USD Million in 2022.



- Reliance on imports could have a chilling effect on the pharmaceutical industry, weakening its ability to remain relevant.
- **Strengthens monopoly** - Most of the imported medicines have monopoly in Indian market.
- Encouraging pharma imports will further strengthen the strong hold of their monopoly.
- **Increases cost** - Imported pharma products have higher costs than domestically produced products.
- This further increases the out-of-pocket health expenditures of Indians which already accounts for nearly 47.1% of the total health expenditure in 2021.

- **Disincentives domestic producers** - Promoting imports reinforces entry barriers faced by the domestic industry such as the product patent regime and the regulatory guidelines.
- New medicines are generally under patent protected thus preventing Indian companies from producing affordable generics/biosimilars.
  - Regulatory guidelines impose costly and time-consuming requirements for obtaining marketing approval of biosimilars.
- **Lose self-sufficiency** - Import facilitation makes the country dependent on imports.

### What are the measures to protect Domestic Indian Pharma?

- **Compulsory Licenses** - Under the Indian Patent Act 1970, if a patented medicine is “not available to the public at a reasonably affordable price,” compulsory licences (CL) can be granted to any company willing to make the product in India.
- **Government use licences** - India’s Patents Act also permits the granting of government-use licences to enable domestic production of generic versions of patented medicines.
- **Price Control** - National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling price of scheduled medicines specified under the Drugs (Prices Control) Order, 2013 (DPCO).

*Drugs (Prices Control) Order, 2013 (DPCO) is issued under Essential Commodities Act, 1955 by Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers.*

### What lies ahead?

- Establish a competitive environment for critical medicines by promoting local production.
- Invoke public interest provisions under the patents act to promote local production.
- Amend the regulatory guidelines for marketing approval of bio-therapeutics to reduce the burden on domestic companies.
- Make use of compulsory license provision to control drug prices and promote domestic industries.
- Eliminate duplicative requirements in biosimilar guidelines saves time and resources to facilitate patient access.
- Align import policies to support the growth of the domestic pharmaceutical industry.

### Quick facts

• **National Pharmaceutical Pricing Authority (NPPA)**

- **Formation** - NPPA was constituted in 1997 as an attached office of the Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers.
- **Objectives** -To ensure availability and accessibility of medicines at affordable prices and to enforce and control prices and availability of the medicines in the India.
- **Functions** - It is to implement and enforce the provisions of the DPCO in accordance with the powers delegated to it.
  - It monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
  - It collect/ maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations;
  - It render advice to the Central Government on changes/ revisions in the drug policy.
- **National List of Essential Medicines** - The NPPA regularly publishes lists of medicines and their maximum selling prices.

## References

1. [The Hindu | Imports weaken Indian pharma](#)
2. [NPPA | Functions and Responsibilities](#)

