Written Brief for the House of Commons Standing Committee on Health (HESA)

Study on Patented Medicine Prices Review Board's Final Guidelines
November 2020

Submitted to:
Jean-Francois Pagé, Clerk of the Committee
HESA@parl.gc.ca

Submitted by:

Robert Woolstencroft, Ph.D.
Head, Patient Access & Government Affairs
robert.woolstencroft@emdserono.com

EMD Serono Canada, a division of EMD Inc.
2695 North Sheridan Way
Mississauga, Ontario L5K 2N6
(905) 919-0200

Subject: Patented Medicine Prices Review Board (PMPRB) Guidelines

On behalf of EMD Serono Canada ("EMD Serono"), I am writing to provide input to the House of Commons Standing Committee on Health's study of the final PMPRB Guidelines ("the PMPRB Guidelines") that take effect on January 1, 2021.

EMD Serono, the Canadian biopharmaceutical business of Merck KGaA, Darmstadt, Germany, is committed to ensure patients in Canada will benefit from innovative products in oncology, neurology, fertility and endocrinology. Our pipeline includes novel investigational therapies in neurology, oncology and immuno-oncology. Globally, our company is also currently investigating potential therapeutic approaches for COVID-19. In Canada, we support research through clinical trials in multiple sclerosis (MS) and oncology. EMD Serono has its headquarters located in Mississauga, Ontario and employs more than 100 people across Canada.

EMD Serono is a member of Innovative Medicines Canada (IMC) and fully supports the position of our industry association. In this letter, I articulate our concerns about the new approaches to regulate the prices of patented medicines in Canada specified in the PMPRB Guidelines.

Our key concerns are outlined as follows:

1. The new Guidelines will negatively impact patient access to new medicines in Canada.
2. The new economic factors act as a new marginal tax on innovation and introduce substantial uncertainty for manufacturers.

At EMD Serono, our mission is to create, improve, and prolong the lives of patients. The PMPRB Guidelines include new measures in the framework that are unprecedented globally; indeed, the measures introduced in the PMPRB Guidelines are more extensive than those used by any other country for the pricing of patented medicines. These new factors introduce uncertainty and devalue significant medical innovations that are designed to advance the health of Canadians. The PMPRB Guidelines put patient access to such innovations at risk.

Recommendation and Request:

We respectfully ask the House of Commons Standing Committee on Health to recommend that the Minister of Health and the PMPRB delay implementation of the Guidelines until a comprehensive analysis of the impacts can be appropriately modelled, published, and transparently discussed to address key concerns raised by numerous stakeholders.

1. The new Guidelines will negatively impact patient access to new medicines in Canada

The belief that excessively lower drug prices in Canada will not negatively impact the availability of new innovative drugs in this country is deeply flawed. Indeed, the approach outlined in the PMPRB Guidelines will prevent or delay the introduction of new innovative treatments in Canada, which will have a profound impact on patients who are desperate for innovative treatments to treat their conditions.

A 2017 survey of multi-national pharmaceutical executives in 31 markets drew attention to the fact that stiff price cuts levied against innovative drugs hamper a country's ability to secure and sustain investment. In particular, the report noted that this finding from the survey should be a "red flag" to

economies considering a similar approach; the report also emphasized "such as Canada in its proposed amendments" to the PMPRB.[1]

More recently, a report of a survey of global and Canadian pharmaceutical executives performed for Life Sciences Ontario about the new pricing regulations reported that **all** respondents thought that the changes would negatively affect their overall business plans in Canada and almost all responded that they would adversely impact product launches, commercialization and supply of current products (97%), employment in Canada (97%) and clinical research in Canada (91%).[2] This research clearly demonstrates the negative impact of the new price regulations on industry and commercialization of patented medicines in Canada.

Recently collected data by IQVIA has further substantiated the concerns of global and Canadian pharmaceutical executives. In 2019, the year the PMPRB guidelines were adopted, there was a dramatic 40% drop in the number of new globally launched drugs commercialized in Canada – this occurred despite the overall number of global launches rising that year.[3] By mid-2020, Canada benefited from less than half of new therapies launched globally in 2018 (16 of 37 [43.2%]).[3] Most of these innovative therapies, which have not been commercialized in Canada, are for rare diseases and cancer.

2. New economic factors act as arbitrary, marginal tax rates on innovation and introduce substantial uncertainty for manufacturers of new medicines

The PMPRB Guidelines include the calculation of market size impact for new medicines and specify arbitrary revenue thresholds that trigger reductions in net revenue. This approach is the equivalent of a marginal tax rate on net revenue for innovative medicines, which devalues innovation. Importantly, this new approach effectively moves the PMPRB from its mandate in regulating excessive pricing of patented medicines to a new role in revenue control. This was not Parliament's intention when enacting the *Patent Act*.

The market-size adjustment is a disincentive to the development and commercialization of innovative medicines in Canada. First, it penalizes the development of innovative medicines that treat larger patient populations. Second, it is a deterrent for manufacturers to expand the clinical benefit of innovative medicines to additional patient populations who need better treatment options. Finally, the market-size adjustment creates significant uncertainty in the final price and commercial potential of new medicines.

The shift in mandate of the PMPRB to revenue control penalizes manufacturers and has unintended consequences on patient access to innovative medicines in Canada. New economic factors and adjustments based on market size make Canada a less favourable environment in which to launch products due to the inherent uncertainty of how these factors will impact net revenue. Indeed, Canada will be deprioritized as a jurisdiction for the timely launch of such medicines and will be skipped over in favour of jurisdictions that place a higher value on access to innovative medicines. Finally, lower prices and revenue may compromise the development by manufacturers of robust support programs that benefit patients and the health care system. Quite simply, the PMPRB Guidelines make Canada a less attractive market for both launch and investment. This means Canadian patients will have reduced patient access to new medicines

Conclusion

The PMPRB is intended to protect Canadians by ensuring that the prices of patented medicines are not excessive. The PMPRB Guidelines should protect Canadians against excessive prices for patented medicines, rather than set arbitrary limits on revenue, which essentially imposes a tax on innovation.

An appropriate balance is required between improving the affordability of medicines, ensuring timely patient access to medicines, and creating a world-class innovative life sciences ecosystem. The implementation of the PMPRB Guidelines will have the opposite effect: If the PMPRB Guidelines are implemented in their current state, with the associated uncertainty and arbitrary limits on revenue, EMD Serono's ability to launch innovative products in Canada on a priority basis will be severely challenged. This will negatively impact patient access to innovative medicines.

With the January 1, 2021 implementation date of the PMPRB Guidelines a few weeks away, this is a critical moment for both the innovative medicines industry and, most importantly, patients in Canada. We respectfully urge the House of Commons Standing Committee on Health to clearly consider the broad and deep impact of the PMPRB Guidelines on Canadian patient access to new medicines. Further, we ask for a delay in the implementation of the PMPRB Guidelines until such issues can be transparently discussed to address the concerns of the numerous stakeholders who will be impacted. Patient access to new innovative medicines in Canada depends on it.

Sincerely,

Robert Woolstencroft, Ph.D.
Head, Patient Access & Government Affairs
EMD Serono Canada, a division of EMD Inc.