June 7, 2019

Bruno Rodrigue
Director
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Health Products and Food Branch
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Sent by email: hc.lrm.consultations-mlr.sc@canada.ca

Re: Canada Gazette, Part I, Volume 153, Number 13: Regulations Amending the Food and Drug Regulations (Improving Access to Generics)

Dear Mr. Rodrigue,

On behalf of the Canadian life and health insurance industry, I would like to thank you for the opportunity to provide input into the proposed regulatory changes (Improving Access to Generics) from the private drug plan perspective, which accounted for about 35% of the spending on prescription drugs in Canada in 2017.

The CLHIA is a voluntary trade association with member companies that account for 99 percent of Canada's life and health insurance business. In Canada, at the end of 2017, the life and health insurance industry provided more than 25 million Canadians with private supplementary health insurance coverage and made payments of about $11.3 billion on prescription drugs.

Brief Overview

The *Regulatory Impact Analysis Statement* confirms that Health Canada has chosen to revise regulations around the abbreviated new drug submission (ANDS) pathway to market. The current in-force regulations set out four criteria that drug manufacturers must meet in order to submit for approval through the ANDS process:

- the new drug is the pharmaceutical equivalent of the CRP;
- the new drug is bioequivalent with the CRP based on pharmaceutical characteristics and, where the Minister considers it necessary, bioavailability characteristics;

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- the route of administration of the new drug is the same as that of the CRP; and
- the conditions for use for the new drug fall within the conditions for use for the CRP.

As Health Canada's experience and knowledge has evolved on the comparison of medicinal ingredients, it has been considered safe and effective to update the definition of equivalence. Proposed under the new regulations is a test of "identical therapeutically active component" defined as "a medicinal ingredient, excluding those appended portions, if any, that cause the medicinal ingredient to be a salt, hydrate or solvate.

Estimated Impact

The insurance industry expects a largely positive impact from the new regulations in the following areas:

- potentially increased health and safety benefits for Canadians through clarification of the different medicinal ingredients with the identical therapeutically active component;
- increased availability of generic drugs to assist with savings for plan sponsors and plan members;
- declaration of equivalence facilitates interchangeability decisions by provinces/territories, potentially allowing for greater generic substitution resulting in additional savings;

In summary, the private insurance industry expects this regulatory change to ultimately have a positive impact on drug pricing for all Canadians by allowing a route to market for new generics that are not pharmaceutically equivalent to the reference product, but contain the same identical therapeutically active component. We support the implementation of the revised regulations as one component of a larger strategy to address high prescription drug costs in Canada.

We look forward to implementation of the revised regulations and would be pleased to discuss any of the issues raised in this submission in more detail at your convenience.

Yours sincerely,

Original signed by

Joan Weir
Director, Health and Disability Policy