canadian BIOsimilars FORUM

Capturing the Opportunity of **Biosimilars** in Canada

The Canadian Biosimilars Forum has 3 Fundamental Goals:

1. Raising awareness of biosimilars - and their distinctiveness - and serving as a credible resource for evidence-based information regarding biosimilars.

2. Informing and supporting public policies that encourage access, awareness and adoption of biosimilars.

3. Providing an opportunity for companies developing biosimilars for the Canadian market to work with key stakeholders on topics instrumental to biosimilars and patient care.

The Canadian Biosimilars Forum

Established in 2016 as the voice and resource for biosimilars in Canada, the Canadian Biosimilars Forum currently encompasses the country's most diverse group of biosimilars manufacturers: Merck Canada, Pfizer Canada, Sandoz Canada, and Teva Canada. This alliance represents the breadth of the biosimilars industry and is dedicated to increasing awareness, access and adoption of biosimilars across Canada.

Members also draw on a wealth of experience gained from developing innovative medicines and lower-cost generic medicines for Canadians, and work to educate policy makers, the public and other key stakeholders on the opportunities presented by biosimilars.

Biologic and Biosimilar Medicines

Biologic medicines are larger and more complex molecules than traditional pharmaceutical drugs, and come from living organisms or from their cells. They are used to treat a range of diseases and medical conditions.

Biosimilar medicines are biologics demonstrated to be highly similar to a reference biologic drug already authorized for sale by Health Canada. A biosimilar and its reference biologic drug are highly similar with no clinically meaningful differences in safety and efficacy between them.

Biosimilars may enter the market once the reference biologic medicine has lost market exclusivity. Due to the size, complexity and natural variability of biologic molecules – and because biologics are made in living cells rather than through chemical synthesis – a biosimilar and its reference biologic drug can be shown to be similar, but not identical.

The Canadian Biosimilars Forum believes that biosimilars can provide additional treatment options for physicians and patients. Biosimilars also support the sustainability of the Canadian health care system once the originator biologic medicine has lost market exclusivity.

As Health Canada itself says, *"Health Canada's rigorous standards for authorization mean that patients and health care providers can have the same confidence in the quality, safety and efficacy of a biosimilar as any other biologic drug."*[1]

Market data clearly shows that the uptake of biosimilars in Canada has been marginal and very slow. The Forum believes that without more proactive and assertive decisions by Canadian policy makers, our country will not have a robust biosimilars market.

The Forum believes it will be impossible to meaningfully grow the use of biosimilars without affording all patients preferential access to biosimilars. There is an urgent need to implement appropriate, evidence-based policies that more directly and effectively expand access to biosimilars beyond what is currently available.

Sustainability of the Canadian Health Care System

The Patented Medicines Pricing Review Board (PMPRB) estimated that public drug plans across Canada could save from $332M to $1.81B in the 3rd year following biosimilar entry across a portfolio of products.[2]

The Forum believes that the savings from biosimilars create an opportunity to invest in new or expanded treatments and medical services, leading to more medicines for more patients. Biosimilars have the potential to offer similar clinical benefits of biologics while making these treatments more cost effective.

Switching

The Government of Canada states that *"Health Canada considers a well-controlled switch from reference biologic drug to biosimilar in an approved indication to be acceptable, and recommends that a decision to switch a patient being treated with a reference biologic drug to a biosimilar, or between any biologics, be made by the treating physician in consultation with the patient and take into account any policies of the relevant jurisdiction."*[3]

In Europe, where biosimilars have been used for over a decade and have generated over 700 million patient days of clinical experience, there are 13 countries already supporting policies to switch patients from a reference biologic medicine to its biosimilar.[4]

The Forum encourages payers to implement well-controlled switch strategies that support a one-time switch of an existing patient from a reference biologic drug to one of its biosimilars. These switch strategies should be accompanied by engagement with multiple stakeholder groups and by robust education programs.

Physicians have a key role to play in switching. After an originator biologic medicine has lost market exclusivity and biosimilars have become available, patients should return to their physician, who will prescribe a treatment from a list of approved biosimilars. Securing a new prescription is essential, since the Forum does not believe that biologics and biosimilars can be automatically substituted at the pharmacy level.

1 Health Canada, Fact Sheet: Biosimilars.
2 Patented Medicine Prices Review Board, Potential Savings from Biosimilars in Canada.
3 Health Canada, Health Canada's 2017 Biosimilars Workshop: Summary Report.
4 Medicines for Europe, Biosimilar Medicines.

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