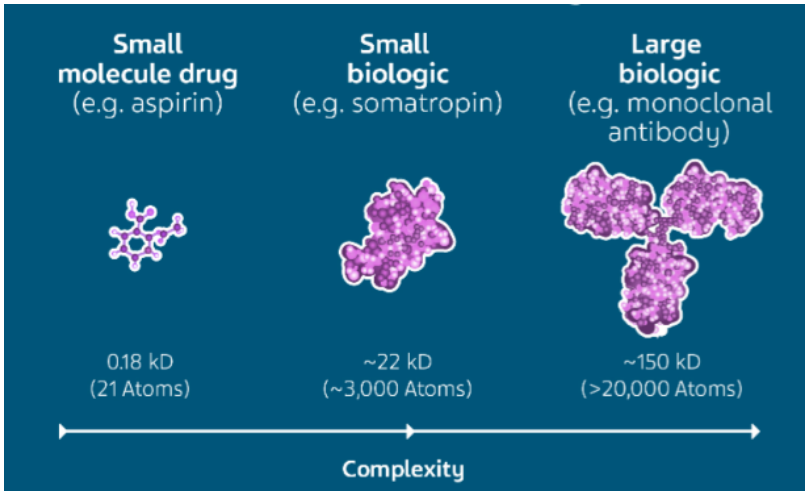
Biopharmaceutical Alliance

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*

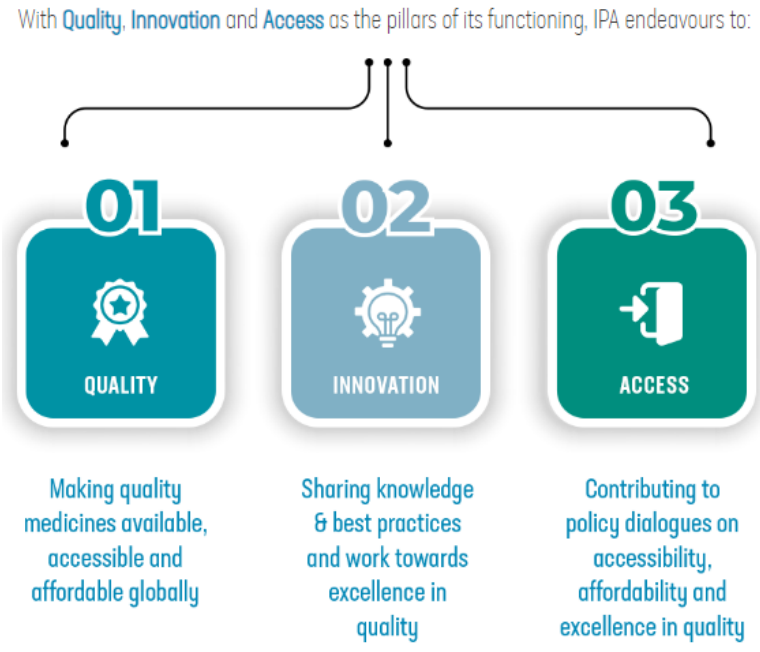
health resilience on a global scale.

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.



- **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

SHANKAR IAS PARLIAMENT
Information is Empowering