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Pharma in brief - Canada

Health Canada releases revised fact sheet on biosimilars

Fact sheet: Fact Sheet: Biosimilars [***Fact Sheet***]
Date: Revised December 7, 2016
Related enactments: *Food and Drugs Act*, RSC 1985, c F-27
Food and Drug Regulations, CRC, c 870 [***Food and Drug Regulations***]

Summary

Health Canada has revised its fact sheet on biosimilar biologic drugs (**biosimilars**), which were formerly known as subsequent-entry biologics. This update follows Health Canada's recent revisions to the *Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs* (the ***Guidance Document***).

Highlights

In line with recent changes to the *Guidance Document*, the *Fact Sheet* has been substantially rewritten and contains an overview and description of the regulatory framework for biosimilars. The *Fact Sheet* also includes a new section on drug and patient access, which includes the following:

- Health Canada's authorization of a biosimilar is independent of provincial, territorial, or private drug plan decisions regarding its formulary listing and reimbursement.
- Health Canada's authorization of a biosimilar is not a declaration of equivalence between the biosimilar and its reference biologic drug, and is independent of any decision as to interchangeability between these drugs. Interchangeability decisions are a matter of provincial and territorial jurisdiction.
- Health Canada recommends that decisions regarding switching to a biosimilar from its reference biologic drug should be made by treating physicians in consultation with the patient.

For more information on Health Canada's revised approach to the regulation of biosimilars, see our report on the full *Guidance Document* here.

Links:

Fact Sheet:	Fact Sheet: Biosimilars
Guidance Document:	Information and Submission Requirements for Biosimilar Biologic Drugs (November 14, 2016)
Previous documents:	Guidance For Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs) (March 5, 2010) Draft - Revised Guidance Document: Information and Submission Requirements for Subsequent Entry Biologics (SEBs) (December 7, 2015)
Related enactments:	*Food and Drugs Act,* RSC 1985, c F-27 *Food and Drug Regulations*, CRC, c 870

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