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Subsequent entry biologics/biosimilars: a viewpoint from Canada

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Received: 1 August 2012 / Accepted: 9 August 2012 / Published online: 26 **August 2012**
Clinical Rheumatology 2012

Journal of Clinical Rheumatology (Springer 2012) 31:1289–1292

Abstract

We have reviewed the issues surrounding the advent of biosimilars in the rheumatoid arthritis biologic field. Our proposals emphasize the need to focus primarily on patient safety and to assess the outcomes of therapy both in the short and longer term.

Biologics, which for the purposes of this paper refer to the drugs as they are used in rheumatology, are very complex molecules. They are made with the aid of DNA recombination technology and are secreted by cells, bacteria, or plants, which have incorporated the appropriate genes. The drugs are then harvested from the secretions. Sometimes a "second-generation" biologic is made that is structurally different from the original molecule and these are intended to
improve performance or perhaps decrease immunogenicity while preserving the mechanism of action. The development of golimumab subsequent to infliximab might be considered an example of this. These second-generation products are not usually considered to be "follow-on" products. Such follow-on products, which are also known as biosimilars or in Canada, subsequent entry biologics, are intended to be sufficiently similar to the reference product that there is no clinically meaningful difference between them in terms of safety, purity, and efficacy.
(p. 1289)

… *Manufacturing* It is as important for SEBs/biosimilars as for the reference drug that there be development of a manufacturing process that consistently produces drug substance within the accepted normal batch to batch variation of the product as regard to the structural features that are most important for the SEB/biosimilar's function. **Biosimilar products are required to be "highly similar to the reference product, notwithstanding minor differences in clinically inactive components" and exhibit "no clinically meaningful differences between the biologic product and the reference product in terms of the safety, purity and potency of the product" (BPCIA 2009) [reviewed in 2–6]**.
(p. 1290)

… *Regulatory framework* **The regulatory framework for SEBs varies in different countries [2–6].**
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References

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