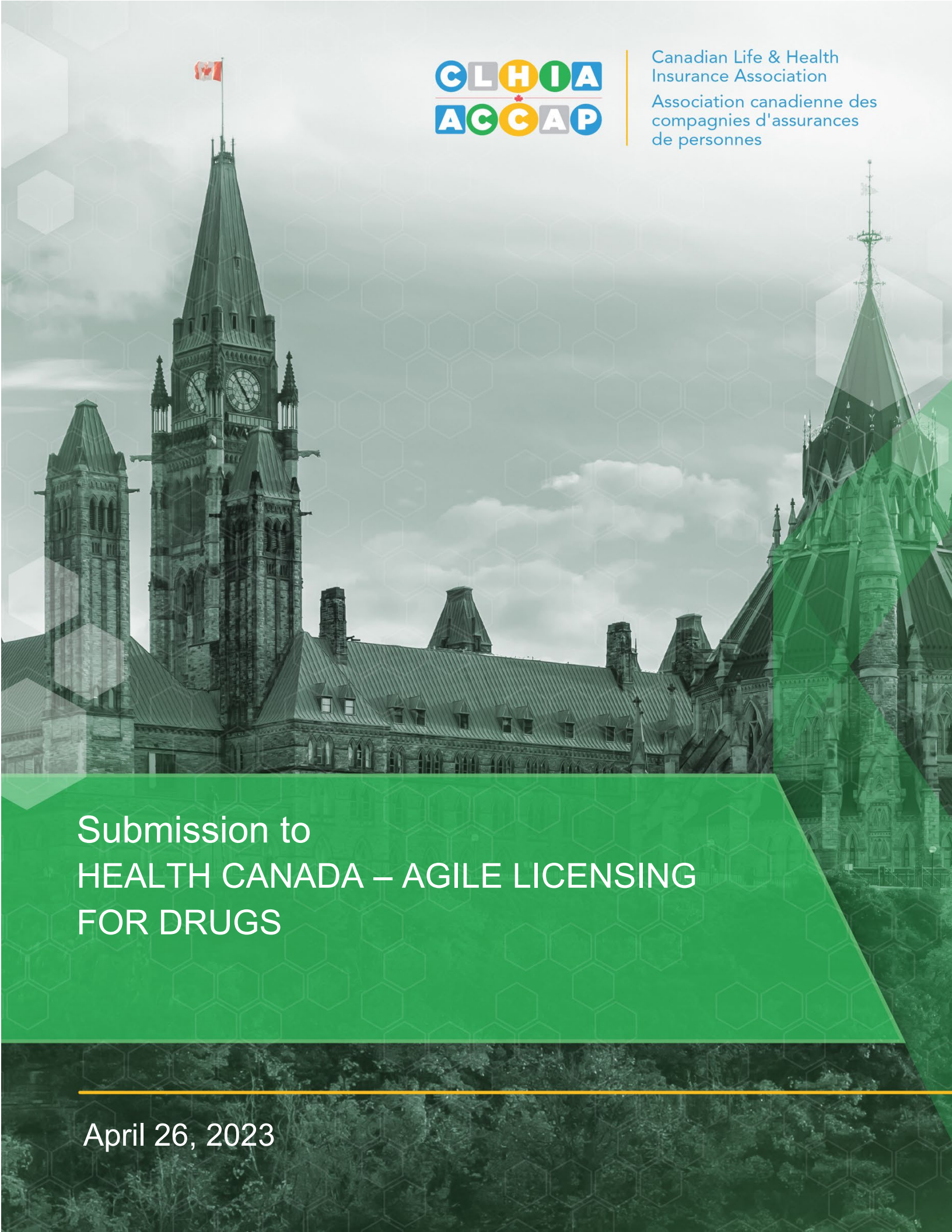


Canadian Life & Health Insurance Association
Association canadienne des compagnies d'assurances de personnes

Submission to HEALTH CANADA – AGILE LICENSING FOR DRUGS

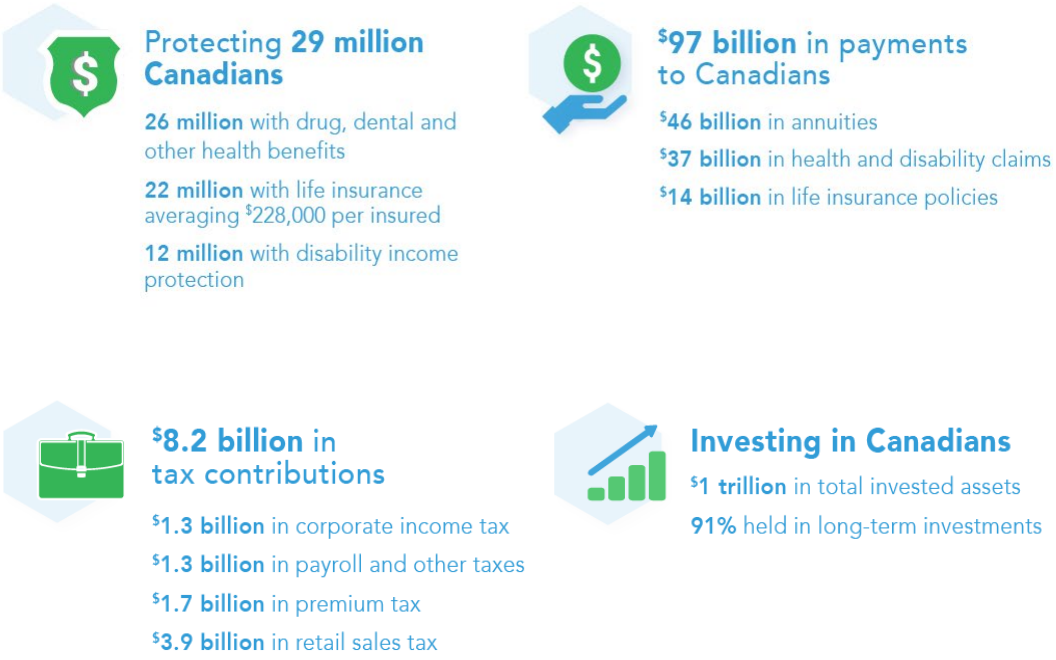
April 26, 2023

OVERVIEW

The Canadian Life and Health Insurance Association (CLHIA) is pleased to provide the views of its members to Health Canada (HC) for consideration regarding the consultation on *Agile Licensing for Drugs*, which proposes to make changes to drug review processes that reduce regulatory issues and roadblocks to innovation while making Canada's regulatory system more agile and internationally-aligned

WHO WE ARE

The CLHIA is a voluntary association whose member companies account for 99 per cent of the life and health insurance business in Canada.



Life and health insurers play a key role in providing financial security to Canadians. Additionally, the industry makes a significant contribution to the economy, employing over 158,000 Canadians in high value, professional jobs (as employees or independent agents). The industry is also a major investor in domestic assets and contributes significant revenue through taxes to the federal and provincial governments.

Support for affordable prescription medicines

Canadian life and health insurers provide 27 million Canadians with access to a wide range of health services and prescription drugs, including rare disease drugs, through supplementary health plans. In 2021 insurers paid out more than $13.4 billion in coverage for prescription drugs in Canada, while in 2020, $650 million was paid for rare disease drugs to 15,000 Canadians. Canadians pay some of the highest prescription drug costs in the world—our drug prices are third highest among OECD countries.

OVERVIEW

1. The insurance industry supports the work Health Canada is undertaking to revise drug review processes, resulting in earlier market access for innovative, promising drugs, as well as providing support for funding decisions by publishing up-to-date evidence about an authorized drug's risks, benefits and uncertainties. We understand that these revised processes may be applied to certain new drugs to market, that carry more uncertainty, such as in the rare disease and gene or stem cell categories.

2. These changes are not made without risks. We encourage Health Canada to give consideration to the push-pull effect of these changes as they may affect pharmaceutical manufacturers' decisions about bringing drugs to market in Canada. We are supportive of close alignment with the requirements of other countries assessing the same drugs, and specifically risk mitigation strategies like the provision of terms and conditions (T&Cs) and risk management plans (RMPs), but also sharing data and clinical trial results that aren't necessarily replicated in Canada. Transparent sharing of information collected through these new pathways and clear reporting on program outcomes will improve the ability of all stakeholders to manage risk.

SELECT NEW AND REVISED REQUIREMENTS

Terms and Conditions

These new regulations will allow Health Canada to impose and amend terms and conditions upon drugs as needed. We are encouraged that the regulations ensure T&Cs are imposed fairly and consistently and will provide ongoing data for decision makers. T&Cs will be an important tool that will allow oversight of an authorized drug's safety, efficacy and/or quality throughout its life cycle. This becomes especially important to prescription drug payers as more drugs come to market with limitations in the clinical evidence.

Risk Management Plan

The regulations propose changes to the submission of RMPs, including moving new submissions to the *Food and Drugs Act* (Canada). The requirement for a submission of an RMP for certain new drugs to market is long-standing. Again, RMPs are an important tool to produce real-world evidence to support a drug's safety and efficacy. It is important that the data collected through an RMP is available to all stakeholders to inform their decisions.

Rolling Reviews for Drug Submissions

Our understanding is that certain drugs may be eligible for a rolling review, beyond the current scope of human vaccines. Rolling review status allows a sponsor to file a drug submission with some but not all of the information necessary for Health Canada to assess the proposed drug's safety, efficacy and quality. Rolling reviews have the potential to bring promising drugs to Canada quickly, and we are supportive of that goal. However, it is important that the foundational standards for safety and efficacy remain robust and that ongoing, transparent reporting and program reviews are established to ensure a reliable process.

While we understand that a drug provided rolling review status have a specified date when the remaining data is due to Health Canada. The guidance provided with this consultation does not indicate what happens if the submission date is missed. This should be made clear in the final requirements.

PERSPECTIVE OF PRIVATE INSURERS

Insurers are a vital part of the prescription drug funding strategy for Canada. Our data, expertise and responsibilities means that we are essential stakeholders in Canadian health policy. We are also decision-makers, committed to effective drug plan management for millions of Canadians. We need access to accurate, up-to-date information to make informed coverage decisions for our programs. Health Canada's new agile regulations may introduce more uncertainty into our reviews and clear, transparent reporting and data sharing is necessary to maintain high quality listing decisions. Independent national and international networks can help address the challenge of having insufficient data and local expertise to support patients.

Although there are many potential benefits to the agile regulations, we must point out that this model also increases risk to drug plans. Private payers have not been included in the drugs for rare disease funding model, which offsets some of these risks for public plans. The lack of financial offset differs from the COVID-19 vaccine model that Health Canada used to develop the agile framework. Ongoing dialogue and transparent reporting are needed to help mitigate these risks and optimize the outcomes of the agile approach.

CONCLUSION

We would like to take this opportunity to thank you for your consideration of the views of the Canadian life and health insurance industry. Should you have questions regarding any of our comments, you may contact Joan Weir, Vice-President, Group Benefits at jweir@clhia.ca.

79 Wellington St. West, Suite 2300
P.O. Box 99, TD South Tower
Toronto, Ontario M5K 1G8
416.777.2221
info@clhia.ca