

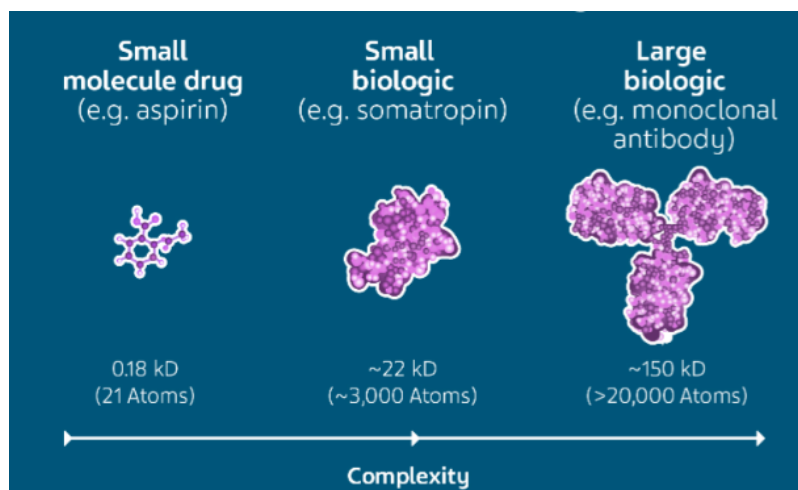
Biopharmaceutical Alliance

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 *come from living organisms*, which can include animal cells and microorganisms, such as yeast and bacteria.
 - **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 drug supply shortages 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 Bio International Convention 2024, the **world's largest biopharmaceutical exhibition**.
- **Members** - **India**, 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.

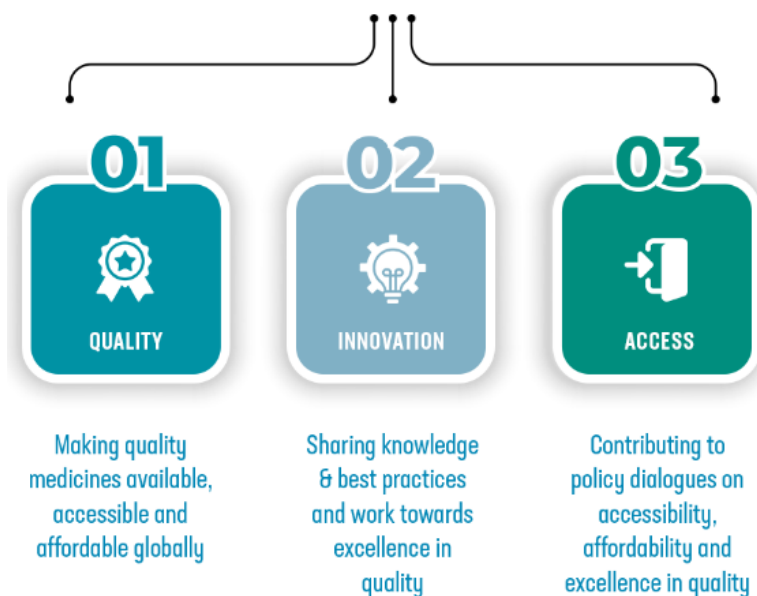
What are the key objectives of the Biopharmaceutical Alliance?

- **Building a resilient supply chain** - It involves ensuring the production of *essential raw materials and ingredients is diversified* 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 *accelerate innovation* 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
 - 85% of the private sector investment in pharmaceutical R&D
 - 80% of India's exports of drugs & pharmaceuticals
 - 62% of the price controlled medicines
 - 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 *3rd in pharmaceutical production* 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 *60% of global vaccine demand*.
 - It is the leading supplier of *DPT, BCG and Measles* vaccines.
 - *70% of WHO's vaccines* (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 *Production Linked Incentive (PLI)* scheme to boost domestic manufacturing and reduce dependency on imports.
- The '*Pharma Vision 2020*' aims to make India a global leader in end-to-end drug manufacturing.

References

1. [The Hindu | Biopharmaceutical Alliance](#)
2. [FDA| Biopharmaceuticals](#)
3. [IPA| Indian Pharmaceutical Alliance](#)