Biotherapeutic Medicines: Putting Patients First

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.

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 should patients know?
- Specific law on Biosimilars in place
- Biosimilar law under development

Where are biosimilars regulated?

What’s in the R&D pipeline?

What is the value they bring?
- Millions of lives saved
- Health costs reduced
- Society as a whole healthier

Where was the journey like?
- Penicillin: first antibiotic discovered 1940
- Structure of DNA discovered 1953
- Human insulin: first approved biotherapeutic product 1982
- Interferon α: first biotherapy for anti-cancer therapy 1986
- First entire human genome sequenced 2003
- EMA: first Regulatory Agency to create biosimilar guidelines 2005
- First biosimilars to treat cancer authorized 2007
- WHO Guidelines on evaluation of Biosimilars 2015
- First cancer vaccine approved US 2016
- DNA machine sequences human genomes in hours 2018