An introduction to biologics, including biosimilar medicines

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Biologics have transformed healthcare for people who can access them

- Are made up of living organisms (such as human cells, bacteria and yeast)
- Offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available
- Have been used for over 3 decades in the clinical practice
- Can either be protected by patents (single manufacturer monopoly) or not (several manufacturers) - a patent lasts 20 years
Biologic medicines are very large molecules: millions of building blocks!

- Complex yet well characterised molecules by today’s analytical technology
- Naturally exists in different versions - differences in regions which do not impact the safety & efficacy profiles
- Well mapped ‘critical regions’ for its safety and efficacy profiles – development and clinical experience
- Clinical profile - Good understanding of their mode of action
Biologic medicines: “high tech” engineering, manufacturing and analytical testing

Building blocks
• Modify Cells to produce target protein

Biologic production
• Grow cells & Harvest protein

Biologic substance
• Isolate & Purify

Biologic medicine
• Formulate, Fill, Package & Label

TARGET
• Thorough analytical testing
• Confirm critical regions / safety & efficacy profiles

patients • quality • value • sustainability • partnership
Biosimilar medicines are biologic medicines

What is the idea behind biosimilar medicines?

How do you make biosimilar medicines?

What’s in it for patients?
What’s the idea behind biosimilar medicines?

Biosimilar medicines are biologic medicines containing one version of existing biologic substances which is no longer protected by patents.

Like all authorised a biologic medicine, the version of the active substance is the same for all critical aspects that matters clinically, to do what it is expected to do.

Variability & heterogeneity will occur in the same way as in the reference biologic medicine, for clinically non-meaningful regions of the molecule, and will be controlled by thorough and sophisticated analytical technics.
How do you make biosimilar medicines?

By the time a patent for a biological medicine expires, a vast body of knowledge exists: from the original clinical trials, the many information gathering through process changes in the life cycle and the clinical experience.

The biosimilar medicine development demonstrate “sameness” of the molecule for what matters clinically (clinical and safety profiles).

Science and knowledge combined are called the ‘totality of evidence’; they prescribe not re-establishing efficacy and safety which are well known, documented and established.

To demonstrate sameness, the most reliable and precise scientific tools are not clinical trials but analytical testing – clinical testing for biosimilars only re-confirm sameness.
What’s in it for patients?

1. Access to modern therapies, in concertation with physicians

2. Same health outcomes, under physicians monitoring

3. Earlier access and same (improved) health outcomes, in concertation with physicians

“When it comes to health, conversation is the best medicine”
Key Messages on Biosimilar Medicines
10 years of positive biosimilar medicines experience; the promise on patient access is huge

- Biologic medicines have transformed healthcare and greatly improved patient outcomes for 3 decades
- Biologic medicines can be protected or not by patents (bio-originator and biosimilars) and solely and only exist in versions
- Biologics versions available to patients all behave the same clinically – same quality, safety and efficacy profiles
- Biosimilar medicines have generated 10 years of positive clinical experience in the EU and confirmed the robustness of the scientific concepts underlying their review and authorisation process
- Biosimilar medicines are biologic medicines that can support overcoming issues of access to modern therapies
Going further
Biosimilar medicines handbook (3rd edition - 2016)

The reference document for anyone interested in learning about biosimilar medicines

THANK YOU!
ANY QUESTION?