MS Canada

Submission in response to A Discussion Guide for PMPRB
Phase 2 Consultations on New Guidelines
August 2024

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 a neurological disease of the central nervous system (CNS), which includes the brain, spinal cord, and optic nerves. Each person is affected by MS differently. In MS, the body's immune system mistakenly attacks myelin, the protective covering of the nerve fibres. Myelin is needed to effectively send messages to and from the brain. Damage to the myelin can result in loss of nerve fibres and over time, these changes contribute to disease progression. The most common MS symptoms include fatigue, problems with coordination, weakness, tingling, impaired sensation, vision problems, bladder and bowel problems, and cognitive and mood changes.

While the exact cause of MS is unknown, it is believed to be caused by a combination of genetic, environmental, and lifestyle factors. The most studied of these risk factors are smoking, low Vitamin D, adolescent obesity, and infection with Epstein-Barr virus (EBV).

In the past five years, there has been a growing body of research on the potential to prevent MS. In 2022, a landmark study by a team of researchers at Harvard University found the strongest evidence to date for the role of EBV as a necessary and initial risk factor required to trigger MS onset. Based on this recent work, there is momentum around the potential to prevent or reduce the incidence of MS through interventions such as vaccines and antivirals. Targeting EBV and other risk factors could prevent or reduce the risk of developing MS in the general population.

Below please find MS Canada's feedback related to the impacts and consequences of the topic areas highlighted by the Patented Medicine Prices Review Board from the Discussion Paper.

Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review

With new disease-modifying therapies (DMTs) for MS on the horizon, there is a need for a predictable, stable, and efficient pricing process to ensure successful market access to therapies in Canada. MS Canada supports Option 1 of the three choices offered in the Discussion Guide. If international prices are used as the initial triage measure for evaluating cost, the highest international price (HIP)

from the PMPRB11 should be used, 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 in Canada.

Topic 2: The length of time staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criteria for an existing medicine is met

Of the options presented, MS Canada supports waiting three years to determine whether the international price comparator (IPC) identification criteria for an existing medicine is met.

Topic 3: In-depth review based on CPI increase criteria

MS Canada supports Option 1, to initiate an in-depth review if the list price is above one-year CPI, as this is more predictable and transparent for rights holders to manage.

Topic 4: The individuals/groups permitted to submit a complaint

Of the options presented, MS Canada supports Option 2B, limiting complaints to the Federal Minister of Health and any related Provincial or Territorial counterparts, plus private and public payors. This option allows for a broader range of complaints for relevant payors while keeping the volume of complaints within reason.

Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines

MS Canada supports Option 1, to have the PMPRB treat patented biosimilars and/or vaccines the same as other medicines. We support the inclusivity and equity of all medications.

Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC.

MS Canada supports Option 2, where each comparator will be assigned a level of similarity.

Topic 7: Future Role of the Human Drug Advisory Panel (HDAP)

MS Canada supports Option 1, where a future Human Drug Advisory Panel will be used only on an ad hoc basis when deemed necessary by staff. It is important to have an additional body available for advice when necessary.

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Conclusion

MS Canada is appreciative of this opportunity to participate in the Phase 2 consultations on new guidelines. We look forward to participating in the proposed twice-year consultative discussions with patient groups to share information about the issues and decisions before the Board, particularly on the structure and implementation of the guidelines, and their expected impact.

MS Canada remains committed to ensuring PMPRB Guidelines find the right balance between their impacts on affordability, availability, and research. As the Board moves forward with amended guidelines, Canadians living with MS and their families should be at the centre of consultation processes and decisions.