BIOTECanada

WHAT PATIENTS NEED TO KNOW ABOUT BIOLOGIC MEDICINE IN CANADA

Subsequent Entry Biologic (SEB) Developments from Health Canada

On January 15, 2014, Health Canada approved two new Subsequent Entry Biologic (SEB) products for the Canadian marketplace. The two products, Remsima™ and Inflectra™ were approved based on comparison to the reference product Remicade® (infliximab) following procedures described in the 2010 Draft Guidance for SEB products published by Health Canada. Details related to the timelines on when these new products will be introduced into the marketplace remain to be determined. Once approved by Health Canada, these products can appear in the market place at any time.

The decision announced by Health Canada contained the following details important for patients and their doctors to be aware of when determining appropriate courses of treatment:

- SEBs are not considered interchangeable with the original biologic product.
- In the case of these approvals, Health Canada has accepted the same non-proprietary name (infliximab) as the original biologic product.
- Health Canada granted limited extrapolation for these products. SEB clinical trials were conducted in support of the rheumatoid arthritis and ankylosing spondylitis indications. Approvals for psoriasis and psoriatic arthritis were granted based on pharmacokinetic studies and the originator's data.

What should patients and their doctors be aware of when considering the use of a SEB product?

INTERCHANGEABILITY:

Health Canada "does not support automatic substitution of a SEB for its reference biologic drug". [1] As such a SEB product should not be considered interchangeable with an original biologic product.

NAMING:

Industry, medical practitioners and patients have strongly recommended clear unique naming and identification of SEB products is essential for post-market surveillance and patient safety. Post-market surveillance must be able to accurately and quickly match any adverse events to the correct drug.

EXTRAPOLATION:

Due to the complexity of biologic medicines, industry, medical experts and patient organizations have called for the best scientific knowledge to support each indication a SEB product is approved for. The data used to support an indication needs to be based on the best science. Health Canada determines the approved indications for SEBs.

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[1] *Excerpt from Health Canada Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs) March 5, 2010*

QUESTIONS FOR PATIENTS TO CONSIDER:

- Was the product tested in a clinical trial for patients with my condition?
- How many patients with my condition have received the drug and for how long?
- Are there any differences in route of administration or the dosage level?

NEXT STEPS

BIOTECanada will continue to seek clarification with Health Canada on the issues of product naming and extrapolation of indications related to the approval of these products. As more information becomes available, BIOTECanada will share it with the national network of patients who have been engaged on this issue.

What is a Subsequent Entry Biologic (SEB)?

Subsequent Entry Biologics (SEBs), also known as "biosimilars" or "follow-on biologics" in Europe and the USA, are follow-on versions similar to an original biologic drug, made by different manufacturers after the patent on the innovator drug has expired.

What is the innovator industry position on SEBs?

BIOTECanada supports the introduction of SEB products in Canada. BIOTECanada has worked for many years through the consultation and publication of the Draft SEB Guidance to ensure the focus of how these products are regulated is guided by scientific principles aimed at addressing patient safety, while protecting incentives for the original innovator products.

BIOTECanada is the national industry association representing over 250 biotechnology companies in Canada. BIOTECanada has been working with Health Canada since 2008 supporting the development of a transparent, predictable regulatory framework for the approval of SEBs.

For more information visit biotech.ca/SEB

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