Biotherapeutic Medicines : Putting Patients First

International Federation of Pharmaceutical Manufacturers & Associations
IFPMA

What is so special about how they are made?

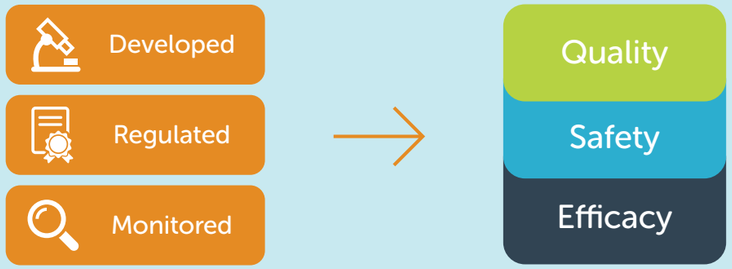
Biotherapeutic medicines are very complex. They are made in living organisms by genetically engineering DNA.

The biologic is modified to ensure it functions as intended.

The most effective cell line is selected for expansion and is grown in bioreactors and carefully monitored.

Production requires highly controlled steps to ensure consistent **quality**, **safety**, and **efficacy**.

What should patients know?



How to differentiate them?

Biotherapeutic Medicine

A medicine which has been licensed by the national regulatory authorities on the basis of a full registration dossier; i.e. the approved indication(s) for use were granted on the basis of full quality, efficacy and safety data.

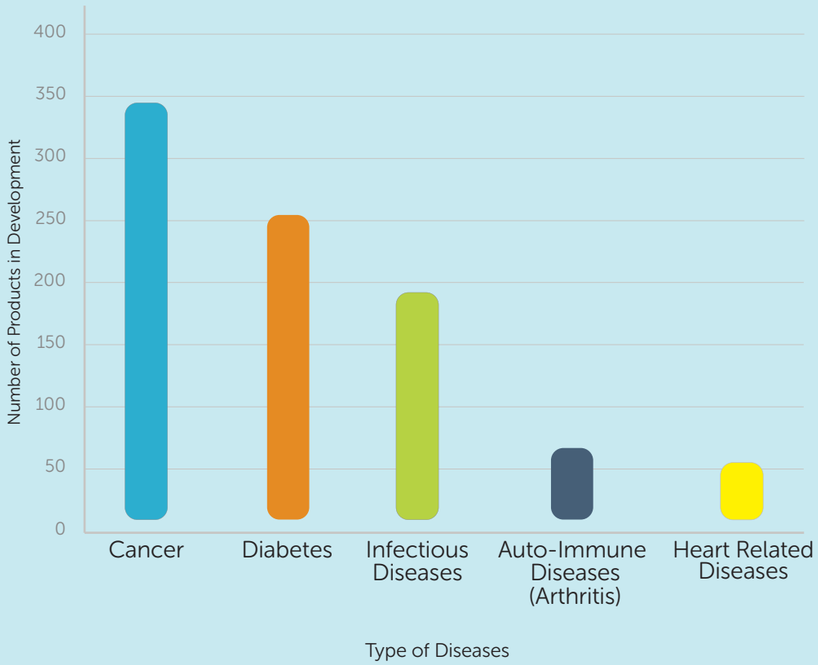
Biosimilar

- Product highly similar to a biotherapeutic medicine that has already been authorized with full dossier.
- Subject to a tailored regulatory data package with full side-by-side analytical and clinical testing.
- Minor variations compared to the original biotherapeutic reference product with no clinically meaningful differences identified.

Non-comparable Biotherapeutic

- Product claiming to be copy of another biotherapeutic medicine yet not approved in alignment with WHO standards.
- A non-comparable biotherapeutic is:
  - Developed with limited side-by-side comparison proving biosimilarity to reference product.
  - Product with unclear approval standards, thereby posing potential risk to patients and public health.

What's in the R&D pipeline?



Source: PhRMA

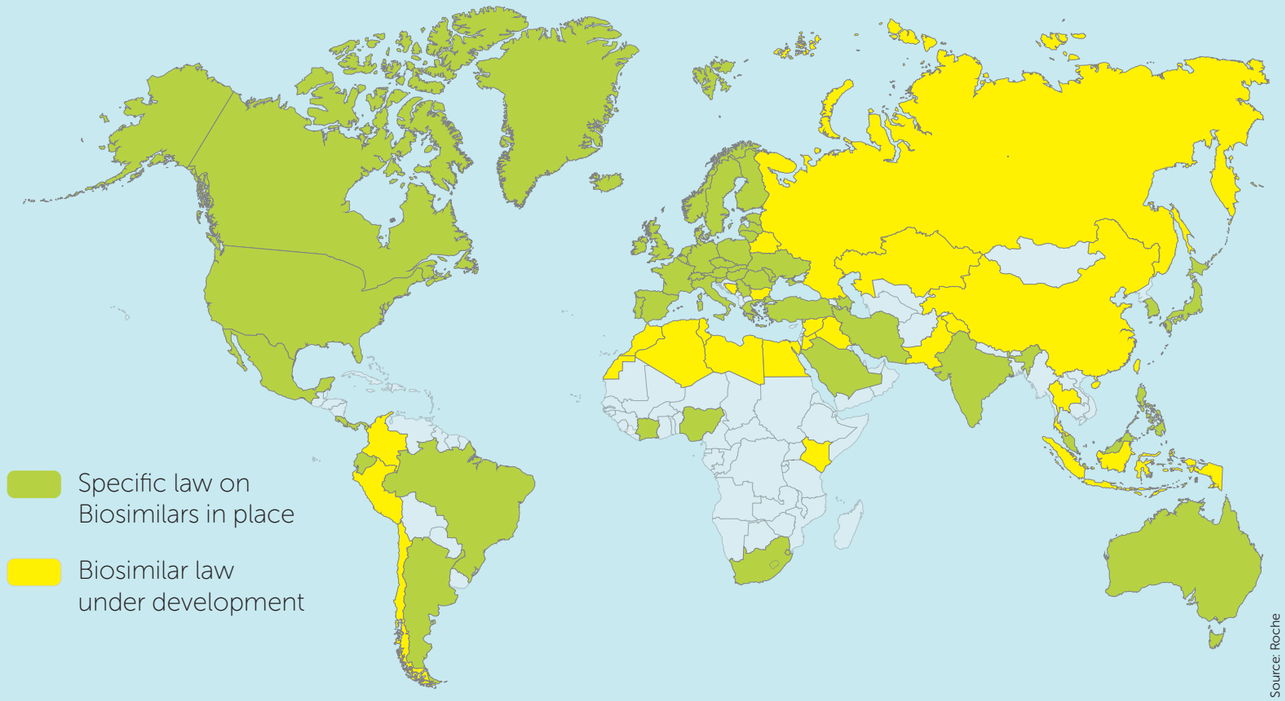
What is the value they bring?

Millions of lives saved

Health costs reduced

Society as a whole healthier

Where are biosimilars regulated?



Source: Roche

What was the journey like?

- **1940's** — **Penicillin** first antibiotic discovered
- **1953** — **Structure of DNA** discovered
- **1982** — **Human insulin** first approved biotherapeutic product
- **1986** — **Interferon α** first biotherapy for anti-cancer therapy
- **2003** — First entire **human genome** sequenced
- **2005** — **EMA** first Regulatory Agency to create biosimilar guidelines
- **2007** — **First biosimilars** to treat **cancer** authorized
- **2009** — **WHO Guidelines** on evaluation of Biosimilars
- **2010** — **First cancer vaccine** approved US
- **2012** — **DNA machine** sequences human genomes in hours