

VIA EMAIL AND POSTED PUBLICLY

April 17, 2019

The Rt. Hon. Justin Trudeau, PC, MP
Office of the Prime Minister
80 Wellington Street
Ottawa ON K1A 0A2

Subject: On PMPRB reform, political leadership and evidence-based approach needed

Dear Prime Minister Trudeau,

On March 7, 2019, we wrote a letter (attached as Appendix B) to you along with your two senior ministers responsible for health and innovation policy regarding the above-noted regulations. On April 15, 2019, we received an email response from the Strategic Health Policy Branch of Health Canada (attached as Appendix A).

This type of dismissive response – even claiming that we are “pharmaceutical industry stakeholders,” as opposed to who we actually are: important representatives of the broader life sciences industries in Alberta, Ontario and Quebec – is both insulting and disturbing and reflects poorly on the whole PMPRB reform process.

No senior official signed the email response and none of the members of cabinet that we sent our original letter to were copied. This makes us very worried that the reform of the Patented Medicine Prices Review Board (PMPRB) is being steamrolled ahead by Health Canada government officials with limited political oversight. The fact that Health Canada was the only signatory to this letter also shows the siloed approach that this government has been taking to date on the PMPRB reform. It validates our concerns that Health Canada’s proposal is not taking a whole-of-government, evidence-based approach. In particular, it is telling that ISED did not co-author the response given the serious concerns we raised regarding the impact of the reform on the life sciences ecosystem.

In this context, we are calling on you and those with broader responsibility to reconsider the proposed PMPRB reform, and thereby stand up for governance and evidence-based policy-making, access to medicines and our innovative life sciences sector.

Health Canada’s defence of the proposed regulations – which we understand have not substantively changed since they were introduced in December 2017, despite the concerns of over 100 stakeholder groups and experts – rests on the report developed by Drs. Dodge and Blomqvist (the Dodge Report). Only selected conclusions from the Dodge Report were highlighted in the response we received from Health Canada, failing to note that the report also emphasizes the lack of transparency in the consultations to date, insufficient engagement with stakeholders, lack of scenario / case studies to test the analysis, concerns about the use of economic factors in price regulation (as opposed to within a pharmacare program) among other issues. The Dodge Report conclusions might have been different if they had had access to more information, including the PMPRB’s own case studies that reviewed proposals for implementing the regulations, which show massive differences in the probable impact of the regulations on industry revenues and prices (up to 30-70%).

Contrary to what is alleged in Health Canada's response, the proposal will not achieve a "balance between innovation and the affordability of patented drugs for Canadians." Granting the PMPRB new regulatory powers, especially the new economic factors, will be devastating for a key driver of Canada's knowledge-based economy, with little upside benefit for the health system and negative consequences for all Canadians who depend on timely access to new therapies.

Finally, and on a positive note, your government appears to be taking new and more holistic approaches to achieving affordable and accessible pharmacare programs in Canada, which should be further explored and considered. Budget 2019-20, which was tabled after our March 7 letter, elaborates the government's step-wise approach to implementing national pharmacare, with anticipated savings for Canadians of \$3 billion annually once the programs are up and running. There is notably no mention of the proposed PMPRB reforms in the Budget Plan, despite several pages devoted to the national pharmacare proposals. We urge you to focus policy efforts on programs that avoid over-regulation via the PMPRB and look for practical and workable solutions through some of the proposed policies in the Budget, such as a national plan for rare disease treatments.

We hope to have an opportunity to discuss with you and your office our concerns regarding the draft regulations and the opportunities presented in Budget 2019-20 in the coming weeks.

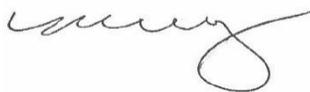
Sincerely,



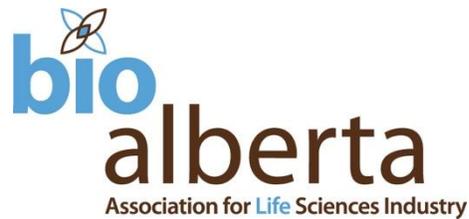
Jason Field
President & CEO Life Sciences Ontario



Frank Béraud
President / CEO Montréal InVivo



Mel Wong
President & CEO BioAlberta



cc. Hon. Navdeep Bains, Hon. Ginette Petitpas Taylor

From: **SPB / DGPS (HC/SC)** <hc.spb-dgps.sc@canada.ca>

Date: Fri., Apr. 12, 2019, 2:58 p.m.

Subject: Proposed Reforms to the PMPRB Regulations

To: mel@bioalberta.com <mel@bioalberta.com>, jason.field@lifesciencesontario.ca <jason.field@lifesciencesontario.ca>, fberaud@montreal-invivo.com <fberaud@montreal-invivo.com>

*Mel Wong, President & CEO
BioAlberta*

*Frank Béraud, President & CEO
Montréal InVivo*

*Jason Field, President & CEO
Life Sciences Ontario*

Dear Mr. Wong, Mr. Béraud, and Mr. Field,

Thank you for your letter dated March 7, 2019 sent to the Honourable Ginette Petitpas Taylor, Minister of Health. This response is being sent on her behalf. We would like to thank you for writing again to share your concerns with respect to the proposed amendments to the *Patented Medicines Regulations*. Please know that your input has been shared with officials who are working on the proposed reforms.

The Government of Canada has taken the concerns expressed by pharmaceutical industry stakeholders with respect to the differences between their and Health Canada's assessments of the regulatory impacts seriously. To examine those concerns, Health Canada asked Dr. David Dodge and Dr. Åke Blomqvist to perform an independent assessment of the proposal's features and the cost-benefit analysis that was completed in support of the regulatory proposal. The independent assessment supported proceeding with the regulatory changes. It also found that Health Canada's analysis of the impact of the regulatory changes on the pharmaceutical industry had been carefully done and was based on empirical analysis. That is why Health Canada continues to work with its partners to support innovation and reduce regulatory barriers to the industry.

The Government of Canada understands the importance of the pharmaceutical, biotechnology and life sciences sectors in supporting research and development and creating well-paying jobs. However, we must also ensure that there is a balance between innovation and the affordability of patented drugs for Canadians.

Thank you for taking the time to write.

Sincerely,

Strategic Policy Branch
Health Canada

7 March 2019

The Right Honourable Justin P. J. Trudeau
Office of the Prime Minister
80 Wellington Street
Ottawa, ON K1A 0A2

The Honourable Ginette Petitpas Taylor
Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9

The Honourable Navdeep Bains
Minister of Innovation, Science, and Economic Development
House of Commons
Ottawa, ON K1A 0A6

Regarding Proposed Reforms to the Patented Medicine Prices Review Board (PMPRB) Regulations

On behalf of several of Canada's leading life sciences innovation organizations, I am writing to reiterate our increasing concern regarding the proposed changes to the Patented Medicine Prices Review Board regulations. In our letter of August 2018, we registered our concerns regarding the serious impacts for the future of Canadian healthcare and our innovation economy, and that the proposed changes are in conflict with the stated goals of your government. These included serious impacts to economic investments and access to innovative, life-saving medicines for Canadians. Since then, the public and private statements from the Government of Canada have done nothing to allay these concerns.

We write on behalf of Canada's broader pharmaceutical, biotechnology and life sciences sector, which employs thousands of Canadians, in exactly the type of high-value, boom-and-bust resilient positions that any government should want to foster. The proposed reforms seem designed to remove the life sciences sector from Canada's economic diversification strategy.

When first announced by then Minister of Health Jane Philpott in May 2017, the proposed reforms were intended to lower the cost of prescription drugs in Canada and better protect Canadians against excessive drug prices. However, in seeking to make drugs more affordable, Health Canada ignores any strategy aimed specifically at the relatively small percentage of Canadians without a public or private drug benefits program and who are prescribed patented medicines. It is our assertion that the proposed approach uses a sledgehammer where a scalpel would do, and the collateral damage will harm patients, Canada's standing as a world-class health system, and threaten thousands of Canadian jobs.

In its 2018 analysis of the proposed regulations, Ernst and Young warned that these reforms would impact market factors in such a way that Canadians could expect fewer innovative products to be launched in Canada. We ask, which innovative medicines and vaccines will Canada forgo under Health Canada's new approach? When Canada can no longer compete for clinical trials because it does not offer the international standard of care, which countries will gladly absorb those clinical trials into their R&D ecosystem?

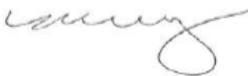
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In its publication of illustrative case studies applying the proposed regulations, the PMPRB showed that price ceilings for the most innovative products would be reduced by up to 70%, an unsustainable policy environment for any industry. Such revenue losses would inevitably lead to thousands of Canadian layoffs, the elimination of many research collaboration investments with Canadian universities, and the severance of ties between pharma and biotech companies and multiple small business incubator services across Canada. Across Canada, we already see the impact of the business uncertainty created by these proposed regulatory changes: pharmaceutical and biotech job openings cancelled, academic partnership and collaboration discussions put on pause, investment and sponsorship renewals delayed or declined.

In this economic environment, the federal government should be seeking opportunities to develop resilient, high-value employment growth in other sectors. Canada's pharmaceutical and biotechnology sector is a natural fit for such an economic diversification strategy. It defies logic that the Government of Canada would seek to hamstring employment growth in this vital industry and reduce patient's access to new medicines.

Our organizations strongly recommend that Health Canada seek alternative approaches to make drugs more affordable for Canadians struggling to pay for their prescriptions, approaches that ensure the next wave of innovative product are available to Canadians and ensure that thousands of Canadian jobs are not put at risk.

Sincerely,



Mel Wong, President & CEO
BioAlberta



Frank Béraud, President / CEO
Montréal InVivo



Jason Field, President & CEO
Life Sciences Ontario

