What’s in a name – biosimilars?

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What is a biosimilar?

A biosimilar is a “copy” version of an approved biological medicine with demonstrated similarity in physicochemical, biological and immunological characteristics, efficacy and safety, based on a comprehensive comparability study.

Biosimilars are variously termed:

• Similar Biotherapeutic Products (WHO)
• Similar Biological Medicinal Products (EU/TGA)
• “biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product” (US FDA)
• follow-on biologics (PMDA, Japan) and
• subsequent entry biologics (Health Canada).
Biosimilar ≠ generic
1. Size

Asprin vs IgG
From: Kozlowski et al NEJM 2011;365:385-388

What's in a name – biosimilars?
1. Size
2. Complexity – 4 levels of structure

Biosimilar
1. Size
2. Complexity - glycosylation

What's in a name – biosimilars?
Variability – e.g. EPO

- Mass = 27948±285 deglycosylated 18240±4
- 2 disulphide bonds
- 3 N-glycosylation
- 2 O-glycosylation sites
- Many types of glycans
- C-terminal truncation

Even the most controlled biotechnological process produces a spectrum of 100 000s of molecules – all having different activity, half-life and potential to induce an immune reaction.
1. Size
2. Complexity
3. Variability

Biosimilar ≠ generic
Comparable ≠ bioequivalent
Naming ➔ safety

• Information
• Warning
• Clarity
Naming → safety

For biosimilars:
- Identify reference product
- Distinguish from other biosimilars
- Clarify use
Naming → safety

TGA biosimilar naming policy:
• ABN of reference product
• Biosimilar identifier based on INN
• Linked to advice in PI
Thank you!