

August 4, 2020

Mr. Doug Clark, Executive Director
Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1
By email: PMPRBConsultations.CEPMB@pmprb-cepmb.gc.ca

The Honourable Patty Hajdu, P.C., M.P.
Minister of Health
Health Canada
Brooke Claxton Building, Tunney's Pasture,
Ottawa, Ontario K1A 0K9
By email: hccminister.ministresc@canada.ca

The Honourable Navdeep Bains, P.C., M.P.
Minister of Innovation, Science, and Industry
235 Queen Street,
Ottawa, Ontario K1A 0H5
By email: ISI.minister-ministre.ISI@canada.ca

Subject: *Impact of new PMPRB guidelines on the life science ecosystem in British Columbia*

Dear Mr. Clark, Minister Hajdu and Minister Bains,

As a follow up to our letter of February 21, 2020, LifeSciences British Columbia ("LSBC") is writing to express our continued concerns regarding the potential negative consequences on the life sciences sector of the proposed Patented Medicine Prices Review Board (PMPRB) changes ("June 2020 Draft Guidelines" or "new Guidelines"). We are urging the PMPRB, Health Canada and ISED Canada to work together to develop a solution for drug pricing in Canada.

LifeSciences BC ("LSBC") has prepared our observations based on careful review of the guidelines, in consultation with our stakeholders, who have knowledge and perspective relevant to the B.C. life sciences ecosystem. We recognize that Canada needs to reform its pharmaceutical pricing process, however, we are concerned that the solution proposed by the PMPRB in the Guidelines released June 19th, 2020, fails to address the risks we identified in our February 21, 2020 letter (attached). At LSBC, we

acknowledge that none of these individual concerns fall within the statutory remit of the PMPRB and therefore need thoughtful consideration before implementing the proposed regulations and guidelines of 2020. Therefore, LSBC is compelled to point out the high-level unintended consequences of the new Guidelines, and potential collateral damage, as far as it can be anticipated, by those who are actively engaged in the sector.

Our concerns are as follows:

1. The new Guidelines are counter-productive to other provincial and federal initiatives critically important to stimulating life sciences innovation and development.
2. A high level of unpredictability to pricing of innovative medicines in Canada will potentially be an investment deterrent to B.C. and Canadian based innovation. Pricing predictability is a key requisite for the continued launch of innovative medicines and corresponding clinical trials in any country.
3. In B.C. we are particularly concerned that clinical trials for innovative oncology and rare disease products will be negatively and immediately affected.

In our view, the new Guidelines raise real and perceptible risks to B.C.'s life sciences ecosystem and the health options for individual British Columbians. Some of the potential negative consequences of the new guidelines include:

1. Reduced number and size of industry-funded clinical trials in B.C., thereby impacting employment in the private, public, and academic sectors.
2. Reduced or delayed access to new pharmaceutical products, particularly innovative medicines, drugs for rare diseases, compassionate use programs, novel formulations and delivery systems including B.C. innovations to B.C. residents.
3. Reduced patient programs, support, and services, currently provided in partnership with industry.
4. Reduced or eliminated pre-competitive investments in our B.C. ecosystem by international pharmaceutical companies;
 - a. at incubators and accelerators
 - b. at centres of excellence and at academic/research centres.
5. Reduced investment in B.C.- created innovation specifically and growing the Canadian life sciences ecosystem broadly.

Namely:

- a. Instability in the pharmaceutical supply chain
- b. Risk of losses of high-skilled and high paying jobs.

To clarify what is at risk; the life sciences ecosystem in B.C. encompasses over 17,000 well-paying jobs generating over \$5.4 billion in revenues, \$1.6 billion in GDP, \$500 million in exports and is the third largest life science ecosystem in Canada, next to Ontario and Quebec.

To avoid the unintended consequences, LSBC is prepared to engage through dialogue, all the implications of the PMPRB Regulations and Guidelines on the life sciences ecosystem. We will join with other participants to find workable drug pricing solutions, while enabling opportunities for innovation, investment, and high-quality patient care outcomes.

LSBC calls on the PMPRB, Health Canada, and ISED, industry and the Provinces, to come together and collectively negotiate a solution that maintains access to innovation, reduces drug prices, and ensures high-quality patient care outcomes are not interrupted, while avoiding unintended consequences and potential collateral damage to the B.C. life science ecosystem.

We thank you for your consideration.

Sincerely,

A handwritten signature in blue ink, appearing to read "Wendy Hurlburt", is written over a light blue circular stamp.

Wendy Hurlburt
President and CEO
LifeSciences British Columbia

CC:
Prime Minister Trudeau
Hon. Chrystia Freeland, Deputy Prime Minister
Hon. Bill Morneau, Minister of Finance



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Hon. Joyce Murray (Vancouver Quadra)
Hon. Carla Qualtrough (Delta)
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About LifeSciences BC

LSBC supports and represents the life science community of BC through leadership, investment initiatives, advocacy, and promotion of our world-class life science community. We are non-profit association which brings together academia, public and private research organizations, including industry and supported by 250 members. Because of this historic and decades long involvement in healthcare initiatives and research-based relationships, LSBC has a unique perspective in matters that directly pertain to the health of British Columbians and the overall sustainability our important and world-renowned life sciences sector.



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The Honourable Navdeep Bains,

February 21, 2020

Minister of Innovation, Science and Industry
House of Commons
Ottawa, Ontario,
Canada
K1A 0A6

The Honourable Patty Hajdu,

Minister of Health
Brooke Claxton Building,
Tunney's Pasture
Ottawa, ON K1A 0K9

Dear Ministers Bains and Hajdu,

Subject: Unintended consequences of PMPRB Changes

On behalf of British Columbia's vibrant life sciences ecosystem, LifeSciences British Columbia is writing to draw your attention to the significant consequences of the August 2019 changes to the *Patented Medicine Regulations* and the draft Patented Medicine Prices Review Board (PMPRB) guidelines on the entirety of this sector and impact on British Columbia's innovation economy.

In principal, these new regulations will impact sector growth, deter much needed R&D investment and potentially stifle, an investment sensitive small and medium-sized enterprise (SME) economy. As of this letter, we formally request a thoughtful delay in implementing these changes, while your two ministries work to find a less consequential solution.

Throughout the two-year process for evaluating changes to these Guidelines, a great many stakeholders within the Life Sciences ecosystem; patients, life science organizations, researchers, biotech and pharmaceutical companies, have expressed concerns over the negative impacts of price changes to pharmaceuticals and to the uncertainty created by the new pricing processes.



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We are aware as a sector organization, the potential impact of PMPRB regulations on manufacturers reluctant to conduct clinical trials here in B.C. unless they are confident, they will be able to commercialize the drug in Canada. Implications will also serve to distance Canada from available compassionate access programs and patient support programs. The impending regulations will without question, negatively impact patient care outcomes. We believe these were not the intended outcomes of the new regulations and guidelines – patient risk should never be part of a solution.

No responsible Canadian including British Columbians, argues with a government’s desire to pursue long-term sustainability of public healthcare. Instead creating a triad of decline; risking patient health, essential clinical investment and overall sustainability of the life science ecosystem, is not the path forward.

LSBC urges the federal Ministry of Health and the Ministry of Innovation, Science and Industry, to delay implementation of the proposed PMPRB guidelines until a more equitable solution can be found.

We are prepared to have a national dialogue that explores all the implications of the PMPRB Regulations and Guidelines. LifeSciences BC endeavours to find workable solutions to mitigate healthcare spending while ensuring patient care outcomes for all Canadians, meets a standard of excellence they are deserving of.

Sincerely,

A handwritten signature in blue ink, appearing to be "W. H. S.", is written over a light blue circular stamp.



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Wendy Hurlburt,
President and CEO
LifeSciences BC

CC:

The Right Honourable Justin Trudeau
Prime Minister of Canada

The Honourable Chrystia Freeland
Deputy Prime Minister and Minister of Governmental Affairs

The Honourable Bill Morneau
Minister of Finance

The Honourable Mélanie Joly
Minister of Economic Development and Official Languages