

ISSUE BRIEF: Subsequent Entry Biologics

THE ISSUE

Canada needs a predictable regulatory framework for Subsequent-Entry Biologic (SEB) approval to ensure patient safety and preserve incentives for the continued introduction of innovative biologics.

RECOMMENDATION

Before approving any Subsequent-Entry Biologic products in Canada, Health Canada must introduce amendments to the Food and Drug Regulations that rigorously ensure patient safety and clearly preserve incentives for the introduction of innovative biologic therapies.

BACKGROUND

- Over the past 20 years innovative biotech therapies, or “Biologics”, have delivered breakthrough medical treatments for serious and life-threatening illnesses, such as cancer, multiple sclerosis, diabetes, and HIV/AIDS, as well as many serious rare diseases.
- “Biologics” are complex medicines that are manufactured using living cells, and are different from and far more complex than most traditional small molecule chemical drugs.
- As intellectual property protections expire on the first generation of biological therapies, interest is growing in the development of copies of these innovative therapies, known in Canada as Subsequent-Entry Biologics (SEBs).
- Due to the complexity of these Biologics, they cannot be exactly copied like small molecule drugs. Therefore, SEBs cannot be considered as “generic biologics” and must be rigorously evaluated using clinical trials to ensure that SEBs are as safe and effective as innovator products.
- The patient safety and intellectual property issues associated with SEBs are complex, and the approval process for these products must be carefully considered through extensive consultation with patients and industry stakeholders.
- Health Canada is currently developing a regulatory framework for the approval of SEBs. The European Union has adopted a workable regulatory framework for SEBs and legislation to establish a SEB approval pathway is currently pending before the United States Congress.
- The approval pathway for SEBs in Canada must be developed using the following principles:
 - Regulatory amendments must precede any SEB approvals to provide a clear and predictable process.
 - Respect all intellectual property protections for innovative biologics including data protection and patent linkage regulations.
 - Allow only Canadian-approved products to be used as comparators for SEBs.
 - Establish product class guidance for clinical trial requirements.

