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THE DUPUIS LANGEN GROUP
SOLUTIONS WITH CLARITY

Benefit brief

THE EMPLOYEE SOLUTIONS NEWSLETTER FOR THE CLIENTS AND FRIENDS OF DUPUIS LANGEN

What's a BIOLOGIC?

Biologic drugs are currently one of the fastest growing areas in pharmaceutical development. This class of drug provides treatment options for serious or rare illnesses where no effective treatments were previously available, such as cancer, rheumatoid arthritis, multiple sclerosis, and diabetes. Some familiar drugs like vaccines and insulin are also **biologics**. But their high cost has created a unique situation for thousands of Canadians who want, but can't have, their life-altering medication.

Traditional Drugs	Biologic Drugs
Produced through chemical synthesis	Produced using living microorganisms (e.g., bacteria)
Smaller, less complex molecules	Large, complicated molecules
Differences in manufacturing processes unlikely to affect finished product	Even small changes in manufacturing process can affect the nature of the finished product and the way it works in the body

Unlike synthetic drugs, **biologics** do not easily penetrate cell membranes and are not very stable in the stomach and intestines . As a result biologics are most often injected or delivered intravenously.

Best Selling Biologics of 2014

Rank	Biologic	Company	2014 Sales	Approximate Cost Per Month of Average Dose	Approved Indication
1	Humira	AbbVie	12.543 billion	$3000-$6000	Rheumatoid Arthritis, Crohn's disease, Colitis,
2	Remicade	Johnson & Johnson and Merck & Co.	9.240 billion	$2600-$5000	Rheumatoid Arthritis, Crohn's Disease, Colitis
3	Rituxan	Roche and Biogen Idec	8.678 billion	$1500	Cancer and Rheumatoid Arthritis
4	Enbrel	Amgen and Pfizer	8.538 billion	$2000-$3000	Rheumatoid Arthritis
5	Lantus	Sanofi	7.279 billion	$450	Diabetes

Data Sources: Genetic Engineering News and Drug Prescribing Information; Healthline: http://www.healthline.com/

So, what's a SEB?

Subsequent entry biologics (SEB) is a term used by Health Canada and describes "a biologic product that is similar to and would enter the market subsequent to an approved innovator biologic product." In Europe these products are called "**biosimilars**," and in the US they're generally called "**follow-on biologics**."

BIOSIMILARS ARE SIMILAR

BUT NOT IDENTICAL TO THE ORIGINAL MEDICINE

Like regular biologics, **SEBs** are complicated to develop and manufacture, and even small differences in production can make a difference in the way they work. Therefore, while they are similar to traditional generic drugs in that they are produced after the patent of the original **biologic** drug ("innovator") expires, they can't technically be thought of as "generic **biologics**." Unlike generic drugs, which are copies of chemical drugs and therefore interchangeable with the brand-name drug, **SEBs** will never be identical to the original innovator brand. **Biosimilars** are not considered "generic" **biologics**; they are not interchangeable, and any new **SEB** that comes along is treated like a new drug.

APPROVING SEBS IN CANADA

Due to the complexity involved in producing biologics, Health Canada requires SEBS manufacturers to follow the New Drug Submission process; however, it may include a "reduced package" of data based on the similarity with the reference **biologic**. The reference biologic must already have adequate safety, efficacy, and effectiveness data available. So far Health Canada has approved three SEBs for sale in Canada :

Trade Name	Common Name	Manufacturer	Reference Biologic	Date Approved
Omnitrope®	somatropin	Sandoz	Genotropin®	April 30, 2009
Inflectra®	infliximab	Celltrion	Remicade®	January 15, 2014
Remsima®	infliximab	Celltrion	Remicade®	January 15, 2014

Biologics tend to be **EXPENSIVE**, and, while **SEBs** are also pricey when compared to traditional generic alternatives, they are a less expensive treatment option than the innovator drug.

A number of **biologics** will come off patent in the near future, so we expect to see more **SEBs** become available. But not all **biologics** will end up having a corresponding **SEB**. Since **SEBs** require the same sort of development and approval process as **biologics**, it's unlikely that a large number of manufacturers will make them. Plus **SEBs** will likely remain high-cost drugs when compared to the cost difference between traditional brands and generics. Mandatory generic drug pricing rules won't apply since to **SEBs** are not considered generics.

Sources:
1 Health Canada, Fact Sheet: Subsequent Entry Biologics in Canada, , www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/fs-fi/fs-fi_seb-pbu_07-2006-eng.php ; 2 Health Canada, Information and Submission Requirements for Subsequent Entry Biologics (SEBs), March 2010, www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/seb-pbu_2010-eng.php; 3 John Norman and Livia Aumand, Subsequent Entry Biologics in Canada, Gowlings, May 2014, www.fdli.org/docs/canadian/john-norman-subsequent-entry-biologics-in-canada.pdf?sfvrsn=0; 4 Greenshield Canada, Fall 2014, http://www.greenshield.ca/

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