Submission to the House of Commons Standing Committee on Health (HESA)

RE: Study on the impacts of the PMPRB

November 6, 2020

Members of the House of Commons Standing Committee on Health:

BioAlberta is the central voice and champion for Alberta's life sciences sector. We are a member-driven, not for profit industry association for a sector of Alberta's economy that has over 300 biotechnology companies and employs over 15,000 people. Our ecosystem includes researchers involved in drug discovery and clinical trials, emerging companies who are commercializing the next modern and innovative therapies to keep Canadians health and safe, and global pharmaceutical companies on the leading edge of our health and innovation sectors.

BioAlberta has been opposed to both the process and results of Health Canada's PMPRB draft regulations since they were first published. Health Canada has not engaged industry in a meaningful way to reach objectives that all of us should aspire to:

- Provide Canadians with a secure supply of safe innovative therapies
- Fairness in pricing
- A policy framework in Canada that balances pricing with access, recognizing that health system cost and security of supply are mandates of the provinces as the deliverer of health services in Canada
- Policies that recognize the importance of research and commercialization as the foundation of Canada's modern economy, and the importance of remaining competitive in the global competition for investment in research

BioAlberta's position is that the regulation changes to PMPRB do not advance any of these objectives, and in fact the negative impact to Alberta and Albertans is significant and unacceptable.

In recent years we have observed the launch of truly transformational medications into the Canadian market in oncology, rare diseases and areas where a targeted therapeutic approach through personalized medication and biomarkers has accurately identified responders to a medication. A recent survey conducted by Research Etc. of major pharmaceutical companies confirmed that the proposed PMPRB changes will have many negative impacts, including delayed new medicine launches in Canada, job losses across the life sciences sector, and fewer investments in clinical research, patient support programs, and compassionate access programs.[1]

These effects are being felt on the ground in Alberta. Even though the new pricing rules are set to take effect in January, we are already seeing job losses, reduced partnership investments, and a decrease in the number of clinical trials in our province. We've also been made aware of a number of drug launches that have been delayed or suspended. Given that the life sciences sector is an important source of jobs for Albertans and key to the economic diversification of our province, the uncertainty of the proposed changes has begun and will impact the growth of this important sector.

[1] https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf

IQVIA[2] recently conducted a review of new drug launches in Canada compared to launches globally. The review found that new drug launches in Canada have decreased in 2018 and 2019 after seeing an increasing trend in the 10 years prior. In 2019, Canada saw a 40% drop in new drugs launched. Canada has received less than ½ of total number of new therapies launched globally in 2018, many of which address either oncology or rare diseases which have significant costs to the provincial health systems. The launch data, when tracked against the timeline of PMPRB and other national policy initiatives, at least in part substantiate concerns raised by Canadian/global life sciences industry that access to medicines could be compromised by this poorly designed new pricing regimen.

These outcomes are in part due to the global economic impact these changes may have and the uncertainty that goes along with it. The guidelines move Canadian list prices to the lower of the median of the new basket of countries (weighted to lower-priced jurisdictions) and the median of the therapeutic class. In turn, other countries around the globe look to Canada to regulate their pricing as a comparator. This change alone will move Canada back or out of potential launch sequence from global pharmaceutical companies to protect pricing in other markets (Germany, Spain, etc.).

The additional implementation of economic factors – which no other country uses to regulate sales across all payers – will only worsen this uncertainty, driving the problems mentioned in the previous paragraph.

Global companies also invest in clinical research where they market their medications prior to market entry. This directly affects researchers and innovators in our province at the University of Alberta and the University of Calgary. This attraction of research activity and research dollars in turn fuels local innovators, investment attraction and high-end talent to our universities. The chain reaction of pricing reform in Canada affects Canadians and Albertans from a health perspective and also from an economic research perspective. Further, we've already observed downsizing of Canadian and Albertan employees from these companies in the sectors by 25-40% with more likely to follow should these draft guidelines be moved forward.

Add to this complexity the business uncertainty of industry having major changes to PMPRB hanging over their head for three years, lack of meaningful engagement by Health Canada on options to clarify and meet their objectives, and a global pandemic that has caused industry and government to focus all resources. Then as we all face the second wave of COVID-19, notification that PMPRB change is coming on January 1.

If this Committee was responsible for making investments in a sector that is competing globally for infrastructure, investment and talent, would you invest in Canada given the uncertainty that has been created by this single regulatory change?

The proposed draft guidelines are also inconsistent with an excessive price standard as reflected in the *Patent Act*. All medications are subject to the same high level of scrutiny, regardless of excessive price risk. It increases the challenge for companies to reliably predict allowable price, does not adequately protect sensitive

[2] https://lifesciencesontario.ca/canada-may-be-losing-its-status-as-a-top-global-destination-for-new-medicine-launches/

confidential business information, and does not provide a fair and appropriate transition for current products on the market in Canada. Each of these components of uncertainty have the unintended consequence on the viability of our life science sector in Alberta.

It is also worth noting that established pricing/cost controls currently exist in Canada. Healthcare delivery, drug pricing, and drug payment are the responsibility and jurisdiction of the provinces. In 2011, the provinces took collective action to address growing drug prices by forming the pan Canadian Pharmaceutical Alliance (pCPA). Today, in coordination with CADTH, the pCPA takes into consideration cost effectiveness, health economic value and affordability which is then acted on by the provinces in a well established and predictable manner. Together the public drug programs are saving over $2 billion annually. This process allows predictability in the Canadian market and has a clear and respected pathway (Health Canada – CADTH – pCPA – provinces) in which manufacturers and governments work together to get new innovative medications to patients that need them. The new rules are therefore unnecessary and beyond the scope of the PMPRB's mandate to protect Canadians from excessive pricing of pharmaceuticals. In fact, we encourage members of the Committee to reflect on what real purpose the PMPRB actually serves, given the positive work undertaken by provinces working together to address their needs and address cost and supply.

Most of all, we feel there is significant risk of impact to **Alberta patients**. With anticipated reductions of product launches, particularly of innovative oncology and rare disease medications, access to therapies that have a significant impact on overall survival and quality of life as Albertans, impacts patients, families and the ability of healthcare professionals to provide the best medications available to their patients. Through this process, there is limited accountability to the patients and the provinces who are responsible for the delivery of healthcare at the local level. These proposed Guidelines undermine the provincial government's ability to ensure health accessibility or to compete effectively for life science investment on a global scale.

Recommendations

These proposed draft guidelines unduly destabilize the pricing and reimbursement landscape in Canada with further consequences that impact patients, researchers, innovators and the entire health system across the country. Health Canada has not articulated an overall vision or objective for the role of PMPRB in context of other policy initiatives such as the National Drug Agency, or the HBEST recommendations to modernize our economy. The lack of meaningful engagement with industry, stakeholders in life sciences and patient groups is resulting in fear among patients who could benefit from future innovative medicines. Health Canada's disregard for legitimate concerns raised has resulted in an unprecedented business certainty, resulting in investments, partnerships and clinical trials moving to other jurisdictions.

We recommend:

1. Changes to the Guidelines be stopped immediately, and that a more thorough assessment on the potential impacts and collateral impact across the provinces has been made. At the very least, there should be no changes implemented while Canada is in the midst of a global pandemic.

2. A new engagement process for proposed changes to pricing regulation be initiated, that is based on meaningful, open consultation with patient and disease groups, industry, and the full chain of the innovation ecosystem. These consultations must be in context of other policy frameworks at the Federal level such as the work underway to implement HBEST recommendations. It must also involve the Provinces, who are looking to technology and life sciences to be a cornerstone of the future economy while accommodating innovation in the health systems they are responsible for under our Constitution.

It is important that changes are done right with broad support and involvement. The potential of years of changes, retrenching and tweaks, coupled with prolonged uncertainty, negatively impacts our ability to attract investment and partnerships in life sciences to Alberta and Canada.

We welcome the opportunity to be a part of future initiatives that impact our members in Alberta and across Canada.

Submitted on behalf of the members of BioAlberta,

Robb Stoddard
President & CEO