BIOTECanada Principles on Subsequent Entry Biologics in Canada

Health Canada has issued guidance to sponsors for the regulation of Subsequent Entry Biologic (SEB) products in Canada. SEBs (also known as Biosimilars) are not generic equivalents in the sense of traditional small molecule pharmaceuticals, therefore patients, physicians, pharmacists and policy makers must understand the unique aspects of SEBs as they enter the Canadian health care system.

BIOTECanada members support the development of a science based, transparent, predictable regulatory framework for the approval of SEB products that rigorously ensures patient safety and preserves incentives for the continued introduction of innovative biologic therapies.

What is a Subsequent Entry Biologic?

- It is a biologic drug that enters the market subsequent to, and "similar" to a reference biologic product authorized for sale in Canada.
- It relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic product.
- Considered "similar" to a given reference biologic product and are not "generic" equivalents.
- The structure of a biological product is extremely sensitive to manufacturing changes and can affect pharmacokinetic or pharmacodynamic profile, biological activity, immunogenicity, clinical efficacy, and safety.

What is Health Canada's Position on SEBs?

- "SEBs are not considered to be "generic" biologics…"[1]
- "Authorisation of a SEB by Health Canada is not a declaration of pharmaceutical, bioequivalence or therapeutic equivalence to the reference biologic product."[2]
- Post-market surveillance/risk management plans are required.
- "…Health Canada does not support automatic substitution of a [SEB] for its reference biologics drug and recommends that physicians make only well-informed decisions regarding therapeutic interchange."[3]
- Comparative clinical trials are required to establish similarity to the originator biologic product.

How Should SEBs be used in Practice?

- Choice of biologic therapy, including SEBs, should be a shared decision made between physicians and patients, based on informed knowledge of the clinical efficacy and safety data of a product.
- SEBs cannot be considered interchangeable or substitutable with the reference biologic product.
- All biologics should have a unique non-proprietary name and a unique brand name for distinguishable prescribing, safety surveillance, adverse event reporting and traceability.
- Patient safety considerations should be the paramount criterion for physicians, pharmacists and policymakers in decisions around use of SEBs.
- The use of SEBs requires pharmacovigilance equivalent to an innovative biological medicine.
- Adoption and access for patients must be in accordance with Health Canada approval process based on clinical and science based principles.

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[1] March 5, 2010 Guidance for Sponsors: Information and Submission Requirement for Subsequent Entry Biologics (SEB)s, Health Canada http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/seb-pbu_2010-eng.php#pol

[2] Ibid

[3] Questions & Answers to Accompany the final Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs) http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/01-2010-seb-pbu-qa-qr-eng.php