

August 4, 2020

Dr. Mitchell Levine,
Chairperson Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
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Submitted electronically: PMPRB.Consultations.CEPMB@PMPRB-CEPMB.gc.ca

Dear Dr. Levine,

Following the release of PMPRB updated draft guidelines in June 2020, the Vaccine Industry Committee (VIC) wishes to submit the below response as part of the consultation process.

The VIC is an industry led group focused on improving vaccine awareness and understanding and supporting the development of vaccine related regulatory policy in Canada. It is a unique mix of large multinationals and pre-commercial Canadian vaccine innovators.

The committee works to ensure secured supply of vaccines for Canada, advocates for equitable access to vaccines for all Canadians, promotes the value of immunization as one of the most cost-effective health interventions available¹, and expands Canadian vaccine innovation and manufacturing capacity.

We would like to reiterate that vaccines are unique and possess features that are very different from other medicines and health interventions. Canadians have been reminded in recent months about the complexity and rapid development of public health risks faced by Canada in a global context. Vaccines can and do play a critical role in addressing many public health challenges. Where novel infectious diseases emerge, our industry works to mobilize the full scope of our scientific and manufacturing resources to respond. Our focus is on doing everything in our power to safeguard public health, and we continue to work urgently to remove any needless barriers, regulatory or otherwise, which may negatively impact achieving that critical objective.

As we have conveyed to PMPRB previously, there is minimal level of consumer risk related to the negotiated prices of vaccines in the Canadian system. Indeed, we see no evidence from the last round of consultations that vaccine prices are a policy concern for Canadians or Canadian health agencies. There is an established and well-functioning vaccine recommendation and reimbursement mechanism through the National Advisory Committee on Immunization (NACI) and centralized procurement via the federal government on behalf of the Provinces and Territories. The value of vaccines is being realized through the use of these entities combining not only competitive tenders and negotiated prices but efficacy, effectiveness, safety, security and predictability of supply. Unfortunately, the proposed guidelines continue to disregard the unique nature of vaccines (tendering process, manufacturing complexity, global allocation, population health objectives, etc.).

In addition, several components of the guidelines could significantly hinder immunization goals across the country.

Vaccine Industry Committee requests all vaccines to 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.

The proposed guidelines will result in high levels of pricing uncertainty for vaccines. There is great concern that this destabilizing uncertainty will complicate vaccine patentee decision making and encourage delays or deferred vaccine product launches. Global manufacturers may deprioritize Canada and choose other jurisdictions to launch vaccines where threshold economic factors and market size does not impede pricing. This would impact the reputation that Canada has withheld as being a leading country to launch vaccines, as well as hinder its access to vaccine clinical trials. For applicability to the Canadian public health context, if a new vaccine emerged for a global health threat, the uniquely Canadian requirements linking vaccine prices to market size, would result in issues of access and supply in Canada, thereby restricting availability for public health officials to manage potential future endemic and pandemic outbreaks. Therefore, PMPRB needs to ensure that this process does not impede Canadians access to new/existing vaccines due to complicated pricing control measures.

We would like to take this opportunity to thank PMPRB for meeting with us to discuss our concerns and as suggested, look forward to the offer of more direct discussions with PMPRB and key stakeholders (Ministries, Public Health Agencies, Health Canada, etc.), in order to ensure the vaccination rate goals and the needs of Canadians are fully considered through the appropriate application of complaint-based mechanisms with Category II designation.

Sincerely,



Catherine Paquette, R.N., B.ScN
Chair, Vaccine Industry Committee

Rational for vaccines to be only Category II, similar to biosimilars and patented generics :

1. Canadian tendering process already ensure competitive pricing and security of supply

Considering the unique Canadian tendering process for vaccines and its proven impact on price reduction, such amendment would be completely aligned with PMPRB's risk-based approach to regulating ceiling prices. Furthermore, it would create the proper conditions to ensure that Canadians have optimal access to vaccines, hence, contributing to improved population health. We believe this ultimate objective is shared by both the VIC and the Government of Canada. By changing the rules to allow vaccines to always be in Category II, will still mean that prices will be competitive in Canada, since vaccines cannot be priced higher than the median price of the PMPRB11 comparator countries.

In addition, the Canadian public tender process is already designed to encourage discounts off the list price. These tenders are usually competitive bids and companies usually give a significant discount off list price to win higher share of doses. For sole source contracts, companies must certify prices are "not in excess of lowest price for similar quality & quantity" charged to any other customers.

2. Market size thresholds for Category I bring no benefit to public health objectives for Canadian patients, as it hinders the ability of manufacturers to provide competitive prices for tenders and to supply additional vaccines during outbreaks

PMPRB's market size threshold conflicts with the Public Health Agency of Canada vaccination rate targets, as the rule penalizes manufacturers when revenues hit a certain threshold. This disincentives companies from providing higher volumes of vaccines, which conflicts with the public health mandate to achieve herd immunity, which requires large volumes of vaccine to protect the population

- As part of the Federal Governments' National Immunization Strategy objectives, vaccination coverage goals and vaccine preventable disease reduction targets were set with the expectation of achieving vaccination goals for various diseases of ~95% in children and upwards of 80% in adults. Which goal is the Federal government looking to achieve – a public health or pricing goal?
- The award criteria in publicly-funded contracts favours the bidder with the lowest price. The current tendering process may be jeopardized, as manufacturers would not be able to bid at the lowest price possible and/or may only be able/willing to secure a limited supply of vaccines for a given price point. This results in provincial governments not obtaining the best possible price for publicly funded vaccines and creates potential challenges in cases of market shortages or higher market demand.
- The changes proposed add uncertainties to manufacturers especially in outbreak situations, which cause significant fluctuations in market size from one year to another and demand rapid decisions from manufacturers regarding supply prioritization on a global scale. Because Canada may be competing with other countries for vaccine supply, delays in making these decisions (i.e., caused by the additional time required to obtain approval for exceptions

from PMPRB, local authorities, or company's global pricing teams) can hold up supply allocations to Canada and negatively impact Canadian public health.

See Appendix 1 for example.

3. Pharmacoeconomic (PE) review process is not applicable to Vaccines: Vaccines do not exceed PMPRBs' planned ICER thresholds and public PE analysis will not be available at product launch

- NACI and CIQ lack a robust Pharmacoeconomic (PE) review process, and PMPRB Guidelines lack clarity on the use of PE for vaccines, making PE price test redundant for vaccines
- The relatively low cost and high effectiveness of vaccine results in most being cost-effective, or even cost-saving¹
- The revised guidelines state that Guidance Reports from NACI will be considered for the PE assessment for vaccines; it is, however, not clear where in the process and for what purpose PE assessments will take place, given the low price per patient of vaccines.
- Further, NACI's mandate to conduct pharmacoeconomic assessments is in its infancy: a framework is currently under development and there is no clear deadline for implementation within their economic recommendations – NACI currently can take up to 650 days² to publish its scientific recommendations.
- The undefined PE review process as well as the uncertain place of PE evaluation, in the context of vaccines, creates predictability issues and feeds into the perception of increased board discretionary powers.

4. Non-Excessive Average Price (NEAP) for Grandfather products will create anti-competitive market dynamics for tenders

Grandfathered vaccines would not be subject to any market size adjustment whereas new-to-market vaccines with forecasted annual sales of over \$50M would be subject to a price adjustment, creating unfair and anti-competitive market dynamics in a tender situation.

Simply put, a vaccine manufacturer with a new vaccine would be competing head-to-head to win a given tender in an uneven playing field - against one or more manufacturers with older vaccines that would be playing under different rules. The case study below illustrates how this could play out in practice, with Company A having a clear advantage over Company B in the tendering process due to favorable treatment for the former under the new rules.

The clear solution to both the NEAP problem and the head-to-head tendering problem described in the case study below would be to follow the example set in the June 2020 Draft Guidelines with respect to biosimilar medicines and simply classify **all** vaccines as Category II medicines

See Appendix 2 for example.

5. Using NEAP will cause confidentiality concerns and create undue administrative burden, while compromising manufacturers' ability to offer volume-based discounts

In addition to the NEAP issue above, the revised PMPRB guidelines state that the lower of the Highest International Price (HIP) or NEAP will be used to set the MLP for Grandfathered products. This is of concern to the VIC as the NEAP for a vaccine can be significantly lower than list price simply due to the competitive bid process and discounts given on public tenders. The NEAP for vaccines

can significantly fluctuate year over year due to win or loss of a public tender adding further complexity to MLP calculations.

If NEAP is used to set the MLP for Grandfathered medicines, there is a risk that:

- Manufacturers may not be able to offer the same discounts on the public contracts, since the NEAP would set a maximum list price based on average transaction prices,
- In the global context, where Canadian list prices are referenced by other countries, this may compromise manufacturers' leeway to offer these rebates.
- It would give a very clear indication of confidential contract tender prices to competitors, since most vaccines sales are at the discount price for public contract and would be in contradiction to the confidential procurement and tender process implemented by Public Services and Procurement Canada (PSPC) for the acquisition of Vaccines under the standard procurement policies issued by the Canadian government.

The PMPRB has offered a solution to this issue in Paragraph 76, where patentees can request a higher MLP if the NEAP is "uncharacteristically low". However, even with the addition of this section, there remains considerable price uncertainty as Section 76 can only be invoked after MLP has been re-set using the NEAP and not before.

Given all of this, implementation of the NEAP as the reference for the new MLP for Grandfathered vaccines moving forward is likely to result in a significant increase in submissions by industry (under Section 76) and workload for PMPRB as it will necessitate reviews for almost all vaccines currently supplied in Canada.

In order to safeguard confidentiality, efficiency and to support the public health mandate associated with access to vaccines for preventable diseases, the VIC asks non-excessive MLPs remain at the level set under the previous regulations and guidelines

6. Inability to consider level of therapeutic improvement in absence of international prices to establish list price creates a clear disincentive to prioritize the Canadian market in the vaccine launch sequence

If a vaccine has not been launched in any PMPRB 11 countries, the list price will be set using highest price of the domestic therapeutic class comparators, which tend to be vaccines using older technologies and are generally less effective. Without any price adjustment for therapeutic improvements, or other offsetting adjustments, companies may decide to delay the launch of vaccines in Canada, and launch in other countries first, in order to get a fair price for them.

References

1. 2019, the World Health Organization (WHO)
2. Vaccine Industry Canada (VIC) internal review and analysis

APPENDIX 1 – CASE STUDY: TWO PLAYER TENDERS IN POTENTIAL CATEGORY 1 SIZE MARKET

Consider two competing products launched within a year to prevent the same condition. The first product to enter the market triggers a NACI review for potential inclusion into routine immunization schedules. By the time NACI has completed its review with a positive recommendation and provinces have moved forward with implementation and procurement, both manufacturers are able to participate in a competitive tender.

TABLE 1. PRODUCT INFORMATION AND PMPRB ASSESSMENT RESULTS FOR 2 COMPETING VACCINES

Vaccine A		Vaccine B	
1st sale	Jan-2021	1st sale	Jan-2022
MIP	\$100	MIP	\$100
MLP	\$100	MLP	\$100
List Price	\$100	List Price	\$100
median dTCC	\$60	median dTCC	\$80
PMPRB Level	III	PMPRB Level	IV
Reduction Floor	40%	Reduction Floor	50%
MRP	\$60	MRP	\$80

We first notice from Table 1 that the introduction of a new entrant in Jan 2021 has the effect of increasing the median dTCC for Vaccine B; however, the level of therapeutic improvement for Vaccine B is lower as it is considered equivalent to Vaccine A, which lowers the potential MRP.

TABLE 2. VACCINE A AND B SALES INFORMATION

	2021	2022	2023	2024	2025
Vaccine A					
Actual Units	100,000	450,000	650,000	50,000	250,000
Revenue at MLP	\$10,000,000	\$45,000,000	\$65,000,000	\$5,000,000	\$25,000,000
Vaccine B					
Actual Units		250,000	50,000	650,000	450,000
Revenue at MLP		\$25,000,000	\$5,000,000	\$65,000,000	\$45,000,000
Situation description	Vaccine A introduction, some level of private sales occurs while NACI is reviewing the new vaccine.	Vaccine B introduction & competitive tender completed (2 years firm + 1 option year); Vaccine A wins majority.	Vaccine B suffers a major supply issue and Vaccine A provides additional units; triggers Category 1 designation.	The situation is inverted in the 3 rd option year, Vaccine B is subject to a higher MRP[a] due to the improved median dTCC after introduction of Vaccine A	Vaccine B wins the new tender. Both vaccines have triggered the Category 1 designation at one point but, neither currently sell above \$50 m

From Table 2, both vaccines have had similar stories and volumes, yet different MRP. Both vaccines were penalized on peak volumes in one year, while vaccine A was further penalized on lower dTCC median.

APPENDIX 2 – CASE STUDY: Vaccines sold only in Public Market

- **2 Companies to tender on a 3-year national Contract (see table for details)**
 - Company A with Product A with NOC before August 2019
 - Company B with Product B with NOC on January 2021
 - Global supply constraint for both products
 - Canadian prices are amongst the lowest in the world, even less than China and Brazil, for example

Company	List Price	Tender price	Units Awarded	Revenues	Comments
A	\$10.00	\$8.00	6.0M	\$48.0M	Not subject to PMPRB factors
B	\$10.00	\$9.00	4.0M	\$36.0M	Subject to market size factor – putting Company B in a disadvantage

Company A goes on backorder in Year 2

Company B cannot provide the additional supply of Company A in Year 2 due to PMPRB market size factor:

- The maximum price in Year 3 would become ~\$8.08 (dTCC = \$7.00) but the supply would go back down to \$36.0M (distortion to price volume market dynamics recognized by Canadian Vaccine Procurement Agencies)
- Due to global constraints – supply would not come to Canada but go to Countries with more favorable environments
- Fairness: Both companies are not treated equally under the PMPRB Guidelines

Vaccines should be Category II PMPRB

New PMPRB Guidelines will negatively impact vaccine market dynamics and become a barrier to Manufacturer' ability to guarantee supply in the Canadian market