

Patented Medicine Prices Review Board Proposed Updates Consultation Submission August 2023

Introduction

MS Canada, formerly the Multiple Sclerosis (MS) Society of Canada is pleased to provide this submission to the Patented Medicine Prices Review Board's (PMPRB) Proposed Updates consultation.

Canada has one of the highest rates of multiple sclerosis (MS) in the world. An estimated 90,000 Canadians live with the disease, and, on average, 12 Canadians are diagnosed with MS every day. About three-quarters of Canadians who live with MS are women and most people are diagnosed between the ages of 20 and 49. The unpredictable effects of the disease will last for the rest of their lives.

In January 2023, MS Canada amalgamated two previously known entities, the MS Society of Canada and the MS Scientific Research Foundation, into one organization: MS Canada. MS Canada fosters meaningful connections both within the MS community and between the MS community and researchers, and offers programs, resources, advocacy, and services to advance the same vision: a world free of MS.

MS is the most common neurological disease among young adults in Canada and is a costly disease for health systems and Canadian society more broadly. A recent study by Deloitte Access Economics highlighted the significant socioeconomic cost of MS to Canada, estimating the total annual cost of illness to be more than \$3.4 billion in 2019. Furthermore, the study investigated the impact and economic cost of COVID-19 on MS care in Canada. The study reported a significant reduction in health service access among people with MS during the pandemic, which resulted in a health services backlog and an accumulation of unmet health needs.

This reality will have a long-lasting negative impact on the health outcomes of people with MS. This is due in large part to delayed diagnosis and delayed, altered, or halted treatment and care. As well, it was noted that a reduction in rehabilitation, coupled with a lack of social and cognitive stimulation during the pandemic, is expected to result in increased disability progression. This has a costly effect on Canada, as health system costs related to MS are estimated to rise to \$1.5 billion in 2024, an increase of \$73 million compared to an unaffected year. The rising economic burden is expected to continue in future years.

As stated in MS Canada's previous eight submissions related to the PMPRB's 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 of the proposed updates, which engender uncertainty and could have a direct impact on the MS community. The fact that medicines without a Maximum Average

Potential Price (MAPP) or Non-Excessive Average Price (NEAP) below the median international price for the PMPRB 11 countries will be considered “under review” until new guidelines are in place is worrisome, as we have no indication of when new guidelines will come into force. 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 proposed updates.

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 the disease by reducing annual relapse rates, slowing disability progression, and reducing the number of new or enhanced lesions.

Without adequate drug coverage, the cost of MS medications can expend a substantial portion of most Canadians’ respective annual salaries. Initiation of MS treatment is often delayed due to plan reimbursement policies, which tend to favour lower-cost medications and are driven by a medication escalation approach, directly impacting which DMTs are accessible and affordable. Consequently, access to new and potentially more effective DMTs is limited and comes at a high personal financial cost. The high cost of new medications is an additional barrier 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.

MS Canada acknowledges the importance of protecting the interests of Canadian consumers by ensuring prices for pharmaceuticals remain fair and affordable, and that the PMPRB’s proposed updates hope to achieve such an outcome. However, given the potentially 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, MS Canada 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.

Finding the Right Balance – Impact on Availability

With the proposed guidelines signaling that list prices cannot exceed both the top of Therapeutic Class Comparison and the Lowest International Price, availability of treatments may become

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

restricted. In the proposed amendments to the interim guidance, the PMPRB states that medicines without a MAPP or NEAP without a list price below the median international price for the PMPRB11 countries will be considered “under review” until new guidelines are in place. This could impact Canadians who need medications for rare diseases, as the uncertainty of when these new guidelines will come into force could deter pharmaceutical companies from introducing new drugs for rare diseases to the Canadian market. 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 updates. With minimal information disclosed about this, 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 reductions 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 being reluctant to introduce new and innovative medications in Canada.

There is a lack of transparency around the proposed guidelines and proposed updates. The proposed guidelines give the PMPRB 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

MS Canada has been at the forefront of more breakthroughs for MS than the world has seen for any other neurological disease. We are on the precipice of new discoveries that have taken decades to reach. Research from 2022 has found the strongest connection to date between the Epstein-Barr virus (EBV), which we believe is the leading risk factor for developing MS. MS Canada partners with researchers, government, and industry to translate knowledge gathered through research into therapeutic and health care options that improve the lives of those 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.

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

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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 growth 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 MS Canada.

Conclusion

MS Canada believes 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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