Canadian Life & Health Insurance Association
Association canadienne des compagnies d'assurances de personnes

September 8, 2025

Centre for Policy, Pediatrics and International Collaboration
Biologic and Radiopharmaceutical Drugs Directorate
Health Products and Food Branch
Health Canada

Via Email: brdd-cppic_brdd-cppci@hc-sc.gc.ca

Re: Consultation on Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs

The Canadian Life and Health Insurance Association (CLHIA) is pleased to provide its comments to the Biologic and Radiopharmaceutical Drugs Directorate at Health Canada on the consultation topic noted above.

Who we are

The CLHIA is the national trade association for life and health insurers in Canada. The industry provides prescription drug benefits to 27 million Canadians and reimbursed $16.6 B in 2024. We are an important part of the drug reimbursement landscape within Canada and value the services the Health Canada provides when reviewing new drug applications.

Overview of the proposed changes to submission packages for new biosimilar drugs:

As an overview, today Health Canada requires that biosimilars be submitted for approval through the New Drug Submission pathway, requiring that they demonstrate a high degree of similarity to the CRBD. This consultation paper considers that a sponsor may include a non-Canadian sourced RBD as a proxy in the review process "*as long as the RBD is marketed in a jurisdiction that has regulatory standards and principles for evaluation of medicines, post-market surveillance activities, and approaches to comparability that are similar to Canada (examples include the United States of America, European Union, United Kingdom, Australia, Switzerland, Singapore and Japan*".

We have reviewed the consultation paper and ask that Health Canada consider the following recommendations:

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1. Streamlined approach to assessment and approval

Health Canada's revised approach emphasizes quality assessments over Canadian clinical trials. This will benefit Canadians and the reimbursement landscape by bringing biosimilars to the market more quickly, reducing the cost of this effort by eliminating clinical trials in Canada, and incenting a greater level of new biosimilars to seek approval in Canada.

There will be times when such a trial is deemed necessary, and we expect Health Canada will determine when that is deemed necessary. Health Canada should encourage manufacturers to consult with them early in the development process regarding these situations.

The new guidance would remove the current requirement for sponsors to provide justifications for authorizing the biosimilar for each of the reference product's indications. This is in line with generic drug submission requirements. The guidance also states that biosimilars would not be eligible for indications for which the originator is NOT approved. This situation would require a new "New Drug Submission" and a different brand name. We would question the need for this where new indications are minor or expansions to existing criteria.

Our industry supports this change in approach to the assessment and approval of new biosimilars to Canada.

2. Managing Risk

Of course, a plan to reduce and/or eliminate Canadian trials given trial and drug approval in the EU or other major markets, may come with additional risks. This approach would necessitate robust post-market surveillance measures to ensure continued patient safety and regulatory confidence. Enhanced reporting requirements could include real-world evidence studies tracking switching patterns between reference biologics and biosimilars through the Canadian Drug Agency (CDA), mandatory reporting of medication errors related to biosimilar confusion or substitution, and expanded data-sharing agreements with FDA, EMA, and other international authorities for improved safety signal detection. These comprehensive post-market monitoring mechanisms would help mitigate potential risks while maintaining the integrity of Canada's drug approval process.

That said, we are confident that the approach, one taken by every other major market, is sound. This approach is already in place in the US and EU. Continuing the status quo of requiring Canadian clinical trials will serve to place Canada off-side with evolving best practices as well as being less attractive as a market to new biosimilars.

Lastly, we encourage Health Canada to be open to early queries from biosimilar manufacturers in order to explore these requirements as they would apply to their biosimilar drug.

We appreciate the opportunity to respond to Health Canada's consultation paper and remain available for follow-up questions.

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