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Report on Active Pharmaceutical Ingredients: TIFAC

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Why in News

Recently, the **Technology Information Forecasting and Assessment Council (TIFAC)** has brought a report titled '**Active Pharmaceutical Ingredients- Status, Issues, Technology Readiness, and Challenges**'.

TIFAC is an autonomous organization under the Department of Science & Technology, Government of India.

Key Points

- **Recommendations from the Report:**
 - **Indigenous production of Active Pharmaceutical Ingredients (APIs)** needs to be scaled up to a level where the production is economically viable.
 - Need for Mission mode Chemical Engineering with defined targets for uninterrupted synthesis of API molecules.
 - **To create mega drug manufacturing clusters** with common infrastructure in India.
 - **Developing a Technology platform for biocatalysis** for cost optimization and **investing in the fermentation sector** of large capacity.
 - **Biocatalysis** refers to the use of natural substances from biological sources (such as enzymes) to speed up (catalyze) chemical reactions.
 - Attention to technologies like hazardous reactions, cryogenic reactions, and membrane technology.
 - **Cryogenic reactions** are chemical reactions performed at very low temperatures (below $-150\text{ }^{\circ}\text{C}$).
 - **Membrane technology** covers all engineering approaches for the transport of substances between two fractions with the help of permeable membranes.
 - **Focus on antiviral drugs**, which require nucleic acid building blocks - Thymine, Cytosine, Adenine and Guanine - none of which are manufactured in India because of lack of manufacturing plants.
 - **Government encouragement for Indian companies** working in chemical segments such as steroids, amino acids, carbohydrates, nucleosides, etc., to collaborate for technology development or quick technology transfer.
 - **Need for closer academia-industry interaction** for technology development and commercialization.
- **India's Pharmaceutical Industry:**
 - It is **third largest in the world, in terms of volume, behind China and Italy**, and fourteenth largest in terms of value.
 - It has a strong network of around 3,000 drug companies and about 10,500 manufacturing units with a domestic turnover of Rs 1.4 lakh crore in 2019, with exports across the world.
 - Recently, India has approved two schemes, namely the Scheme on **Promotion of Bulk Drug Parks and Production Linked Incentive (PLI)** and Scheme to promote domestic manufacturing of critical Key Starting Materials/Drug Intermediates and Active Pharmaceutical Ingredients in the country.

- **Issues Involved:**

- **Low-profit margins and non-lucrative industry** forced domestic pharmaceutical companies to stop manufacturing APIs and start importing, which is a cheaper option with increased profit margins on drugs.
- With the availability of cheaper APIs from China, **the pharmaceutical industry relies heavily on imports**. The imports from China have been increasing steadily and now stand around 68%.

Note: Active Pharmaceutical Ingredients (APIs), also called bulk drugs, are significant ingredients in the manufacture of drugs. The Hubei province of China is the hub of the API manufacturing industry.

Way Forward

- Implementing the recommendations of TIFAC will help India to become **self-reliant (Atmanirbhar)** in the Pharmaceutical sector by reducing its import dependence.
- Indigenous manufacturing will boost India's pharma sector and will help generate jobs.

Source: PIB