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Patented Medicine Prices Review Board
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Re: August 2021 - Comment on three proposed amendments to the new PMPRB Guidelines

The MS Society of Canada is writing this letter in response to the recent consultation opportunity on the three proposed amendments to the new PMPRB Guidelines related to the decision to delay the coming-into-force date of the Regulations Amending the Patented Medicines Regulations ("Regulations"). We support the role of the PMPRB in setting the ceiling price for patent medicines and while our organization appreciates the opportunity to provide additional patient-centered perspectives on the guideline implementation process, the impact of the amended guidelines on our MS Community and moreover on all Canadians who require treatments is unclear. Our core concerns regarding the guidelines' impact on access to treatments for people living with MS – as highlighted in our previous six submissions dated June 2017, February 2018, February 2020, August 2020, February 2021, and June 2021 – continue to remain unaddressed and as such we question the utility of requesting stakeholder feedback from patient groups if it is not going to be applied to the amendment process. This letter serves to summarize our previous submissions, as our position and key recommendations related to the work of the PMPRB remains the same.

The MS Society recommends that the PMPRB undertake an incremental approach to the implementation of the amendments to ensure that they can evaluate the impact of changes regarding the basket of comparator countries and incorporation of pharmacoeconomic and market size factors on drug prices, drug availability, and ultimately on patient choices. Further to this, establish a multi-stakeholder dialogue to evaluate the impacts of these changes as it relates to access to medications with a specific focus on the potential consequences of pharmacoeconomic assessments as a regulatory factor.

Another key recommendation is for the federal government to 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. The MS Society is increasingly concerned that the anticipated amendments to the guidelines will reduce clinical trial opportunities in Canada significantly.

Finally, and at the centre of our work, the PMPRB must 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. Currently, these processes are not explained clearly, nor presented in a meaningful or transparent manner and furthermore do not provide insight into the impact they will bear on patients who rely on life-altering medications that these amendments will impact most.

We look forward to a continued dialogue on the affordability, availability and access to medicines for Canadians as one discussion cannot happen in isolation of the other. Thank you for your consideration of our feedback.

Sincerely,

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