

**Patented Medicine Prices Review Board Draft Guidelines Consultation
Submission by the Multiple Sclerosis (MS) Society of Canada
November 2022**

Introduction

The Multiple Sclerosis (MS) Society of Canada is pleased to provide this submission to the Patented Medicine Prices Review Board (PMPRB) Draft Guidelines Consultation.

MS impacts all Canadians – not only affected individuals, but also their families. The unpredictable, episodic, and progressive nature of MS makes it significantly challenging for many people to maintain a similar quality of life they had prior to their diagnosis. For Canadians living with MS, timely and affordable access to treatments is vital to increasing quality of life, as it can delay disability caused by MS and improve health outcomes. As Canada navigates a strained health care system while emerging from the COVID-19 pandemic, Canadians living with MS face many additional challenges, including further barriers to accessing MS treatments.

As stated in the MS Society’s previous seven submissions (June 2017, February 2018, February 2020, August 2020, February 2021, June 2021, and August 2021) regarding the proposed amendments and guidelines, we remain committed to ensuring these changes find the right balance between their impacts on affordability, availability, and research. We are concerned about the vagueness in the 2022 Proposed Updates to the PMPRB Guidelines, which engender uncertainty and could have a direct impact on the MS community. The fact that clinical efficacy and innovation does not guarantee appropriate pricing is particularly worrisome, as it is likely that the most innovative medications will be the most impacted from these draft guidelines. We continue to posit that people living with MS and their families should be at the centre of the PMPRB’s consultation process and decisions, as they will potentially bear the brunt of policy decisions made under the new guidelines.

Finding the Right Balance – Impact on Affordability

While a cure for MS remains on the horizon, life-altering advancements in disease-modifying therapies (DMTs) have grown significantly over the past two decades. DMTs can dramatically alter the course of

Canada has one of the highest rates of MS in the world.

MS is a chronic, often disabling, disease of the central nervous system. Since that includes the brain, spinal cord, and optic nerve, MS can affect vision, memory, balance, and mobility.

More than 90,000 Canadians live with MS. On average, 12 Canadians are diagnosed with MS every day. Most people are diagnosed between the ages of 20 and 49 and the unpredictable effects of the disease will last for the rest of their lives.

MS is unpredictable and may cause symptoms such as extreme fatigue, lack of coordination, weakness, tingling, impaired sensation, vision problems, bladder problems, cognitive impairment, and mood changes. Its effects can be physical, emotional, and financial.

the disease by reducing annual relapse rates, slowing disability progression, and reducing the number of new or enhanced lesions (as seen on MRI).

The cost of most MS medications is equivalent to or exceeds most Canadians' respective annual salaries. As noted in a December 2020 report from the Conference Board of Canada, [Accessing Disease-Modifying Therapies for Multiple Sclerosis: A Pan-Canadian Analysis](#), initiation of MS treatment is often delayed due to drug plan reimbursement policies, which often favour lower cost medications and are driven by a medication escalation approach, directly impacting which DMTs are accessible and affordable. Consequently, access to more innovative and potentially more effective DMTs is limited and comes at a high personal financial cost. The high cost of some innovative medications are additional barriers to access "with the number of medications with an annual cost of at least \$10,000 [having] more than tripled since 2006."¹ Ensuring that MS treatments are priced at an appropriate cost that is not excessive increases the chances of those treatments being added to private insurance plans and public formularies – which Canadians living with MS rely on.

The MS Society acknowledges the importance of protecting the interests of Canadian consumers by ensuring prices for pharmaceuticals remain fair and affordable, and that the PMPRB's amended guidelines hope to achieve such an outcome. However, given the potential significant impact that the proposed updates could have on drug pricing, there remain concerns about what those changes mean for overall drug availability and access for patients. In past submissions, the MS Society has asked the PMPRB for a multi-stakeholder dialogue to better evaluate the impact of these changes. We advocate that the federal government require the PMPRB to employ a third party to conduct a formal assessment of the potential and actual ramifications of the regulatory reforms. We also support a more fulsome consultation process, with more time between the submission deadline and the planned implementation date.

Finding the Right Balance – Impact on Availability

With the proposed changes signaling that list prices cannot exceed both the top of Therapeutic Class Comparison and the Lowest International Price, availability of treatments may become restricted. Under the proposed updates, the fact that the PMPRB will no longer consider the degree of innovation, such as breakthrough and substantial improvement, in its assessments is of significant concern as it will impact Canadians who need medication for rare diseases. Controlling drug costs, in addition to reducing the financial impact on individuals and governments, may result in an overall reduction of treatments reaching Canada's market, reducing access to certain medications in Canada.²

It is expected that several existing medications will require price adjustments within the next 12 months under the proposed guidelines. With minimal information disclosed about this in the draft guidelines,

¹ The Conference Board of Canada. "Accessing Disease-Modifying Therapies for Multiple Sclerosis: A Pan-Canadian Analysis." 2020, page 11.

² The Conference Board of Canada. "Accessing Disease-Modifying Therapies for Multiple Sclerosis: A Pan-Canadian Analysis." 2020, page 29.

there is no clear picture of how this will impact MS DMTs, but we assume there may be a significant impact on our community as a result. As mentioned in previous submissions, one of the potential impacts of price drop in medications is that availability of new treatments may become restricted. The new basket of countries under PMPRB11 will lower drug prices and could result in manufacturers departing the Canadian market or reluctant to introduce new and innovative medications in Canada.

If implemented, the proposed guidelines would automatically trigger a PMPRB investigation of medications for a disease state with no reference points because it has not previously been introduced into the Canadian market. These proposed guidelines also give PMPRB staff more autonomy, and we are concerned about how this will impact the timeline of a new medication becoming available for Canadians, since there is no transparency about timelines for these investigations. This could provide the flexibility needed to acknowledge innovation with a particular drug, but we are unsure of this intent. We are also unsure if negotiations with the pan-Canadian Pharmaceutical Alliance (pCPA) can continue while the PMPRB's automatic investigation is underway. We continue to request more transparency from the PMPRB about how these proposed guidelines will ultimately impact Canadians who depend on innovative medications.

Finding the Right Balance – Impact on Research

The MS Society partners with researchers, government, and industry to translate knowledge gathered through research into therapeutic and health care options that improve the lives of people living with MS. Innovative research in MS also provides the important functions of stimulating economic growth and attracting and retaining talent in the Canadian health care system. Innovation also has commercial benefits for industry, which plays an important role in the health-research ecosystem.

We are concerned the proposed guidelines' impact on pricing and lack of consideration for innovative medications will lead pharmaceutical companies to reduce investments in innovative research in Canada or slow their introduction into Canada. Forcing prices down offers no provision to reward innovation by offering manufacturers the opportunity to achieve price premiums for new technologies that represent significant advances in treatment compared to existing therapeutics. This has repercussions for clinical trials, as manufacturers may overlook holding clinical trials in Canada based on reduced incentives. Clinical trials are critical to the development of therapeutic options and provide significant opportunities for research grown in Canada. A reduction in investment from manufacturers could curtail the robustness of Canada's existing health research infrastructure, impeding the work and progress of innovative research supported by patient organizations, including the MS Society.

The PMPRB guidelines should align with the federal government's National Strategy for Drugs for Rare Diseases; however, the degree of innovation not being considered under the proposed guidelines strongly indicates alignment could be in question. The PMPRB is encouraged to consider postponing the January 1, 2023 implementation date to evaluate and consider the National Strategy for Drugs for Rare Diseases when drafting future guidelines.

Conclusion

The MS Society continues to believe that it is the responsibility of the Government of Canada to ensure that Canadians living with MS have equitable, affordable, and timely access to treatments and that the PMPRB plays an important role in achieving this commitment. We continue to have outstanding concerns, as addressed above. We look forward to a continued dialogue on the affordability, availability, and access to medicines for Canadians, as one discussion cannot happen in isolation of the other. Thank you for your consideration of our feedback.

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