

Biopharmaceutical Alliance

Why in news?

Recently, the biopharmaceutical alliance was launched to build a resilient supply chain in the biopharmaceutical sector.

What are Biopharmaceuticals?

- Biopharmaceuticals are complex medicines made from living cells or organisms.
- **Production** They are often produced using cutting-edge biotechnological methods.



- **Types** There are two classes of biopharmaceuticals.
- **Biologics** It include medicines that generally *<u>come from living organisms</u>*, which can include animal cells and microorganisms, such as yeast and bacteria.
 - \circ *Insulin* became the first biologic cleared for human use in 1982.
- **Biosimilar** It is a biologic that is highly *similar to another biologic* that is already patented (original biologic).
 - A *human growth hormone* was first biosimilar, which was approved in Europe.

Feature	Biologic	Biosimilar	Generic
Representation	~		***
Origin	Living organisms	Similar to the reference biologic	Identical to the brand-name drug
Manufacturing process	Complex	Complex	Simple
Regulatory approval process	More rigorous	More streamlined	Similar to biologics
Safety and efficacy	Same standards	Same standards	Same standards
Time Investment	8-10 years	7-8 years	2-3 years
Cost	More expensive	Less expensive	Less expensive
Savings	Less savings	More savings	More savings than the brand -name drug

- Biologics cannot be copied exactly, and so biosimilar are not identical to their original biologic.
- **Usage** They are potential for precise and targeted treatments, usually injected into the body.
- **Challenges** They tend to be heat sensitive and easy to contaminate.
- They are difficult and expensive to make, store and transport.

What is Biopharmaceutical Alliance?

- **Need** There was a huge <u>drug supply shortages</u> seen during the Covid-19 pandemic.
- The production of essential *raw materials and ingredients* of pharma products are *concentrated in a few countries* posing a greater risk in supply chain.
- **Formation** It was initially organized during the U.S.-Korea Critical and Emerging Technology Dialogue in 2022.
- The first meeting of the Alliance was held in San Diego during the <u>Bio International</u> <u>Convention 2024</u>, the <u>world's largest biopharmaceutical exhibition</u>.
- Members <u>India</u>, US, South Korea, Japan and the EU.
- **Primary focus** To identify and *mitigate the weaknesses in the bio-pharmaceutical supply chain* through advanced manufacturing technologies and robust research and development (R&D) initiatives.
- Importance It is a crucial step towards enhancing *economic security and public*

health resilience on a global scale.

What are the key objectives of the Biopharmaceutical Alliance?

- **Building a resilient supply chain** It involves ensuring the production of <u>essential</u> <u>raw materials and ingredients is diversified</u> and not overly concentrated in a few regions.
- **Coordinating bio-policies and regulations** By *harmonizing standards and procedures*, it will facilitate smoother cross-border collaborations.
- It may also *reduce bureaucratic hurdles* that can impede the swift delivery of critical biopharmaceutical products.
- **Supporting research and development** It places a strong emphasis on joint R&D efforts.
- By pooling resources and expertise, the member countries intend to <u>accelerate</u> <u>innovation</u> in the biopharmaceutical field.
- It also plans to ensure that new and effective treatments are developed and made accessible more rapidly.
- **Creating a detailed supply chain map** A comprehensive pharmaceutical supply chain mapping will identify critical nodes and potential points of failure within the supply chain.
- This will enable the alliance to proactively address weakness and enhance the overall resilience.

What is Indian Pharmaceutical Alliance (IPA)?

- It is an *association of 23* leading research-based *pharmaceutical companies in India*, committed to patient care globally.
- **Formation** IPA began its journey in 1999 with six top drug makers Cipla, Dr Reddy's, Lupin, Piramal, Ranbaxy and Wockhardt as its founding members.
- Aim To create a collaborative environment for the Indian pharma industry to discover, develop and deliver quality-assured medicines equitably.



With Quality, Innovation and Access as the pillars of its functioning, IPA endeavours to:

- **Significance** It has evolved as the most potent voice for the Indian pharma industry, promoting high standards in pharmaceutical production and quality assurance.
- IPA companies collectively account for
 - \circ 85% of the private sector investment in pharmaceutical R&D
 - 80% of India's exports of drugs & pharmaceuticals
 - $\circ~62\%$ of the price controlled medicines
 - $\circ~60\%$ of the domestic market sales

India's Pharmaceutical Sector

• Market Size - It is currently valued at \$50 Bn.

• India is the *largest provider of generic drugs* globally, accounting for 20% of the global supply by volume.

- Globally, India ranks <u>3rd in pharmaceutical production</u> by volume.
- Export market India supplies
 - Over 50% of Africa's requirement for generics
 - About 40% of generic demand in the US
 - About 25% of all medicine in the UK.

• **Vaccine market** – India accounts for about <u>60% of global vaccine</u> <u>demand</u>.

• It is the leading supplier of *DPT, BCG and Measles* vaccines.

• <u>70% of WHO's vaccines</u> (as per the essential Immunization schedule) are sourced from India.

• **Measures** – 100% Foreign Direct Investment (FDI) in the pharmaceutical sector is allowed under the automatic route for Greenfield pharmaceuticals.

• 100% FDI in the pharmaceutical sector is allowed in brownfield pharmaceuticals, wherein 74% is allowed under the automatic route and thereafter through the government approval route.

• The <u>Production Linked Incentive</u> (PLI) scheme to boost domestic manufacturing and reduce dependency on imports.

• The <u>'Pharma Vision 2020'</u> aims to make India a global leader in end-to-end drug manufacturing.

References

- 1. <u>The Hindu | Biopharmaceutical Alliance</u>
- 2. <u>FDA| Biopharmaceuticals</u>
- 3. IPA Indian Pharmaceutical Alliance

