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Canadian Liver Foundation — *Bringing liver research to life*
Fondation canadienne du foie — *Donner vie à la recherche sur le foie*

December 2, 2022

Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Attention: PMPRB Members

The Canadian Liver Foundation (CLF) was founded in 1969 by a committed group of business leaders and doctors who believed that liver disease needed a champion. Since then, the organization has grown, and we know the need for a liver disease champion remains important. We are still committed to making sure the liver disease community across Canada is supported, and that we are continuously bringing research to life.

The CLF recently presented six strategic priorities, developed in consultation with Canada's liver health community, to shape our path forward, ensuring we are making the most meaningful impact possible as Canada's leading organization to promote liver health and disease resolution and provide broad community outreach. The consultation included engagement with patients, caregivers, healthcare providers, researchers, volunteers, supporters and the general public. It is through this critical lens of community engagement that we are reaching out to you today to champion the voices of the 1 in 4 Canadians who may be affected by liver disease – that's over 9 million Canadians from across the country.

The CLF is a member of the Health Charities Coalition of Canada (HCCC) and we individually (as a national liver health charity) and collectively (as a member of HCCC), value the mission and the work of the Patented Medicine Prices Review Board (PMPRB) as we believe that it is in our collective best interests to work together to improve the health of all Canadians. Regarding the 2022 PMPRB Guidelines Consultation, HCCC members have consistently requested that the PMPRB seek opportunities to engage patient representatives meaningfully and continuously in their decision making and regulatory processes.

While we were pleased that some of the HCCC recommendations were incorporated in your 2020 guideline consultation, we remain concerned that some of our recommendations were not applied in 2020 and continue to be absent for this 2022 consultation. With this in mind, **we request that the implementation of the new guidelines (scheduled to be launched on January 1, 2023) be paused until the recommendations below are properly addressed and that patient input is meaningfully integrated into the PMPRB process:**

1) **That an independent third-party be hired to conduct a formal assessment of the potential and real-time impacts of the guideline changes on access to medicines (including access to clinical trials) in Canada and across therapeutic areas.**
    - With over 100 different forms of liver disease, early access to new products will better serve the liver health needs and improve liver health outcomes for all Canadians affected by liver disease.

- There should be no changes to guidelines that may create additional barriers or delays in the length of time that it takes for Canadians to access new products. While some liver diseases are slow-moving chronic illnesses, many liver diseases are acute or are not diagnosed until very late stages and unfortunately require urgent intervention or may necessitate a liver transplant or treatment of end-stage liver disease. Delays in access to therapeutic options may be the difference between life and death for these Canadians.

2) **That the PMPRB establishes formal mechanisms for meaningfully and continuously engaging patient representatives in its decision-making and processes to ensure patient voice, choice and representation.**
   - The PMPRB website clearly articulates that the Board "is committed to listening to the voices and views of Canadians and including them in decision making". The CLF has developed its strategic priorities based on community engagement and we feel it is essential for the PMPRB to similarly incorporate effective and meaningful stakeholder engagement into the consultation process in order to fulfill its mandate, deliver programs, launch new initiatives, and build public trust.
   - To date, there continues to be no formal process for meaningfully engaging patient representatives in the PMPRB processes and decision-making, therefore, we respectfully request that the PMPRB identify and implement a formal process for patients to be involved in policy development and decision-making.
   - The PMPRB has designed a Guidelines Modernization and Evaluation Process (GMEP) that will in part track the impact of the guideline changes on patients, healthcare providers and other stakeholders. A specific area of focus will measure the impact on medicine access. The CLF works directly with and supports patients, so we are well positioned to provide valuable input from the liver community to the PMPRB on both the qualitative indicators that are relevant to patients as well as contribute quantitative data. Opportunities to participate in this level of engagement and multi-stakeholder dialogue to determine how to collectively monitor and evaluate progress going forward have not been extended to the patient community.

3) **That the consultation process allows for respectful consideration of stakeholder feedback prior to the implementation date.**
   - It is unclear how feedback will be considered and where possible, integrated into the guidelines with a tight turnaround time from the closure of the consultation on December 5th, 2022 to the implementation date of January 1, 2023.
   - While the CLF respects the need for presenting and implementing the updated guidelines in a timely manner, we also want to be sure that these are done effectively and with the patient at the center of the decision-making process.
   - If it is the intention of the PMPRB to fully integrate stakeholder feedback received by December 5, 2022 into the release and implementation of the new guidelines on January 1, 2023, we ask for an explanation of how this will be done and how implementation and efficacy will be measured.

4) **That changes to new investigative criteria will not inadvertently put some patient populations at a disadvantage resulting in further delays in accessing new medicines.**
   - For some new medicines, there may not be a therapeutic class comparator price which would increase the likelihood of the product being referred for an investigation and extend the length of time that it takes to assess the medicine. This could be a real disadvantage for certain patient populations who have few or no therapeutic options currently available to treat their illness.

- Many forms of liver disease are considered "rare" diseases, many of which have few or no therapeutic options except for treatment of symptoms as opposed to treatment of the disease itself. Changes to new investigative criteria which may put these patients in harms way by delaying or impeding access to new medicines is not an acceptable outcome for a new modernized review system and must be carefully considered during this process. Consultation with the liver patient and healthcare communities will provide much-needed insight on how possible delays to treatment access may impact the lives of Canadians living with liver disease.

Thank you very much for your consideration of our input and our request to pause the implementation of your new guidelines. If you should have any questions, please do not hesitate to contact me. We look forward to your collaborative response.

Sincerely,

Jennifer Nebesky
President & CEO