Introduction

The Multiple Sclerosis (MS) Society of Canada is pleased to provide this submission to the PMPRB Draft Guidelines Consultation.

As noted in our June 2017 and February 2018 submissions regarding the proposed amendments, MS impacts all Canadians – not only the affected individuals, but also their families. The unpredictability and episodic yet progressive nature of MS makes it particularly challenging in maintaining an adequate quality of life. The needs of people with MS and their families should be at the centre of health and drug policy decisions, Therefore, their perspectives and experiences should be a top priority in this consultation.

Affordability, equal and timely treatment and healthcare access, as well as accountability remains a priority for Canadians living with MS. Consequently, there are a number of concerns we have in regard to the proposed regulation amendments which are discussed below.

Finding the Right Balance - Impact on Affordability

Health Canada has approved 14 disease-modifying therapies (DMTs) to treat relapsing forms of MS. They reduced annual relapse rates (ARR) 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). Last year, Health Canada approved the first DMT for primary progressive MS.

The annual cost of DMTs for MS is over $10,000 annually and can go up to approximately $50,000 (or more). Second line therapies, which are taken after a patient has failed on an initial or first line therapy, have higher efficacy and higher cost.

Most MS medications cost the same as or exceed an average annual salary. Without drug plans in place (public, private or industry), financially, 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, including but not limited to, their doctor having filled the paperwork incorrectly, the patient having coverage under another plan; not being enrolled in the provincial plan; cancelled 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 remains a primary concern for Canadians living with MS.

While the MS Society appreciates that the new regulations align with the mandate of the PMPRB which is aimed at protecting the interests of Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive, the impact of the new regulations are significant, and their potential repercussions should be considered. For example, in addition to the changing of the basket of comparator countries the implementation of other factors such as pharmacoconomics and market size are of concern, as they would reduce prices even further, without the impact of the initial changes not having been fully evaluated.

Our concerns over the potential impact of these changes (discussed below) would be mitigated if the PMPRB undertook an incremental approach to the implementation of the amendments. 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.

Impact on Availability

One of the potential impacts of a significant drop in prices for medications is that access to treatments may become restricted. Following our 2017 poll, 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 potentially more important.

A reduction in pharmaceutical list prices of up to 20 percent could result in the cumulative effect of driving prices down to unsustainable levels for manufacturers resulting in their departure from the market and/or a reluctance to introduce new medicines in Canada. This issue is particularly relevant for Canadians living with MS, who as a result of strides in innovative research, have access to an increasing number of options when it comes to therapies.

This is further compounded by the concern of drugs that are subjected to the new 85 factors (pharmacoeconomic, market size and GDP). As mentioned in our 2018 submission, the pharmacoeconomic assessments which are currently used by the Canadian Agency for Drugs and Technologies in Health (CADTH) for the purposes of determining clinical and cost-effectiveness of a medication, do not include metrics that are important to patients, such as frequency of taking medications and quality-of-life measures. Quality Adjusted Life Year (QALY) assessments do not have favourable outcomes for patients who require rare disease medicines, known as orphan therapies. Using this methodology, QALYs, orphan therapies are typically found to be “cost-ineffective” and lacking in long-term data on safety and effectiveness relative to other conditions and disease. This is indicative of a system limitation of the
method, rather than the medicines. If the PMPRB relies on the same methods as CADTH, the ceiling price could be expected to be set at a level which could make access and availability even more difficult than it is currently. The price for any new therapy designed for a small patient pool would potentially be reduced well below a commercially viable rate, resulting in delays in manufacturers launching their product in Canada.

Overall, we are concerned that the full impact of how the implemented changes would impact drug availability are not adequately or fully understood. A multi-stakeholder dialogue should be established to better evaluate the impacts of these changes, with particular reflection on the potential consequences of pharmacoeconomic assessments as a regulatory factor.

**Impact on Research**

Canada is 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 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 may lead pharmaceutical companies to reduce investments in innovative research in Canada. Forcing prices down to the lower 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 therapies. 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 to the development of therapeutic options, but they also provide significant opportunities for research growth in Canada (and is particularly relevant in the MS space). Reduced incentives to bring therapies to market which have undergone clinical trials in Canada creates further ethical issues as it relates to access, specifically as it relates to patients who are on a medication that has undergone clinical trials but which has not been approved by Canadian regulators due to the manufacturers delaying or altogether neglecting to bring that drug to the Canadian market.

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. Consequently, 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 PMPRB website indicates that the PMPRB is “committed to listening to voices and views of Canadians, and to including them in decision making.” The MS Society was pleased with the opportunity to provide submissions throughout the PMPRB consultations on the proposed regulations changes. However, we were profoundly disappointed that the input and recommendations provided by the MS Society and other
patient groups were not reflected in the final regulatory draft and no notable changes were made to the proposed amendments despite having provided multiple submissions. Patient voices must be at the forefront of changes to regulatory systems which have an impact on prices and availability of therapies for those patients. The MS Society, as with other patient organizations, work directly with patients and are well positioned to provide input to PMPRB on both qualitative and quantitative patient indicators that are directly relevant to the regulatory amendments.

To this end, 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. In response to the amended regulations, 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 in regards 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 access, with particular reflection 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 specific reflection on the effect on clinical trials.
- 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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