Patented Medicine Prices Review Board Draft Guidelines Consultation

Submission by the Multiple Sclerosis (MS) Society of Canada (February 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 to increasing 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 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 consultation process. While our organization appreciates the opportunity to continue to provide patient-centred perspectives on the guideline implementation process, our core concerns in regard to the guidelines' impact on access to treatments for people living with MS as highlighted in our previous submissions (June 2017, February 2018, February 2020, and August 2020) continue to remain largely unaddressed. The current consultation on the guidelines further highlights this issue as the two proposed changes put forward relate to industry implementation and do not address patient-access concerns as the guidelines come into force.

Finding the Right Balance – Impact on Affordability

When it comes to MS treatments, affordability is strongly interwoven with patient access. Most MS medications cost the same as or exceed the majority of Canadians' respective annual salaries. As noted in the Conference Board of Canada's recent report, *Accessing Disease-Modifying Therapies for Multiple Sclerosis: A Pan-Canadian Analysis*, despite the emergence of broader treatment options for MS, the high costs of some innovative drugs act as additional barriers to access, "with the number of medications with an annual cost of at least $10,000 [having] more than tripled since 2006." Ensuring that MS treatments are priced at an appropriate cost that is not excessive increases the chances of those treatments being added to public formularies and private insurance plans – which many Canadians living with MS rely on.

Finding the Right Balance - Impact on Availability

One of 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 report, 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." In 2018, the MS Society hosted a *Listening to People Affected by MS 2.0* quality of life survey which heard from over 6000 Canadians affected by MS. That poll saw 80 percent of respondents identify having the financial resources to meet the changing needs of MS as a priority. However, the one other

priority that superseded the financial concern was ensuring access to comprehensive and effective treatments and care, with 86 percent highlighting this issue as being more important.

Finding the Right Balance - Impact on Research

Canada is a world leader in MS research and innovation. 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.

Reaffirmed Commitment to Meaningful Patient Input

The MS Society, as with other patient organizations, work directly with patients and are well positioned to provide input to the PMPRB on both qualitative and quantitative patient indicators that are directly relevant to the regulatory amendments. 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 strains on organizational resources

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 in regard to the basket of comparator countries and incorporation of pharmacoeconomic and market size factors on drug prices and ultimately on 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 MS Society also 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 process in a meaningful way, and that such processes are fully transparent.

Visit our website to access our previous PMPRB consultation submissions, and for further information, contact:

Benjamin Davis, Senior, Vice-President Mission
MS Society of Canada
Benjamin.davis@mssociety.ca