

July 31, 2020

Patented Medicine Prices Review Board  
333 Laurier Avenue West, Suite 1400  
Ottawa, Ontario  
K1P 1C1

By email: [PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca](mailto:PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca) via Portal at  
<https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html#submissions>

**Subject: BioAlberta submission to PMPRB Draft Guidelines Consultation**

Dear members of the Patented Medicine Prices Review Board (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. The proposed changes will have a punitive effect on the life science industry in Canada and on Alberta in particular. The most recent guideline amendments do little to improve the situation for the Alberta market and if anything, add complexity, bureaucracy and increased uncertainty for our members who currently invest and conduct important research and investment in our sector in Alberta.

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.<sup>1</sup>

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 in January 2021, we are already seeing **job losses, reduced partnership investments, and a decrease in the number of clinical trials in our province at our primary research centres at the University of Calgary and the University of Alberta**. We've also been made aware of a number of **drug launches that have been delayed or suspended** through input from our members. Given that the life sciences sector is an important source of jobs for Albertans and key to the economic

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



diversification of our province, the uncertainty of the proposed changes has begun and will impact the growth of this important sector.

The proposed reforms will also negatively affect provincial health systems:

- Lack of new medicines and delays in access could lead to additional expenses such as an increase in otherwise avoidable hospital admissions and readmissions;
- Canada is already struggling with more than 2,000 ongoing medication shortages. These reforms will only make the situation worse;
- Research hospitals like the Universities of Alberta and Calgary may lose important sources of dependable funding because of the inability to attract clinical trials to Canada, affecting clinicians and patients.

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 move Canada back or out of potential launch sequence from global pharmaceutical companies to protect pricing in other markets (Germany, Spain, etc.) which has been observed over the past year. One of our partner associations, Life Sciences Ontario (LSO) commissioned IQVIA – a global leader in health data and analytics – to examine the commercialization of new medicines in Canada and other top global jurisdiction from the past 20 years (2000-2019). The report highlights that in 2019, the year the drug price controls were communicated, there was a dramatic 40% drop in the number of new drugs launched in Canada, despite a growth of global launches in the same year. This has a significant impact on Canadians and their access to new innovative therapies in oncology, rare diseases, etc. while having an additional impact of decreasing investment in clinical research from industry in Alberta (and Canadian) universities. These same universities are home to some of the brightest minds on the globe who look to partner with global organizations to advance new therapeutics, vaccines and diagnostics for COVID-19, cancer, rare diseases, chronic diseases and other issues that impact our broader health system.<sup>2</sup>

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. The most recent amendments to the economic factors provide increased complexity for our partners, leading to more uncertainty in price determination on a global scale, further contributing to the issues described above related to decreased product launches in Canada, decreased investment in the life sciences sector and decreased investment and involvement in clinical research.

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<sup>2</sup> Life Sciences Ontario | IQVIA | New Medicine Launches: Canada in a Global Context | June 2020. [link](#)



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 revised 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. Changes to PMPRB must be aligned with mechanisms currently establishing price and supply in Canada, as part of any proposed national drug agency, as well as alignment with the Government of Canada's proposed HBEST recommendations to modernize the economy.**

**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 business confidence for companies operating, investing in or supplying to Canada, and 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.



Robb Stoddard  
President & CEO  
BioAlberta

