Active Pharmaceutical Ingredients - UPSC Notes

Active Pharmaceutical Ingredients or APIs are also known as bulk drugs and a term that is often heard in business news. Hence, it is important to understand what the term means and India's production of APIs, for the IAS exam Indian economy segment.

Active Pharmaceutical Ingredients (APIs)

Active Pharmaceutical Ingredients are the active ingredients contained in a medicine.

- It is that part of the medicine that produces the intended therapeutic effects.
- For example, in a painkiller, the active ingredient relieves pain. In the OTC drug Crocin, the API is paracetamol.
- Only a small amount of the API is required to produce the effect and so the medicine contains only the required amount of the API.
- Some drugs contain multiple APIs to treat varied symptoms.
- API is the most important raw material in the production of medicines.

Components of Drugs

All drugs contain two parts:

1. API
2. Excipient - These are chemically inactive substances that help deliver the API to the system. Eg. lactose, mineral oil, etc.

Intermediate is the chemical substance that is in the process of becoming an API from a raw material. Sometimes, many intermediates are produced before the final API is manufactured.

Manufacture of APIs

India has a thriving pharmaceutical industry and is the world's leading supplier of generic medicines. What worked for Indian companies is their ability to reverse engineer drug formulations and produce cheaper medications, thus creating a market both globally and domestically. India also has one of the lowest manufacturing costs in the world.

- Indian companies are known for their manufacture of generic drugs and APIs. Dr. Reddy's Laboratories is one of the leading producers of APIs globally.
- India's pharmaceutical exports stood at $19.14 billion in 2019.
- Despite being a major provider of drugs globally, Indian companies today are increasingly reliant on Chinese imports for APIs.
- In the early 90s, the country was self-reliant on APIs, but the Chinese have been able to capture the API market in the country owing to their cheaper products.
- Indian manufacturers have gradually stopped manufacturing APIs because of this.
- China's Hubei province is the hub of the API manufacturing industry.
- Currently, around 68% of the Indian API demand is met by Chinese imports.
- During the COVID-19 pandemic, India's ability to meet the global demand for medicines was affected because of the inability to import APIs from China.

The government has come up with new schemes to promote bulk drug manufacturing in India, so that the import of APIs can be reduced. The schemes are discussed in the next section.

Bulk Drug Parks Scheme

With an active partnership with states, the government aims to develop three bulk drug parks in the country.

- Funding to states will be in the form of grants-in-aid with a maximum limit of Rs. 1000 Crore per Bulk Drug Park.
- The parks will offer common facilities to manufacturers such as distillation plants, solvent recovery plants, power and steam units, effluent treatment plants and so on.
- The scheme aims to reduce the manufacturing cost of bulk drugs in India and bring down the dependency on other countries for bulk drugs.
- It is expected to help in the continuous and uninterrupted supply of drugs in the country meeting the huge healthcare needs.
- The state governments will set up State Implementing Agencies (SIA) to implement the scheme.

Production Linked Incentive (PLI) Scheme

The second scheme expected to give a fillip to the domestic drug manufacturing industry is the PLI Scheme.

- This scheme aims to promote the domestic manufacturing of, apart from APIs, drug intermediates and key starting materials (KSMs).
- In this scheme, financial incentives will be provided to eligible manufacturers of identified 53 critical bulk drugs on their incremental sales over the base year (2019-20) for a period of 6 years.
- The scheme will be implemented through a Project Management Agency (PMA) to be nominated by the Department of Pharmaceuticals.