

The Comparability Conundrum: Biosimilars in the United States, Europe and Canada

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A biosimilar contains an active ingredient that is similar, but not identical, to the active ingredient in an approved reference drug. This raises the issue of when and how a biosimilar should be allowed to compare to a reference drug for marketing approval. This paper looks at the current regulation of biosimilars in Europe, the United States and Canada. The response to the challenge of regulating biosimilars has been varied. For example, Europe implemented a specialized, abbreviated legal pathway about five years before the United States. In Canada, abbreviated approval by comparison to an approved reference biologic was already available under the existing regulatory framework. Regulators have significant discretion to set criteria establishing when a biosimilar is deemed comparable to a reference biologic. The comparability standards for review of the one biosimilar approved in all three jurisdictions (Omnitrope, a human growth hormone) were largely consistent. Omnitrope may be instructive as to the potential standard of review for future single chain protein biosimilars. In contrast, the United States approved a second-entry low molecular weight heparin with no clinical trials, whereas European guidelines state that clinical trial data will be required.

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