November 6, 2020

Standing Committee on Health (HESA)
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6
Canada

Subject: Study on the Patented Medicine Prices Review Board's (PMPRB) Reform

Dear Committee Members,

On behalf of Merck Canada Inc. (Merck), thank you for conducting a study on the reform of the Patented Medicine Prices Review Board (PMPRB), and for the opportunity to provide input to help inform your deliberations.

Merck is a leading global biopharmaceutical company committed to improving health and wellbeing by developing vaccines and medicines in many areas, including oncology, infectious diseases and diabetes. We employ approximately 680 people across the country and are one of the top R&D investors in Canada, with investments totalling more than $1 billion since 2000. We are currently investing in over 100 clinical trials involving over 500 research sites and over 3,000 patients across Canada. Our company has also responded to the COVID-19 pandemic by committing $500,000 to its COVID-19 Community Support Plan and is currently working on developing two vaccines and an antiviral treatment for COVID-19.

With just weeks before the PMPRB changes come into force, your committee's review is the first substantive parliamentary consideration of this uncertain and unconstitutional regulatory barrier to the introduction of new medicines in Canada. While Health Canada and the PMPRB have provided stakeholders with opportunities to provide written input on the reform, there has been no public forum involving our elected officials to openly discuss these critical changes. We think it is important to shine a light on the detrimental impact they are having on Canadian patients, our health system and our research ecosystem, especially during this critical time with the COVID pandemic, to hopefully correct course and implement a more balanced approach by January 1, 2021.

We have outlined in this submission our key concerns with the PMPRB reform and our proposed solution to address them.

New economic factors: the crux of the problem

The crux of the problem with the PMPRB reform lies with the new economic factors – the pharmacoeconomic value and the market size adjustments – that were added to the *Patented*

Medicines Regulations in August 2019 and operationalized in the final PMPRB guidelines. These economic factors are creating an unsustainable and unworkable pricing regime that will discourage many companies from bringing their medicines and vaccines to the Canadian market for the following two key reasons:

- **Unreasonable price reductions:** The PMPRB changes, in particular the application of the new economic factors, will result in price reductions of more than 50% for treatments for many specialty medicines, including cancer therapies.[1]

- **Untenable commercial uncertainty:** The economic factors create significant business uncertainty, as it is impossible to predict what prices will be considered acceptable for new medicines and vaccines. Pharmaceutical companies, such as Merck, will have to navigate through a convoluted pricing system, with limited clarity on how the various new formula and criteria will be applied. Specifically, pharmacoeconomic analyses, which are currently used by the Canadian Agency for Drugs and Technologies in Health ("CADTH") and the Institut national d'excellence en santé et en services sociaux ("INESSS"), are intended to help inform the reimbursement of medicines and support negotiations between manufacturers and governments or private insurers to arrive at agreed-upon reimbursement terms, including pricing. Given such analyses are highly subjective and vary substantively depending on their inputs and who conducts them, they have never been used by any country to date in a regulatory setting to help determine maximum prices.

New medicines and vaccines are generally first made available in countries that have a clear and predictable pharmaceutical pricing process in place. Ultimately, if there is this much uncertainty on how to price Canadian products, it will be very challenging for pharmaceutical companies to make a compelling business case to their global headquarters to prioritize Canada for new medicine launches and clinical trials.

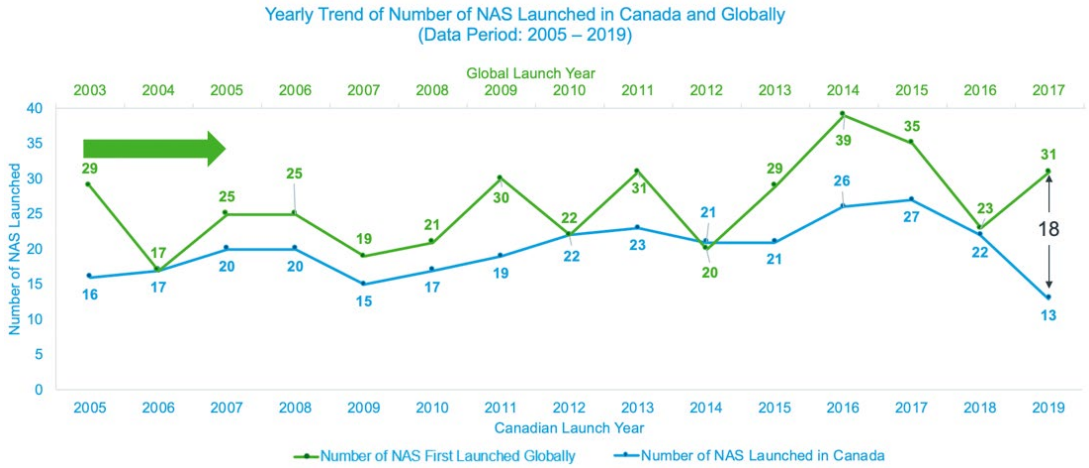
There is too much at stake, especially in the current environment, to adopt the flawed new pricing framework. At a time when new vaccines and medicines are needed to help combat COVID-19, we cannot afford to implement the untested new economic factors that would compromise Canadians' health. We should not be lowering prices of medicines to a level that will preclude patients from accessing new therapeutics to prevent or treat life-threatening or life-altering diseases.

Patient access to medicines and health research already negatively affected

Unfortunately, there is evidence that the federal reform has already reduced launches of new medicines (i.e., commercialization of new medicines) and clinical trial activities in Canada.

[1] PMPRB Final Guidelines: https://www.canada.ca/en/patented-medicine-prices-review/services/legislation/about-guidelines/guidelines.html.

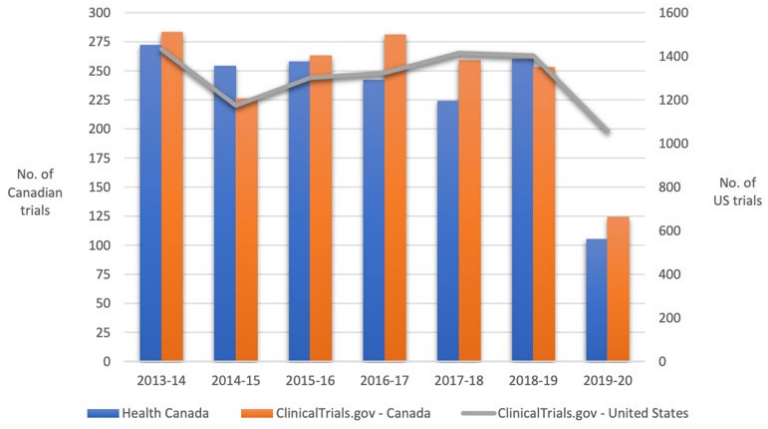
Specifically, according to recent data produced by IQVIA, a global leader in health data and analytics, there has been a sharp decline in the number of new drug launches in Canada in 2019. While Canada benefitted from 22 globally launched medicines (those that were launched in at least two major jurisdictions) in 2018, this number fell to just 13 in 2019 (see graphic below). Canada should have benefitted from closer to 30 launches last year.



IQVIA MIDAS Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance; Presented for Life Sciences Ontario as, *IQVIA, New Medicine Launches: Canada in a Global Context, June 2020, p. 14*: https://lifesciencesontario.ca/wp-content/uploads/2020/06/EN_LSO_Global-Launch-Benchmarking_Webinar-June22-20_Final.pdf

According to another recent study, the number of clinical trials registered by Health Canada between November 2019 and mid-March 2020 fell by 52% compared to the average number registered during the same period in the previous six years (see Chart 1 below). Of note, this drop in clinical trials occurred prior to COVID-19 hitting Canada, and much of this research includes high-cost, multi-centre clinical trials for cancer and other life-threatening diseases. Finally, it should be noted that clinical trials are important to patients and the health system, as they provide early access to new breakthrough therapies and vaccines.

CHART 1: Numbers of clinical trials registered between November 1 and March 15, 2013-14 to 2019-20, Canada and the United States.



Source: Nigel SB Rawson, PhD, *Canadian Health Policy*, April 2020, p.4: https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada-decrease--a-sign-of-uncertainty-regarding-changes-to-the-pmprb-.html?buy_type=

The "COVID exception": an acknowledgement that the reform is flawed

The federal government and the PMPRB adopted interim orders and a special policy to decrease the PMPRB's regulatory scrutiny of COVID vaccines and treatments as part of a "government wide effort to provisionally ease the regulatory pathway" for these therapeutics.[2]

There are two important things to note about this provisional exception. First, while the federal government has eased the pathway for COVID therapeutics, they can be the subject of an investigation and the new pricing regime will apply to them in part once the interim orders expire, thereby creating some uncertainty for the commercialization even of these therapeutics.

Second, by adopting this exception, the federal government clearly recognizes that the PMPRB reform is a regulatory burden and that it will preclude new medicines and vaccines from coming to the Canadian market. Since the PMPRB changes were proposed in 2017, Health Canada insisted that they will not have an impact on access to medicines and that there would be negligible regulatory and administrative burden on medicine developers.

Partial provisional suspension of the economic factors does not lessen the negative impact

In its final guidelines, the PMPRB provisionally limited the application of the new economic factors pending the federal Court of Appeal's decision on the judicial review of the amendments to the *Patented Medicines Regulations*.[3] While this may seem like a positive step forward, the PMPRB staff can still use the economic factors in the context of investigations and hearings on drug prices. This is problematic as the guidelines afford them very large discretion in terms of the tests and criteria they can apply in this context, and a complaint by anyone could trigger an investigation. Further, the PMPRB could revert its position to start consistently applying the economic factors to determine price ceilings if the government succeeds in its appeal.

Ultimately, medicine developers would still have to launch new medicines or vaccines at huge risk, and this will of course continue to discourage manufacturers from commercializing new medicines and vaccines in Canada or will significantly delay their plans to do so.

The PMPRB reform is a federal intrusion into provinces' jurisdictions

We believe that the PMPRB's powers and the use of the new factors to reduce the prices of medicines constitute an encroachment on provincial jurisdiction over property and civil rights, which includes the control of prices, the regulation of industries that are not under federal jurisdiction, and insurance (s. 92(13) of the Constitution Act, 1867), the management of

[2] PMPRB NEWSletter: October 2020, Volume 24, Issue 1: https://www.canada.ca/en/patented-medicine-prices-review/services/pmprb-newsletter/october-2020-volume-24-issue-1.html.
[3] *Ibid.*

hospitals and the hospital system globally (s. 92(7) of the Constitution Act, 1867), as well as matters of a merely local or private nature (s. 92(16) of the Constitution Act, 1867).

In addition, given that the reimbursement of medicines falls within the purview of provinces, provincial governments have already set up processes to control the prices of medicines, including CADTH and INESSS that evaluate medicines, the pan-Canadian Pharmaceutical Alliance (pCPA) that negotiates the prices of medicines on behalf of the provinces and provincial-level reimbursement regulations and policy. While pCPA negotiations are confidential, Canadian governments have reported that these negotiations are saving them, in aggregate, billions of dollars annually.[4]

A simple and balanced solution: remove the new economic factors

The vast majority of stakeholders who provided input in the recent consultations on the PMPRB guidelines expressed concerns about the PMPRB reform, which indicates there remains a serious problem to address before it can be implemented.[5]

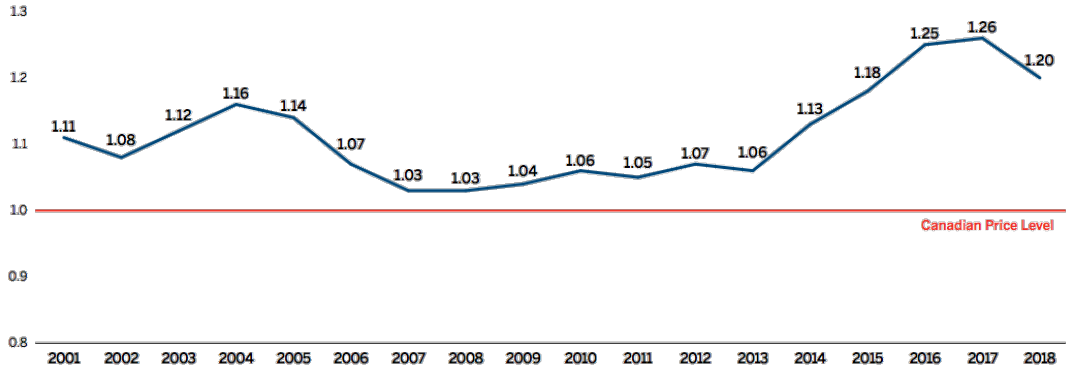
We believe this problem could be solved by revising the *Patented Medicines Regulations* to remove the contentious economic factors, including the pharmacoeconomic value and the market size adjustments.

If the economic factors were removed, the reform would still rely on the modified list of countries, which alone would lower current drug prices for both public and private insurance plans by 15-20%. This price reduction is already substantive, and sufficient on its own to achieve the savings originally contemplated by Health Canada at the outset of this reform.

Further, it should also be underlined that the PMPRB's latest annual report shows that Canadian prices have consistently remained well below the median of prices found in the current basket of seven comparator countries (see Figure 26 below where the red line representing Canadian price level is always below the international median). As well, it should be stressed that these prices do not reflect the substantive rebates provided to Canadian governments though the pCPA negotiations.

[4] Canada's Premiers' website: https://www.canadaspremiers.ca/premiers-committed-to-healthcare-sustainability-call-on-federal-government-to-be-full-partner/.
[5] See: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html.

Figure 26. Average Ratio of Median International Price (MIP) to Canadian Price, at Market Exchange Rates, 2001 to 2018



Data source: PMPRB

Source: PMPRB 2018 annual report, p. 45:
https://www.canada.ca/en/patented-medicine-prices-review/services/reports-studies/annual-report-2018.html

Conclusion

Merck commends the Health Committee for taking on this important study. We hope that the Committee will consider including as part of its recommendations the concrete solution outlined in this submission and that the federal government will ultimately remove the economic factors from the regulations. This would greatly contribute to our sector's collective efforts to develop and deploy new therapeutics so that Canadians can continue to have access to the vaccines and medicines they need to survive and thrive.

Sincerely,

Jennifer Chan
Vice President, Policy and External Affairs
Merck Canada Inc.