Pharmaceuticals Import into India

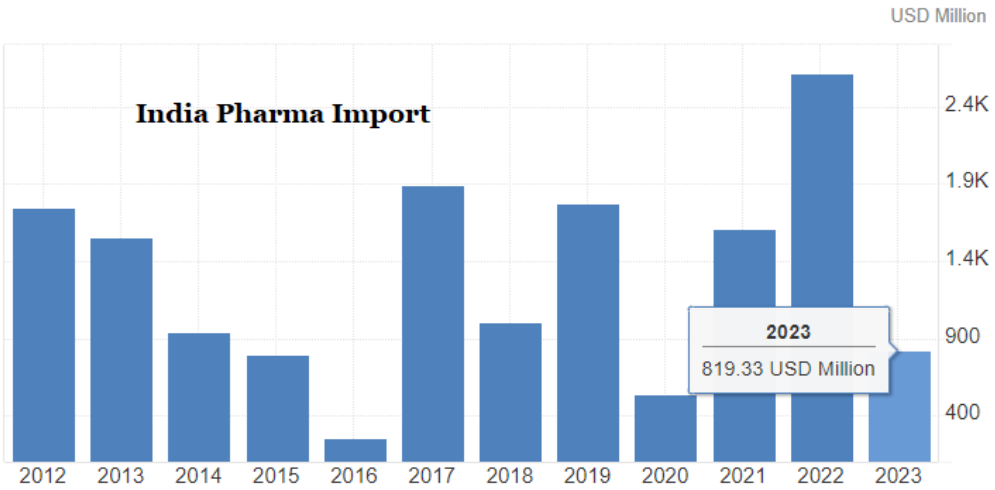
Why in news?

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?

- Stablish 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

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