Active pharmaceutical ingredients and Schemes Approved to Promote Drug Manufacturing

Part of: GS-III- Economy and Manufacturing (PT-MAINS-PERSONALITY TEST)

The pharmaceutical drugs which are biologically active are called active ingredients (AI). In medicine, terms such as bulk active and active pharmaceutical ingredient (API) are also interchangeably used. For natural products, the term active substance is used. There are certain medication products that could comprise of multiple active ingredients. “Pharmacon” or “Pharmakon”, is a traditional word for Active Pharmaceutical Ingredient originally denoting a magical drug or substance.

Often, “active constituent” is used while giving references to the active substance of interest in a plant (For example, arecoline in areca nuts, salicylic acid present in the bark of a willow tree) as the term “active ingredient” may in many sense imply a perception of human agency (something that is manually combined with other substances), whereas the natural products in plants occur naturally and will not be added by human agency. Therefore, the plant does not have ingredients but has active substances.

About:

- All drugs are made up of two core components: (1) Active Pharmaceutical Ingredient (API), which is the central ingredient, and (2) excipients.
- The Active Pharmaceutical Ingredient (API) is the part of any drug that produces its effects. Some drugs, such as combination therapies, have multiple active ingredients to treat different symptoms or act in different ways.
- Excipients are substances other than the drug that helps deliver the medication to your system. Excipients are chemically inactive substances, such as lactose or mineral oil.
- Example: For instance, if you have a headache, acetaminophen is the API, while the liquid in the gel-capsule or the bulk of a pill is the excipient.
- Raw material vs API: API and raw material are often confused due to the similar usage of the two terms. Raw material refers to chemical compounds that are used as a base to make an API.
- Indian scenario: India is currently dependent on China for imports of APIs to make “certain” essential medicines, with around Rs 12,255 crore worth of these ingredients imported from the country in 2016-17, as per government data.

Schemes and Drugs production

Recently, the Union Cabinet has approved two schemes, namely the scheme on Promotion of Bulk Drug Parks and Production Linked Incentive (PLI) Scheme to promote domestic manufacturing of critical Key Starting Materials/Drug Intermediates and Active Pharmaceutical Ingredients in the country.

Promotion of Bulk Drug Parks Scheme

- Number of Parks: The government aims to develop 3 mega Bulk Drug parks in India in
partnership with States.

- **Funding:** Government of India will give Grants-in-Aid to States with a maximum limit of Rs. 1000 Crore per Bulk Drug Park.
  - A sum of Rs. 3,000 crore has been approved for this scheme for next 5 years.
- **Facilities:** Parks will have common facilities such as solvent recovery plant, distillation plant, power & steam units, common effluent treatment plant etc.
- **Need of the Scheme:** Despite being 3rd largest in the world by volume the Indian pharmaceutical industry is significantly dependent on import of basic raw materials, viz., Bulk Drugs that are used to produce medicines. In some specific bulk drugs the import dependence is 80 to 100%.
- **Objectives:** The scheme is expected to reduce manufacturing cost of bulk drugs in the country and dependency on other countries for bulk drugs.
  - The scheme will also help in providing continuous supply of drugs and ensure delivery of affordable healthcare to the citizens.
- **Implementation:** The scheme will be implemented by State Implementing Agencies (SIA) to be set up by the respective State Governments.

**Production Linked Incentive (PLI) Scheme**

- **Aim:** The PLI scheme aims to promote domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country.
- **Funding:** Under the scheme financial incentive will be given 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.
- **Impact:** PLI scheme will reduce India’s import dependence on other countries for critical KSMs/Drug Intermediates and APIs.
  - This will lead to expected incremental sales of Rs.46,400 crore and significant additional employment generation over 8 years.
- **Implementation:** The scheme will be implemented through a Project Management Agency (PMA) to be nominated by the Department of Pharmaceuticals.

**Essential Medicines**

India’s drug pricing regulator, National Pharmaceutical Pricing Authority (NPPA), has allowed an increase in the maximum retail prices of 21 drugs currently under price control by as much as 50%.

- The decision has been taken by invoking paragraph 19 of the Drug Prices Control Order (DPCO), 2013 which until now has been used only to reduce the prices of stents and knee implants.
- Most of these drugs are used as the first line of treatment and are crucial to the public health program of the country.
- The decision by the NPPA will apply to formulations like the BCG vaccine for tuberculosis, vitamin C, antibiotics like metronidazole and benzylpenicillin, antimalarial drug chloroquine and leprosy medication dapsone.

**Drug Prices Control Order, 2013**
Under the provisions of DPCO 2013, only the prices of drugs that figure in the National List of Essential Medicines (NLEM) are monitored and controlled by the regulator, the National Pharmaceutical Pricing Authority.

- Essential medicines are those that satisfy the priority healthcare needs of the majority of the population. The primary purpose of NLEM is to promote rational use of medicines considering the three important aspects i.e. cost, safety and efficacy.

- Paragraph 19 of the DPCO, 2013, deals with increase or decrease in drug prices under extraordinary circumstances. However, there is neither a precedent nor any formula prescribed for upward revision of ceiling prices.

**Background**

- Manufacturers have been citing difficulties in supplying these drugs and many companies even have applied for discontinuation of the product on account of unviability.

- NPPA has been receiving applications for upward price revision under para 19 of DPCO, 2013, since last two years citing reasons like “increase in Active Pharmaceutical Ingredient - API (key ingredient) cost, increase in cost of production, exchange rates etc. resulting in unviability in sustainable production and marketing of the drugs.

- **India is dependent on China for over 60% of its API requirement**, higher API costs for price-controlled medicines reduce profits and sometimes even make production of these drugs unviable in India. For instance, the cost of ingredients to make vitamin C went up as much as 250%, leading to a 25-30% shortage of this drug in India in 2019.

**Key Points**

- The decision has been taken to ensure that the life saving essential drugs must remain available to the general public at all times. This is to avoid a situation where these drugs become unavailable in the market and the public is forced to switch to costly alternatives.

- This is the first time the NPPA — which is known to slash prices of essential and life-saving medicines — is increasing prices in public interest.

On a longer term, **India needs to build capabilities to manufacture the key ingredients** for these medicines.