

February 14, 2020

Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

By email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Subject: BioAlberta submission to PMPRB guidelines consultation

Dear Members of the PMPRB,

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 biotech companies and employs over 15,000 people.

The impact of the proposed PMPRB draft regulations 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

We can confirm that these effects are being felt on the ground in Alberta. Even though the new pricing rules are set to take effect later this year, 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.

These outcomes are in part due to the global economic impact these changes may have and the uncertainty that goes along with it. The draft 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

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



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.

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 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.

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.

Recommendation

These proposed draft guidelines unduly destabilize the pricing and reimbursement landscape in Canada with further consequences that impact patients, researchers and innovators 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 changes to the Guidelines be stopped in their current form until a more thorough assessment on the potential impacts and collateral impact across the provinces has been made.

We also recommend a new patient group and industry engagement process for proposed changes to pricing regulation be initiated. It is important that changes are done right with broad support and involvement. The potential of years of changes, retrenching and tweaks negatively impacts our ability to attract investment and partnerships in life sciences to Alberta.

Along with other life science organizations across the country, we welcome the opportunity to be a part of future initiatives that impact our members in Alberta and across Canada.

Sincerely,



Robb Stoddard
President & CEO