February 20, 2023

Re: Letter of Resignation

Dear Minister Duclos,

It has been a privilege to serve as a member of the Patented Medicine Prices Review Board since 2018. In view of recent events, in particular, the lack of support from your office and the government, I no longer believe it is possible to serve the public good in this role. I must regretfully resign.

It is important to provide context for my decision.

Prior to the creation of the PMPRB, Canadians enjoyed access to relatively affordable medicines through a robust system of compulsory licensing and generic drug manufacturing.[1] In 1987, Canada reformed its patent laws in an effort to satisfy its major trading partners while also encouraging the brandname pharmaceutical industry to finance more drug research and development (R&D) in the country. Industry, in turn, promised to spend 10% of its sales on R&D in Canada. At the same time, the PMPRB was given a mandate by Parliament to protect consumers from "excessive" drug prices.[2]

In the 35 years that have followed none of these objectives has been achieved. Industry has not met its 10% R&D spending target since 2002. In 2021 industry allocated only 3.4% of its total sales towards R&D in Canada—an all-time low.[3] And for the past several years the prices of patented medicines in Canada have been the third highest in the world, behind only the United States and Switzerland.[4]

The reasons for these policy outcomes are complex. However, the ways in which the PMPRB has historically regulated the prices of patented medicines was one area where there was clearly room for improvement.[5]

That is why—when the PMPRB embarked upon a process of modernizing its guidelines in 2016,[6] which the government expanded with the introduction of new regulations in late 2017[7]—I

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[1] *Report of the Commission of Inquiry on the Pharmaceutical Industry (Eastman Commission)*, by Government of Canada (1985).
[2] *Celgene Corp v Canada (Attorney General)*, [2011] 1 SCR 3.
[3] Patented Medicine Prices Review Board, "Annual Report 2021", (18 November 2022), online: <https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2021.html>.
[4] *Ibid*.
[5] Rujun Zhang, Danielle Martin & C David Naylor, "Regulator or regulatory shield? The case for reforming Canada's Patented Medicine Prices Review Board" (2017) 189:14 CMAJ E515–E516.
[6] Patented Medicine Prices Review Board, "PMPRB Guidelines Modernization – Discussion Paper – June 2016", (15 June 2016), online: <http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines/discussion-paper>.
[7] Public Works and Government Services Canada Government of Canada, "Canada Gazette – Regulations Amending the Patented Medicines Regulations", (2 December 2017), online: <https://gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html>.

applied to become a member of the Board. The new regulations, which, when they were initially introduced, sought to 1) alter the list of countries that the PMPRB uses as a point of comparison, 2) allow the PMPRB to take "confidential rebates" into account, and 3) consider the pharmacoeconomic value and market size of a given medicine, promised major change.

The onset of COVID-19 complicated the implementation of these critically important reforms. Nevertheless, the government and/or your office has, on multiple occasions, failed to follow through.

First, the government failed to effectively defend the policy change in the courts. In 2019-2020, industry initiated court challenges to both the new regulations (as passed Governor-in-Council) as well as corresponding guidelines (developed by the PMRPB to implement the new regulations). When the Québec Court of Appeal ruled that elements 2) and 3) of the new regulations (noted above) were unconstitutional,[8] the government chose *not* to seek leave to appeal before the Supreme Court of Canada. The net result is that only one element (i.e., the new list of comparator countries) of the regulations remains good law—a far cry from what the government described as the "biggest step to lower drug prices in a generation" when the new regulations were first enacted.[9] In choosing not to seek leave to appeal, the government effectively countenanced the evisceration of its own reform.

Second, the government has delayed when the new regulations would "come into force," i.e., become law, on four separate occasions since they were introduced. In each case, the stated rationale for the delay was the uncertainty posed by the pandemic and the time needed by industry to bring their pricing practices up to speed. While this rationale may have held water initially, subsequent delays (often announced at the 11th hour) caused immense strain upon the Board, particularly Board staff. Many Canadians may not realize that the PMPRB cannot enforce the new regulations as soon as they come into force. A minimum of two reporting periods would need to elapse before staff could even initiate an investigation into whether a given medicine's price is excessive. Despite this gradual approach to enforcing the regulations, which the PMPRB communicated to stakeholders, the government accepted again and again industry's claim that it needed more time to comply with the new regulations.

Third, the government has fundamentally undermined the Board's independence and credibility. While the regulations were repeatedly delayed and challenged in the courts, the Board initiated multiple consultations to develop and put into place new guidelines. All told, these consultations included hundreds of in-person meetings across the country, online webinars, and bilateral meetings with all of the Board's stakeholders, including patentees, wholesalers, insurance companies, industry-funded patient groups, independent patient groups, individual patients, community-based organizations, provincial government officials, and others. The proposed guidelines were challenged in court, in the court of public opinion, and discussed intensely internally among staff and Board members. We brought multiple major revisions to the proposed

[8] *Merck Canada inc c Procureur général du Canada*, 2022 QCCA 240.
[9] Health Canada, "Government of Canada Announces Changes to Lower Drug Prices and Lay the Foundation for National Pharmacare", (9 August 2019), online: <https://www.canada.ca/en/health-canada/news/2019/08/government-of-canada-announces-changes-to-lower-drug-prices-and-lay-the-foundation-for-national-pharmacare.html>.

guidelines in response to stakeholder feedback—industry feedback in particular—over a two-year period. During our most recent round of consultations, it was evident that industry would not accept the Board scrutinizing any price below the highest international price of the new basket of comparator countries. That position is fundamentally at odds with the relevant body of jurisprudence, the government's stated policy objectives in bringing forward the new regulations, and the statutory scheme underlying the Board's core mandate of "policing excessive prices."[10] Each successive revision to the new guidelines, including the most recent draft that we consulted on during the fall, sought to center that role.

In this context, your "request" in late November that we suspend our consultations for reasons that were largely indistinguishable in form and substance from industry talking points on the proposed guidelines undermined the Board's credibility and interfered with the exercise of a function that goes to the very heart of its expertise as an independent, arms-length administrative tribunal.[11] In my view, the government is holding the Board to an impossible standard, one that requires it to impose lower ceiling price based on a new group of comparator countries but in a manner that is agreeable to the very parties that stand to earn less revenue if those changes are rendered effective. It is difficult enough for a sector-specific regulator to do its job in the face of a hostile industry. But when government adds its voice to that of industry, all that lies before the regulator is an endless tunnel with no light.

For all of these reasons, I resign from the Board.

I arrived at this decision after a great deal of reflection. During my tenure I have had the privilege to work with a number of exceptionally dedicated colleagues. I have been amazed by the integrity and expertise of Board staff. The Board's Executive Director, Douglas Clark, and his colleagues have worked tirelessly to improve the system and in my view embody the very finest of what the civil service can and should be. The last thing I want to do is hurt the organization. However, in the absence of the political courage to support meaningful policy reform, the position of the PMPRB has become untenable.

Canadian healthcare is in crisis. Jurisdictional issues complicate the federal government's ability to intervene. That the federal government is unwilling to support real change in a domain where its jurisdiction over patented medicines cannot be questioned, and those same medicines are the fastest growing contributor to the rising costs of healthcare,[12] is deeply disappointing.

Sincerely,

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[10] *Innovative Medicines Canada v Canada (Attorney General)*, 2022 FCA 210.

[11] Patented Medicine Prices Review Board Canada, "2022 Proposed updates to the PMPRB Guidelines", (29 September 2022), online: <https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/2022-proposed-updates-guidelines.html>.

[12] Patented Medicine Prices Review Board Canada, "Increased use of higher-cost medicines continues to put pressure on Canadian public drug plans", (31 January 2023), online: <https://www.canada.ca/en/patented-medicine-prices-review/news/2023/01/increased-use-of-higher-cost-medicines-continues-to-put-pressure-on-canadian-public-drug-plans.html>.

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