Submission to the Standing Committee on Health (HESA)

Briefing from the Multiple Sclerosis (MS) Society of Canada on the Patented Medicine Prices Review Board's Guidelines

November 6, 2020

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Introduction

Today's trying times resemble what it's like to live with MS – every single day. Every day, people with MS wake up to adversity and do everything in their power to persevere…

- The woman with progressive MS who struggles to button her shirt in the morning yet is determined to dance at her granddaughter's wedding.
- The high school athlete who ignores the tingling and numbness in his legs to rally his team to victory.
- The lawyer with blurred vision and foggy thoughts. The father struggling to say his child's name. The avid cyclist feeling her balance go.

Canada has one of the highest rates of MS in the world. Canadians know that MS can be harsh. Unfair. Overwhelming. A disease that always takes away, never gives back, and always threatens to take again. 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 to ensuring access to MS treatments.

The MS Society has been involved throughout the Patented Medicines Prices Review Board's (PMRPB) consultation process on its proposed amended guidelines, and we provided submissions as part of this process in June 2017, February 2018, February 2020, and August 2020. As we noted in those submissions, the changes proposed previously, and the now final version of the guidelines stand to have a direct adverse impact on the MS community. Additionally, several of our concerns shared through those previous consultations remain largely unaddressed.

People with MS and their families should be at the centre of the PMPRB's consultation process and decisions. Econometric modeling, while important, cannot take precedence over the real-life experiences and struggles of our community and others with life limiting illnesses. We remain committed that PMPRB changes need to find a balance between their impacts on affordability, availability, and research as well as meaningful patient engagement.

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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. **We recommend**:

- The PMPRB 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 ultimately on patient choices;
- A multi-stakeholder dialogue be established 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 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; and
- The federal government require the PMPRB 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.

Finding the Right Balance – Impact on Affordability

When it comes to MS treatments, affordability is strongly interwoven with patient access. Health Canada has approved 15 disease-modifying therapies (DMTs) to treat relapsing forms of MS. These therapies reduced annual relapse rates by between 30 and 70 per cent, depending on the agent being used. These medications are also effective in slowing disability progression and reducing the number of new or enhanced lesions (as seen on MRI). The recently revised 2017 criteria for diagnosing MS allow Canadian neurologists to diagnose individuals earlier and more accurately, which also means earlier treatment with a DMT. It is recommended that individuals diagnosed with relapsing-remitting MS start DMT treatment soon after their diagnosis is confirmed to reduce risk of worsening disability over time and choosing a DMT should be a shared decision-making process between an individual and their neurologist.[1] Early intervention is vital to avoid many of the long-term economic and personal costs that result from unnecessary irreversible disability. Literally – for brain health - time matters in MS.

The annual cost of DMTs for MS is over $10,000 annually and can rise to $50,000 (or more).[2] Second line therapies, which are taken after a patient has failed on an initial or first line therapy, have higher efficacy and even higher cost. When the overall healthcare costs (physician, hospital, and drug costs) of the MS population are compared to the costs of the general population, the greatest disparity is found in drug

[1] Mark Freedman et. al. "Treatment Optimization in Multiple Sclerosis: Canadian MS Working Group Recommendations" *Canadian Journal of Neurological Sciences* Volume 47-4 (437-455). July 2020. Available at https://www.cambridge.org/core/services/aop-cambridge-core/content/view/6F71BA9F915D7AC1228BBB52EF3B8AD7/S0317167120000669a.pdf/treatment_optimization_in_multiple_sclerosis_canadian_ms_working_group_recommendations.pdf

[2] MS Society of Canada. "Disease-modifying therapies." Available at https://mssociety.ca/managing-ms/treatments/medications/disease-modifying-therapies-dmts#:~:text=The%20base%20cost%20of%20disease,clinic%20costs%20and%20dispensing%20fees.

costs, which are over 40-fold higher for people living with MS (the cost disparity is greater when comparing younger populations, and grows smaller in older age brackets).[3]

For many people living with MS, paying for these treatments out-of-pocket is unrealistic. Institutionalizing a model that enshrines this requirement would lead to significant social inequities. Most MS medications cost the same as, or exceed, most Canadians' respective annual salaries. That means only the wealthy would have access to the therapies they deserve, without appropriate coverage. 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. To be clear, thousands of Canadians rely on this coverage.

Without drug plans in place (public, private or industry), access to these drugs would be unattainable by the vast majority of Canadians who live with MS. Most of these drugs are included on some provincial, territorial and federal formularies, overseen by "special" or "exceptional access" drug programs that require a case-by-case approval for reimbursement due to their high cost.

Individuals with MS must meet certain criteria in order to be eligible for public reimbursement. Many people do not meet the necessary criteria for various reasons -- for example, their doctor having filled the paperwork incorrectly, the patient having coverage under another plan, not being enrolled in the provincial plan, cancellation of coverage due to arrears in premiums, or the patient not meeting the specific medication criteria. As highlighted in a targeted poll conducted via the MS Society's social media channels in 2017, more than 80 percent of the 232 polled respondents stated that they would be unable to continue treatment if they did not have access to an insurance plan, private or public. When combined with other financial factors, including unstable employment issues as a result of the episodic nature of MS, high costs remain a primary concern for Canadians living with MS.

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 changes hope to achieve such an outcome. However, given the potential significant impact that the changes could have on drug prices, there remain concerns about what those changes mean for overall drug availability and access for patients. Specifically, while the changes may represent lower drug costs at the point of sale, there may be unintended consequences which may not be visible immediately, and the changes may have repercussions in terms of drug availability in Canada. The underlying reality is that making a medication affordable does not improve health outcomes of Canadians if the drug ultimately does not launch in the Canadian market at all. Our concerns regarding drug availability are discussed in further detail below.

[3] Nana Amankwah et. al. "Multiple sclerosis in Canada 2011 to 2031: results of a microsimulation modelling study of epidemiological and economic impacts" *HPCDP* Volume 37-2. February 2017. Available at https://www.canada.ca/en/public-health/services/reports-publications/health-promotion-chronic-disease-prevention-canada-research-policy-practice/vol-37-no-2-2017/multiple-sclerosis-canada-2011-2031-results-microsimulation-modelling-study-epidemiological-economic-impacts.html

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. Following our 2017 poll as noted above, the MS Society hosted a *Listening to People Affected by MS 2.0* quality of life survey in 2018, which heard from over 6000 Canadians living with MS. That poll again 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.

The concern for drug availability over pricing is itself reflected in the PMPRB's approach to future treatments and vaccines for COVID-19. In its final version, COVID-19 treatments or vaccines would only be subject to review *only* if a pricing complaint is received[4], implying that if this exemption did not exist, the entrance of some high-cost COVID-19 treatments into the Canadian health-care system may be delayed or may not happen altogether.

Overall, we are concerned that it is not yet adequately understood how the implemented changes would affect drug availability. While the PMPRB has put in place a Guideline Monitoring and Evaluation Plan (GMEP), which includes ongoing assessment of the guidelines' impact on availability of medicines, there is a concern that any potential negative consequences caused by the amendments may be difficult to reverse, due to the fact that (as the PMPRB itself notes), "Some impacts…may take longer to materialize."[5]

While we appreciate that the PMPRB has stated that it will seek stakeholder input in the development and implementation of the GMEP, the potential impact of the guidelines will still be immediate and be felt widely. Should a downward trend in drug availability occur, the ability for the PMPRB to course-correct would be limited.

Rather than taking a retroactive evaluation approach, the PMPRB should undertake an incremental approach to the implementation of the changes in order to mitigate any negative consequences they will have on patient access to drugs. This type of approach would ensure that the PMPRB could separately evaluate the impact of these changes on drug prices and ultimately on patient choices.

Finding the Right Balance - Impact on Research

Canada is a world leader in MS research and innovation. Since 1948, the MS Society has provided over $190M in funding for MS research and researchers. We regularly partner with researchers, government and industry to translate knowledge gathered through research into concrete 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

[4] PMPRB NEWSletter: Octobover 2020, Volume 24, Issue 1. October 2020, *Patented Medicines Prices Review Board.* Available at https://www.canada.ca/en/patented-medicine-prices-review/services/pmprb-newsletter/october-2020-volume-24-issue-1.html

[5] Revised PMPRB Guidelines: Overview of key changes. July 2020. *Patented Medicines Prices Review Board*. Available at https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/2020/PMPRB-Public-Webinar-July8-2020.pdf

health care system. Innovation also has commercial benefits for industry, which plays an important role in the health-research ecosystem.

On this note, the MS Society is concerned that changes to price regulations will lead pharmaceutical companies to reduce investments in innovative research in Canada. Forcing prices down to the lowest of international comparison prices will be interpreted as a punitive measure as it offers no provision to reward innovation. In short, it would fail to offer manufacturers the opportunity to achieve price premiums for new technologies that represent significant advances compared to existing treatments. This would have severely negative 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 MS therapeutic options, but they also provide significant opportunities for growth in MS research across Canada.

Additionally, reduced incentives to bring therapies to market, which have already undergone clinical trials in Canada, would create further ethical issues relating to access -- specifically there would be groups of patients who are on a medication that has undergone clinical trials, but which also has not been approved by Canadian regulators due to the manufacturers delaying or altogether neglecting to bring that same drug to the Canadian market. Overall, a reduction in investment from manufacturers would curtail the robustness of Canada's existing health-research infrastructure and would also impede the important work and progress in innovative research conducted and sponsored by patient organizations, including the MS Society.

To help address these concerns, a holistic approach is needed, and we recommend that a multi-stakeholder dialogue involving all aspects of Canada's health-research infrastructure, including patients and patient-organizations, should be established to better evaluate the impacts of these changes.

Additionally, 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 on research investment and activity in Canada, with specific reflection on the effect on clinical trials.

Reaffirmed Commitment to Meaningful Patient Input

The MS Society has been pleased over the past 5 years to have had the opportunity to participate in the PMPRB's consultation processes. 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. While it was encouraging that some of the patient input was incorporated, nonetheless, and despite these changes, the core issues and recommendations put forward by the MS Society and other patient groups haven't been adequately addressed.

Furthermore, for patients and patient groups, it is important that policy decision-making processes and consultations surrounding drug availability remain transparent and accessible. Information provided to stakeholders in the PMPRB's last consultation, particularly in regard to the calculation of pharmacoeconomic/market size/ GDP factors was opaque. The ability to break down the calculations that were presented to better understand their implications was 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 was also, and continues to be, further hindered because of COVID-19 which has added additional strains on organizational resources. As a result of COVID-19, the MS Society has had a 60% reduction (over $25 million) in revenue, and we foresee further challenges to our ability to fundraise in the near future. To this end, a longer consultation timeframe would have mitigated some concerns patient organizations have had in their ability to respond appropriately to the consultations.

Consequently, we recommend that the federal government require the PMPRB to 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.

Conclusion

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. The MS Society continues to have outstanding concerns as addressed above and given the changed circumstances for all of our communities globally as a result of COVID-19 and in response to the changes, we continue to recommend:

- The PMPRB 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;
- A multi-stakeholder dialogue be established 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 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; and
- The federal government require the PMPRB 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.

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