Vaccine Industry Committee
Le comité de l'industrie du vaccin

February 12, 2021

Doug Clark, Executive Director
Patented Medicine Prices Review Board (PMPRB)
Box L40|Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1

RE: Vaccine Industry Committee Comment - Change to the definition of Gap medicines and the timeline of compliance

Dear Mr. Clark:

Further to PMPRB's invitation to stakeholders to comment on two proposed consequential amendments to the new PMPRB Guidelines resulting from the decision to delay the coming-into-force date of the Regulations Amending the Patented Medicines Regulations ("Regulations") a further six months, from January 1, 2021 to July 1, 2021, the Vaccine Industry Committee (VIC) submits the comments below as part of the consultation process.

As previously expressed by the VIC during the consultation process, the Regulations and Guidelines create additional uncertainty and do not reflect the uniqueness of the vaccines industry. Health Canada's late reversal of including vaccines in the PMPRB Regulations may have unintended consequences of these new pricing rules, such as no alternative supply during market shortages or delayed new vaccine 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 latest Guidelines, vaccines were granted "complaint-based only" status, but given their unique market dynamics and low risk level, further changes are needed to ensure that vaccines receive similar treatment to that of generics and biosimilars.

Regarding the timeline and reporting periods, the VIC disagrees with reducing the timeline to comply with MLP for Grandfathered and Gap medicines from 2 reporting periods (July 2021 for a July implementation) to 1 reporting period (by December 2021). Member Companies will not know the allowable Maximum List Price (MLP) until after the PMPRB assessment received in July/Aug. Given our members' laser focus in responding to the pandemic, we welcome the Government of Canada's recent decision to extend the planned implementation date of the new PMPRB pricing regulations to July 1, 2021 as a move in the right direction although further discussion is required. However, considering that the latest estimates from the Federal Government indicate that COVID-19 vaccines will not be broadly available to all Canadians until September 2021, this extension is clearly insufficient. Given the multiple necessary steps and sequencing that would be required to properly implement the pricing reforms mandated by these regulations (the most significant pricing reforms in over 30 years), the VIC respectfully submits that the PMPRB's proposal to shorten the implementation time horizon from 12 months to 6 months (ie. from two standard reporting periods down to one standard reporting period) is highly impractical and frankly administratively unworkable.

The VIC notes that PMPRB staff had previously indicated to industry as well as in public forums that manufacturers would be provided with an 18-month transition period[1], presumably to afford sufficient time to put into place the necessary systems and to work with provinces and wholesalers to comply with the new pricing requirements ("PMPRB Executive Director Doug Clark told Reuters companies could be given an 18-month grace period to comply with parts of the regulation, and that cost-effectiveness measures may be applied to fewer treatments."). Under the PMPRB's latest proposal however, this 18-month transition window would be shortened to 6 months, which coupled with required additional administrative processes to have the maximum allowable price confirmed by the PMPRB, the time to be able to alter pricing to be in compliance would effectively be only 8-12 weeks. Additionally, the PMPRB's proposal is misaligned to the timing of standard processes established by provinces for pricing changes (eg. Ontario requires pricing changes to be made in the Spring, not in the Fall as is proposed under the new PMPRB proposal). Finally, there is some question as to whether manufacturers would be able to satisfy the legal requirements of Quebec's 'Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications,' under the truncated approach proposed by the PMPRB.

In light of this, the VIC respectfully recommends that the PMPRB return to its original plan for a 2 reporting period phase in (ie. 12 months), beginning as of the new effective date of the regulations.

Kind regards

J. McCarles

Jacqueline McCarles
Chair, Vaccine Industry Committee

Reference

1. https://www.reuters.com/article/us-canada-pharmaceuticals-exclusive-idUSKBN20E2LI