BIOSIMILARS UPDATE

Biosimilars may enter the market after the expiry of originator biologics drug patents and data protection. Health Canada's rigorous standards for authorization mean that patients and healthcare professionals can have the same confidence in the quality, safety and efficacy of a biosimilar as any other biologic drug. Health Canada evaluates all the information provided to confirm that the biosimilar and the originator biologic drug are similar and that there are no clinically meaningful differences in safety and efficacy between them.[1]

The European biosimilars market

- Europe has over 10 years of clinical experience with biosimilars.[2]
- European regulators have recognized that biosimilar competition can offer advantages to healthcare systems, and expect it to improve patients' access to biological medicines.[2]

Biologics in Canada

- Biologics are one of Canada's fastest growing segments in pharmaceutical spending.[3] In 2017, biologic medicines accounted for $7.6 billion in sales in Canada,[3] a growth more than doubling that of total drug expenditures.
  - Biologics spending growth was 10.7% compared to 5.3% for total prescription drug expenditures*.[3]
  - Biologics represent 35.5% of total brand prescription sales in dollars*, including seven out of the top 10 pharmaceutical products. [3]

Biosimilar benefits for Canadian drug plans

- The cost of biologics is expected to result in significant financial pressure on healthcare budgets over the next decade based on a 2014 estimate .[4]
  - In 2018, total health expenditure in Canada was expected to reach $253.5 billion, or $6,839 per person, and as prospects for economic growth improve, growth in health spending could be higher in the future. [5]
- Biosimilars offer a choice for patients and may improve access.[6]

- Over the last two years, Canadian provinces have begun to list biosimilars preferentially for patients starting treatment with a particular drug molecule, while some private payers have instead chosen to give preferential status to biosimilars.
  - However, despite savings potential,[7] uptake of biosimilars in Canada remains low.

* For the 12 months ending December 2017. Clinical significance unknown.

BIOSIMILARS UPDATE

Merck Canada's position on transition policies

- To capitalize on potential cost savings offered by biosimilars,[7] Merck believes 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.
- Merck believes we can learn from the implementation of transition policies in other jurisdictions. This includes European countries such as France and the UK, where transition policies are actively supported by the respective national health authorities.[8, 9]
    - With over 10 years of clinical experience with biosimilars, European regulators have recognized that biosimilar competition can offer advantages to healthcare systems and expect it to improve patient access to biological medicines.**Error! Bookmark not defined.**
- Merck continues to work actively with various stakeholders, including government partners, to create a viable market for biosimilars. This forms part of Merck's ongoing commitment to bringing innovative solutions to Canadian healthcare.

Engaging patients and physicians

- Transitioning generally refers to a one-time change from an originator biologic drug to a biosimilar.
    - The decision to transition a patient being treated with an originator biologic drug (innovator product) to a biosimilar should be made by the treating physician in consultation with the patient and taking into account available clinical evidence and any policies of the relevant jurisdiction.[1]
- Provincial legislators have a continuing role to play in helping create the conditions for a viable and sustainable biosimilars market, as all interested stakeholders work together to accelerate the uptake of biosimilars.
- Health Canada considers a well-controlled switche 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 .[10]

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