Consultation on the PMPRB Guideline Monitoring and Evaluation Plan

Submission by the Multiple Sclerosis (MS) Society of Canada (June 2021)

Multiple sclerosis (MS) impacts all Canadians – not only affected individuals, but also their families. For Canadians living with MS, timely and affordable access to treatments is vital. It increases quality of life as it can delay disability caused by MS and improve overall health outcomes. With the onset of COVID-19 in Canada, Canadians living with MS face many additional challenges, including further barriers in access to MS treatments.

The MS Society of Canada supports the role of PMPRB in setting the ceiling price for patent medicines. Additionally, we recommend that the PMPRB seek opportunities to meaningfully and continuously engage patient representatives in their decision making and regulatory processes. Our organization appreciates the opportunity to continue to provide patient-centered perspectives on the guideline implementation process. Our core concerns regarding the guidelines' impact on access to treatments for people living with MS – as highlighted in our previous submissions (June 2017, February 2018, February 2020, August 2020, and February 2021) – continue to remain unaddressed.

The PMPRB's amended guidelines will ultimately impact patients and patient-access to life-changing treatments. As a result, it is critical that people with MS and their families be at the centre of the PMPRB's Guideline Monitoring and Evaluation Plan.

In this submission, the MS Society provides the following input in relation to the four key areas of focus: I. prices of medicines; II. access to medicines; III. the pharmaceutical ecosystem; and IV. PMPRB processes.

I & II: Prices & Access

When it comes to MS treatments, pricing, and affordability are strongly interwoven with access. While it is imperative to monitor and evaluate drug price changes, the impact of the Guideline changes to the larger pharmaceutical landscape within Canada is more significant to the MS community as we anticipate consequences related to access to innovative therapies for people living with MS. If the focus for PMPRB is on a *'minority of medicines that are believed to be at greater risk of excessive pricing'*, this will directly impact emerging MS therapies. Most MS treatments cost the same as, or exceed, most Canadians' annual salaries. As such, there is deep concern that targeting medicines with excessive pricing will force Canada out of the pharmaceutical research and development space in MS, as it will be perceived as an unattractive market.

Further compounding this is the introduction of the first generic medication for MS approved in 2019, and more generic options currently pending Health Canada approval. In addition, provinces have begun implementing biosimilar initiatives to address the need for drug plan sustainability. While it is good to see more affordable medications entering the MS therapeutic space, the MS Society strongly believes that a therapeutic approach which includes offering the full range of therapies that can reduce disease activity – thus improving the chance of finding the best option for each person with MS. If the changes to the Guidelines limit innovative treatments from entering Canada, the existing MS therapeutic armamentarium will continue to see generics and biosimilars replace branded treatments and treating

MS will no longer aim to treat an individual with the best therapy for their clinical situation; rather, they will be treated with the most cost-effective medication available to them.

"The PMPRB will also monitor the extent to which the prices of patented medicines align with their therapeutic value...", in the context of treating MS optimally, assessing the therapeutic value is challenging due to the heterogenicity of the disease and highly varied response rates of the MS therapies between individuals. Should the therapeutic value of a new MS medication be assessed as *similar* to existing medication(s) within the Canadian market, this will prohibit innovative medications for MS from entering the country.

Additionally, the potential impacts of a significant drop in prices for medications is that availability of treatments may become restricted. As mentioned in the Conference Board of Canada's recent report, Accessing Disease-Modifying Therapies for Multiple Sclerosis: A Pan-Canadian Analysis, 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, which in turn, "could lead to reduced access to some medications for Canadians." Based on a nation-wide quality of life survey which heard from over 6,000 Canadians affected by MS, 86 per cent of respondents identified ensuring access to comprehensive and effective treatments and care as the most important issue.

III. Pharmaceutical Ecosystem

High-cost medications pose a barrier to treatment for people living with MS. Excessively priced medications are typically higher efficacy treatment options in most disease areas. While high-cost medications often place an added financial burden on patients, the current reimbursement criteria for high-cost treatments requires patients to fail clinically on lower efficacy, lower cost treatments. Medication response failure results in increased medical appointments, hospitalizations, additional disease management, and the need for government income supplementation programs due to employment absenteeism. Monitoring of high-cost medications should adopt a systems approach versus the fragmented approach currently undertaken.

Aspects of assessment of the pharmaceutical ecosystem not reflected in the PMPRB monitoring and evaluation plan:

Canada is a world leader in MS research and innovation. Since 1948 the MS Society has contributed over $200 million towards MS research. This investment has enabled the advancement of critical knowledge of MS, and the development of a pipeline of exceptional MS researchers and principal investigators of Canadian clinical trials. The MS Society is concerned that changes to price regulations may lead pharmaceutical companies to reduce investments in innovative research in Canada. Forcing prices down to the lowest of international comparison prices may prove punitive as it offers no provision to reward innovation by offering manufacturers the opportunity to achieve price premiums for new technologies that represent significant advances compared to existing treatments. This has repercussions for clinical trials, as manufacturers may display greater reluctance in holding clinical trials in Canada due to these reduced incentives. Clinical trials are not only important for the development of therapeutic options, but they also provide significant opportunities for research growth in Canada. This reduction in investment from manufacturers, which would curtail the robustness of Canada's existing health-research infrastructure, would also impede the important work and progress in innovative research conducted and sponsored by patient organizations, including the MS Society.

Less than two per cent of all MS Society revenue stems from pharmaceutical companies. Of this, 100 per cent of the revenue goes directly to patient and caregiver focused programming related to education, advocacy, and wellbeing. The MS Society receives very limited government funding and are in need of additional sources of funding including from Government as we have been severely and negatively impacted by COVID-19 in terms of our grassroots fundraising, consequently we rely on industry grants and donations to support the delivery of essential quality of life programming to the MS community.

IV. PMPRB Processes

In delivering on the Government of Canada's commitment to equitable, affordable, and timely access to treatments, the MS Society continues to highlight the need for the PMPRB to:

- Undertake an incremental approach to the implementation of the amendments. This approach would ensure that the PMPRB could separately evaluate the impact of changes regarding the basket of comparator countries and incorporation of pharmacoeconomic and market size factors on drug prices and patient choices.

- Establish a multi-stakeholder dialogue to better evaluate the impacts of these regulatory changes as it relates to drug availability with a specific focus on the potential consequences of pharmacoeconomic assessments as a regulatory factor.

- The PMPRB monitoring and evaluation plan needs to be designed so as to ensure timely access be prioritized and not further delayed by the "wait-and-see" approach currently being suggested.

The MS Society further recommends 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 on research investment and activity in Canada, with a specific focus on the effect on clinical trials.

- Establish a formal mechanism that continuously engages patient representatives and other key stakeholders in the decision-making and regulatory processes in a meaningful way, and that such processes be fully transparent.

The MS Society, as other patient organizations, works directly with patients and is well positioned to be a key advisor to the PMPRB. We are positioned to provide relevant input on both qualitative and quantitative patient indicators that are directly relevant to the regulatory amendments as well as the monitoring and evaluation plan. However, despite multiple PMPRB consultations, core patient and patient group concerns remain.

Furthermore, the ability to break down the calculations presented by the PMPRB to better understand the implications of the amended guidelines is challenging for many patient groups who do not have access to the same resources that are available to both industry and government. Patient groups' capacity to analyze the information provided has also been further hindered because of COVID-19, which has added additional strain on organizational resources.

The MS Society continues to believe that the Government of Canada should ensure people with MS have equitable, affordable, and timely access to treatments and that the PMPRB plays an important role in achieving this commitment. Ultimately, we believe the PMPRB Guideline Monitoring and Evaluation Plan needs to prioritize and include patient-centered perspectives in all four areas of the plan.

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