Submission to the Scoping Paper for the Consultations on the Patented Medicines Prices Review Board's Guidelines
December 2023

Introduction

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.

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.

This is MS Canada's tenth submission to the Patented Medicine Prices Review Board (PMPRB) since 2017. As stated in the previous nine submissions related to PMPRB's proposed amendments and guidelines, we remain committed to ensuring the Guidelines find the right balance between their impacts on affordability, availability, and research. We continue to posit that people living with MS and their families should be at the centre of PMPRB's consultation processes and decisions, as these Canadians will be most affected by any forthcoming policy changes.

Theme 1: Efficient Monitoring of Prices without Price Setting

If PMPRB is to develop an administrative review process for efficient monitoring of potential excessive pricing, that review process must be fully transparent to all stakeholders. There has been uncertainty and a lack of transparency from PMPRB over the past six-plus years of a reform

process. With new disease-modifying therapies (DMTs) for MS on the horizon, there is a need for a predictable, stable, and efficient authorization process to ensure successful market access to innovative therapies in Canada. If international prices are used as the initial triage measure for evaluating cost, the highest international price (HIP) from the PMPRB11 should be used as the triage measure, since Switzerland and the United States, notably higher-priced countries, have been removed as comparator nations. Using the median international price (MIP) has the effect of constraining the ceiling price of new medicines, which disincentivizes pharmaceutical companies from introducing new and life-altering therapies within Canada.

Theme 2: Transition to PMPRB11 – New versus Existing Medicines

The transition from PMPRB7 to PMPRB11 does not include any grandfathering clauses for existing medications, causing all information to be filed using PMPRB11, regardless of the original date of introduction of the medicine. MS Canada strongly advocates that the Guidelines distinguish between medicines that existed as of July 2022 and medicines introduced after.

Many Canadians living with MS have managed their disease successfully with the same DMT for years and have therefore come to rely on the ability to remain on that medication. If there is an unfavourable review of an existing DMT due to its price exceeding the HIP of PMPRB11, this has the potential to impact thousands of Canadians living with MS.

We do not believe the Board should review existing medicines with prices above the HIP of PMPRB11as this could potentially negatively impact millions of Canadians who rely on medicines.

Theme 3: Price Reviews during Product Life Cycle

Any price reviews that take place during the product life cycle that may have an impact on the market availability of a medication must be communicated to pharmaceutical companies to share with prescribing clinicians/patients actively being treated with medication to ensure there are no disruptions in treatment.

MS is a disease that impacts everyone differently, and no two people respond the same way to the same medication. What works in one person may not be as effective in another. Access to the full armamentarium of Health Canada-approved MS treatments is critical as they can reduce the financial burden on our health and social systems through fewer MS relapses requiring hospitalization and loss of employment.

Theme 4: Investigations and Referral to Hearing

The 2010 Guidelines for commencing an investigation appear to remain appropriate; however, it is not known how the adjustment to PMPRB11 will impact the criteria and outcomes. Overall, MS

Canada supports the monitoring and review of medication prices to ensure they are not excessive, provided investigations do not interrupt access to treatments by Canadians living with MS and other disease areas. MS Canada also supports and encourages the current practice of notifying patentees of all activities related to their medications and investigations.

Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives

Currently, in Canada, it takes approximately 1,301 days for a new medication to be reimbursed from its global launch. In the United States, global launch to reimbursement is 152 days.[1] There is a fundamental need to simplify and streamline the process a new medication must currently undergo. Once a new medication is approved by Health Canada, its pathway is extensive and often delayed at various stages of the process. Some new and innovative medications never reach public reimbursement and have only significantly limited private reimbursement. The administrative requirements at each stage along the path to reimbursement are often cumbersome and, in some cases, futile as some new medications reach as far as the pan-Canadian Pharmaceutical Alliance (pCPA) and do not go any further.

Fewer new and innovative, life-altering medications are anticipated to reach Canadians living with MS as the incentive for manufacturers to continue applying for market authorization weakens, given the currently long time frames and continued delays in the aftermath of the COVID-19 pandemic.

Theme 6: Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders

While MS is not categorized as a rare disease, DMTs indicated for MS are classified as high-cost medications. Though the treatment landscape for MS has changed with the introduction of generic products and biosimilar policies, the out-of-pocket cost for these non-branded DMTs still places many Canadians in situations of significant financial strain. All DMTs for MS are excessively priced.

MS Canada has appreciated PMPRB's requests for stakeholder feedback; however, we do not have any indication of our concerns being heard. Since 2017, MS Canada has submitted nine submissions to PMPRB and as of December 2023, we remain firm in our position that the feedback we have shared thus far continues to be unaddressed.

Engagement with PMPRB is perceived as one-sided, with MS Canada providing patient group feedback for all stakeholder consultations, without any follow-up, or clear understanding of how the input will be used, or why it is being requested. According to the PMPRB's *Consultation Policy,* the objectives of stakeholder engagement are: i) to facilitate input and feedback from stakeholders and the public on the Board's activities, ii) to ensure that the Board is able to take

[1] Innovative Medicines Canada. INCREASING ACCESS TO INNOVATIVE MEDICINES. Pre-Budget Consultations in Advance of the 2023 Budget, October 7, 2022. *Retrieved on November 30, 2023.*

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into consideration the views of all stakeholders in making policy decisions, and iii) to facilitate an ongoing exchange of information and feedback among the Board, its stakeholders, and the public.[2]

Since 2017, only the first objective of PMPRB's stakeholder consultation has been apparent to MS Canada. It is not clear if PMPRB has considered patient group input, and there has not been an ongoing exchange of information and feedback between PMPRB and its patient group stakeholder, MS Canada.

Conclusion

Approximately 12 Canadians are diagnosed with MS every day and many of these people will come to rely on DMTs to manage their disease. Early intervention and treatment are vital to avoiding many of the long-term economic and personal costs that result from unnecessary irreversible disability. DMTs have significant cost, which is often covered by public or private insurance. MS Canada remains committed to ensuring PMPRB Guidelines find the right balance between their impacts on affordability, availability, and research.

At the same time, it is important that all Health Canada-approved DMTs for MS are available in every Canadian jurisdiction. It is imperative that throughout PMPRB and its updated PMPRB Guidelines, transparency and communication to all stakeholders is prioritized. The ongoing uncertainty can disincentivize manufacturers to continue applying for market authorization, ultimately limiting access to medicines for Canadians living with MS, which has an enormous socioeconomic cost to Canadian society, as noted in the above-mentioned Deloitte Access Economics report. As the Board moves forward with amended guidelines, Canadians living with MS and their families should be at the centre of the consultation processes and decisions.

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[2] Patented Medicines Pricing Review Board, Consultation Policy. Retrieved on December 1, 2023