Vaccine Industry Committee
Le comité de l'industrie du vaccin

August 31, 2021

Dr. Mitchell Levine
Chairperson Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario Kl-P 7C1

Submitted electronically: pmprb.consultations.cepmb@pmprb-cepmb.gc.ca

SUBJECT: **Consultation on proposed changes to the PMPRB Guidelines regarding the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions**

Dear Dr. Levine,

Vaccine Industry Committee (VIC) members are the leading vaccine manufacturers serving the Canadian market and early-stage Canadian companies developing advanced vaccine technologies. The committee works to ensure a secure supply of vaccines for Canada, advocates for equitable access to vaccines for all Canadians, and promotes the value of immunization as one of the most cost-effective health interventions available. We are a unique mix of large multinationals and pre-commercial Canadian vaccine innovators. Several of our members are focused on the critical work of developing COVID-19 vaccines and deploying them in Canada. Many VIC members are also working to ensure supply of publicly funded vaccines to support existing immunization programs across Canada. Many of which have seen significant delays due to access issues during the pandemic – especially school based programs - contributing to the ripple public health effects of the health crisis.

With respect to the above-noted consultation, we are extremely concerned with the latest and unexpected proposed changes to the PMPRB guidelines and are opposed to the implementation of them. We urge the PMPRB to reconsider the changes. **We also reiterate our request that vaccines be categorized as Category II and only subject to review based on a complaints-based approach**, given how they are regulated, reviewed and procured by an effective tendering process through Public Services and Procurement Canada (PSPC), which ensures vaccines prices are competitive and non-excessive.

There are several specific reasons for the PMPRB to reconsider the changes proposed. In summary, these proposed Guideline changes: (a) add complexity with a reduced compliance period; (b) divert focus from supplying COVID-19 vaccines; (c) are contrary to the recently announced Federal Government's Biomanufacturing and Life Sciences Strategy; (d) destabilize

the Canadian market for vaccines; (e) lack transparency and clear guidance with regards to implementation; and (f) constitute regulatory overreach. These reasons are explained in more detail, below.

a) **Add complexity with a reduced compliance period:** The PMPRB is proposing to shorten the effective compliance period for grandfathered medicines and line extensions by **six months**. This timeline reduction is also contrary to the PMPRB's April 2021 decision to provide grandfathered products with two reporting periods (i.e., 12 months) to comply with the new rules from the coming into force of the regulatory amendments. Further, the proposed new pricing test for grandfathered medicines is adding unprecedented workload and confusion to an already complex environment at a time where patentees should be focusing their time and resources on COVID-19, as intended by the government's regulatory delay, and given that we are now entering a fourth wave of this pandemic. Notably, neither the background document nor the latest Questions and Answers document issued by the PMPRB as part of this consultation acknowledge the pandemic context.

b) **Divert focus from supplying COVID-19 vaccines:** During a time of unprecedented and excessive uncertainty during this pandemic, as acknowledged by Health Canada, this additional and unexpected consultation has created more work for VIC member companies. These changes contradict the reason for the recent delay of the amended *Patented Medicines Regulations* granted by the government coming into force, which was to provide manufacturers more time to prepare for and comply with the pricing reforms given the ongoing COVID-19 pandemic. Health Canada recognized that this delay was necessary to allow patentees to focus their efforts on responding to the pandemic, including many VIC member companies who are supplying COVID-19 vaccines to Canada.

c) **Contrary to the Biomanufacturing and Life Sciences Strategy:** These latest changes completely undermine the goal of this strategy to grow the life sciences sector to build Canada's resiliency in the face of pandemics and other health challenges. In particular, they are inconsistent with the fifth pillar of the strategy, which is to enable innovation by ensuring world class regulation.

d) **Destabilizing Canadian market for vaccines**: Given many members of the VIC are global vaccine manufacturers, head offices have communicated that these continuous and ambiguous changes to the pricing framework are making it very difficult to include Canada as part of their long-term planning efforts for launching future vaccines. Companies have relied on previously announced vaccine price tests and compliance timelines for business planning. As evidenced during the current pandemic, vaccines have never been more important to the health and economy for Canadians, and we need to find ways to protect and ensure patients have access to new vaccines, rather than destabilize the vaccine market.

e) **Continued lack of transparency regarding practical implementation of the new pricing regime**: The latest changes add another unnecessary source of confusion regarding Canada's vaccine pricing environment. It appears that two levels of regulated vaccine price reductions could be required for grandfathered vaccines within a single year, although this is not clearly stated in any PMPRB document. First, the vaccine list prices will need to be compliant with a new test using the PMPRB7, and a second price reduction may be required to comply with the PMPRB 11 when the regulations take effect. Moreover, no explanation or guidance was provided in the consultation package on how these changes will be implemented (e.g., how will this work with public contracts?). As well, the proposed new rule of using the median PMPRB7 price to set maximum list prices generates many technical questions. Due to the tight deadline to respond to this consultation and the focus on submitting required data by August 30th, 2021, VIC member companies have not been able to fully assess the impact of these changes on vaccines. The PMPRB has provided no information as part of this consultation to help in this regard.

f) **Regulatory overreach:** The recent ruling of the Federal Court of Appeal (FCA) in the Alexion case[1] has clearly confirmed that the PMPRB does not have a consumer protection mandate, but rather a mandate to assess whether prices are excessive based on an abuse of patent market exclusivity. It appears as though the PMPRB is using its powers arbitrarily to impose a new price test for grandfathered medicines and vaccines without regard to the scope of its mandate as set out in the *Patent Act*. Further, the PMPRB has not provided any reasonable explanation for this proposed change. A change of this magnitude should require the PMPRB to explain why this change is warranted. Specifically, the PMPRB has failed to demonstrate that the change is required to prevent vaccines from being excessively priced. Any changes to the PMPRB guidelines must be consistent with the PMPRB's mandate to regulate excessive prices.

In addition, in light of the above considerations, and given the VIC has had a strong responsibility in supporting public health's efforts to respond to the pandemic, we feel this is an opportune time to reaffirm the VIC's position for vaccines to at least be classified as Category II products like biosimilars as previously expressed by the VIC in earlier consultations. The new pricing regulations and guidelines create significant uncertainty and do not reflect the uniqueness of the vaccines industry.

Health Canada's decision to include vaccines in the PMPRB regulations may have unintended consequences, such as no alternative supply during market shortages or delayed new vaccine

[1] Alexion Pharmaceuticals v. Canada (Attorney General), 2021 FCA 157: https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do

launches, despite the fact there is minimal risk on prices due to the current government competitive bids process. **As such, the VIC believes that all vaccines should be treated in the same fashion as biosimilars and generic products in a complaint-based manner and, at minimum, be classified only as Category II, to eliminate the market size threshold and other rules, which could restrict supply at times of extreme public health need**.

In the October 2020 Guidelines, vaccines were granted "complaint-based only" status but given their unique market dynamics and low risk level with pricing in the tendering process where the Government in the end determines the vaccine price, further changes are needed to ensure that vaccines receive similar treatment to that of generics and biosimilars. It is also worth noting that vaccines for COVID-19 could be subjected to significant price reductions once the current interim order ends, potentially impacting availability, making the establishment of the status for vaccines permanently Category II all the more important at this critical stage.

Thank you for the opportunity to provide input.

Sincerely,

J. McCarles

Jacqueline McCarles
Chair, Vaccine Industry Committee