Vaccine Industry Committee
Le comité de l'industrie du vaccin

February 13, 2020

Dr. Mitchell Levine, Chairperson
Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario K1P 1C1

Submitted electronically: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Dear Dr. Levine:

On behalf of the BIOTECanada Vaccine Industry Committee (VIC), I would like to offer comments and recommendations regarding the proposed changes to the PMPRB Guidelines, from the perspective of the Canadian vaccines industry, of which will have unintended consequences to public health in Canada.

The VIC membership includes the leading vaccine manufacturers serving the Canadian market, as well as 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. Where vaccines are under patent protection and marketed in Canada, they fall within the PMPRB's jurisdiction, therefore, the VIC membership is directly impacted by the proposed Guidelines changes.

Vaccines Present Unique Policy Consideration that have Not Been Fully Contemplated in the Drafting of Proposed Guidelines with High Potential for Unintended Consequences that May Negatively Affect Canada's Public Health Objectives

As a reminder in November 2019, the Vaccine Industry Committee communicated with Health Canada about their late reversal of including vaccines in the PMPRB regulations (see attachment). This policy change was not made with proper consultation of all stakeholders including Industry. As a consequence, the Regulations and Guidelines create additional uncertainty and do not reflect the uniqueness of the Vaccines Industry. While there are many common elements shared by preventative vaccines and other medicines from a regulatory submission and approval standpoint, at the level of pricing and reimbursement, vaccines are handled very differently by the Canadian healthcare system. For the most part, new vaccines are subject to class-specific scientific and economic expert review by the National Advisory Committee on Immunization (NACI). This mandatory step is a key prerequisite to participate in the highly centralized and well-established procurement mechanisms administered by the Federal Government (on behalf of the Provinces and Territories) and the province of Quebec (who purchase many of their own vaccines). In fact, the competitive tendering process through Public Services and Procurement Canada (PSPC) and the Province of Quebec, for most publicly funded vaccines, inherently puts downward pressure on prices. The award criteria in these contracts favours the lowest bidder with the lowest price. Under the current procurement system, manufacturers wanting to gain market share are incentivized to bid at the lowest price possible. As such, the changes proposed by PMPRB add uncertainties to manufacturers (e.g. potential additional price reductions based on market size) and consequently risk jeopardizing the tendering process, as manufacturers would not be able to bid at the lowest price possible or may have limited supply in cases of market shortages. Vaccines are complicated to manufacture – some vaccines take many years to make and, as a result, Global companies need to allocate stock based on a variety of different criteria including measures such as country price.

The public policy challenge in this context is not related to vaccine pricing but rather to ensure multiple supplier market participation while improving on the timeliness and uptake of new vaccines within our public healthcare system. Of greatest concern, the proposed Draft Guidelines are in direct conflict with the

Government of Canada's Vaccine Coverage Goals and Vaccine Preventable Disease Reduction Targets set for 2025, as part of the National Immunization Strategy Objectives[1]. As per the Public Health Agency of Canada (PHAC), high vaccine coverage rates are necessary in order to continue to maintain specific diseases under elimination and to maintain low- to moderate-level incidence of other endemic diseases. The PMPRB Draft Guidelines, including the regulatory metric of *market size*, may be difficult to explain to the Canadian population by any Health Minister, if Canada's vaccine coverage rates are not met and the incidence of disease increases due to these Guidelines. Overall, public immunization programs and the health of Canadians may be negatively impacted by the proposed Draft Guidelines.

The Draft Guidelines Are Not Risk-Based and Have Unintended Consequences for Public Health

The proposed approach is highly complex by any standard, and even more so when contrasted to the prior "bright line" Guideline approach, as referenced in the first consultation with Health Canada. To date, the PMPRB has promoted the value of voluntary compliance for patentees – this makes sense for all parties in that it promotes regulatory and market stability for planning purposes, while ensuring the PMRPB retains any necessary resources and tools to investigate and address specific cases of concern. Again, significant policy conflict exists with the proposed Draft Guidelines, which penalizes manufacturers based on market size as immunization rates increase. Due to the vaccine tendering process, the price of vaccines are already considered low risk when comparing to other molecules sold, and this should be reflected in the Guidelines.

The Draft Guidelines Promote Uncertainty for Public Health Safety

Under the Draft Guidelines, patentees will no longer be able to know, with any workable level of certainty, whether a given vaccine price is compliant or not in advance of commercializing that vaccine in Canada. Price compliance will be subject to variable factors following the approval of a new patented preventative vaccine. It remains unclear what reporting obligations will fall on vaccine patentees including expectations for specific information for submission templates, of which have not been made available, despite the July 2020 deadline. Vaccine patentees are challenged to identify and plan for any required new resources or system adjustments to align with the PMPRB's future requirements, now months away.

There is great concern – aligned with the overwhelming stakeholder feedback provided to the Government of Canada and the PMPRB to date – that this destabilizing uncertainty will complicate vaccine patentee decision-making and encourage delays or deferred vaccine product launches. A compliance system in a regulatory context where uncertainty is positioned as a core feature falls well short of the basic standards of governance within the Canadian public healthcare system. For applicability to the Canadian public health context, if a new vaccine emerged (e.g. Coronavirus vaccine) within a global public health threat, the uniquely Canadian requirements, as proposed in the Draft Guidelines, would negatively affect a potential new vaccine candidate, and could 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, the government needs to ensure that this process does not impede Canadians access to new/existing vaccines due to complicated pricing control measures.

Lack of "Grandfathering" and Increased Compliance Burden

Reference was made to the intention to "grandfather" certain categories of products within the Draft Guidelines. This is inaccurate. All products, including vaccines will be subject to lower non-excessive price thresholds, given proposed changes of international price reference from highest (current guidelines) to median (proposed) prices. This is a major departure from existing PMPRB practice, which has yet to be fully explained, with unintended consequences.

[1] Government of Canada (2020, January 31). Vaccination Coverage Goals and Vaccine Preventable Disease Reduction Targets by 2025. Retrieved from: https://www.canada.ca/en/public-health/services/immunization-vaccine-priorities/national-immunization-strategy/vaccination-coverage-goals-vaccine-preventable-diseases-reduction-targets-2025.html.

Moreover, this set of proposals would represent an increased compliance burden including reporting for vaccines manufacturers. As discussed above, vaccines occupy a clearly unique space within Canada's healthcare system whereby vaccines are designed to be a public health prophylactic preventative measure unlike most other drug products, which are therapeutic in nature.

Extensive use of centralized procurement has proven highly effective at minimizing financial risks to Canadian consumers. Nonetheless, the Draft Guidelines make no accommodation for this longstanding reality of the Canadian system, instead subjecting vaccine manufacturers to the equivalently high level of compliance requirements as any other patentee.

Impact to Canadian Public Health Standards and VIC Recommendations

The PMPRB should be encouraged to consider temporarily pausing implementation to assess different Guidelines approaches to achieve its overarching policy objectives as they relate to vaccines. In their current form, the Draft Guidelines provide no additional value to Canadian patients or purchasers of vaccines and would only serve to increase costs and resources to manufacturers, uncertainty, and raise new (and unnecessary) barriers to the future availability of innovative vaccines for Canadians. As previously mentioned, this policy change is in direct conflict to the Government of Canada's public health immunization goals of achieving maximum population coverage which will be impeded by the market size regulation. This will place our Canadian population at risk of increased exposure to infectious diseases, which would impact the growing issue of antimicrobial resistance (AMR) and threatening the safety and health of our Canadian community.

Accordingly, the VIC strongly recommends that the implementation of the proposed Guidelines be deferred for a significant period to allow for adequate and inclusive consultations on alternate approaches and in consideration of the public health immunization coverage objectives and to align compliance requirements.

Major revisions are required to implement the new regulations consistent with actual levels of market risk for vaccine products as well as to promote greater overall stability and predictability for all stakeholders. The VIC would welcome any opportunity to work with the PMPRB staff on a comprehensive and risk-based approach, reflective of the realities of preventative vaccines in Canada.

Sincerely,

C Paquette

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

cc: Tina Namiesniowski, President of PHAC
Theresa Tam, Chief Public Health Officer, PHAC / Pan-Canadian Public Health Network Council
Saqib Shahab, Chief Medical Officer, Canadian Public Health Network
Gina Charos, Director General, PHAC
Erin Henry, Director, PHAC
Alan Thom, Manager, Vaccine Supply and Assurance, PHAC
The Honourable Patty Hajdu, Minister of Health, Health Canada
Sabina Saini, Chief of Staff, Health Canada
Anita Anand, The Honourable Minister of Public Services and Procurement Canada
The Honourable Navdeep Bains, Minister of Innovation, Science and Economic Development, ISIC
Ryan Dunn, Officer, ISIC
Ben Chin, Senior Advisor, PMO
Rick Thies, Policy Advisor, PMO
Paul Rochon, Deputy Ministry of Finance

Attachment

Vaccine Industry Committee
Le comité de l'industrie du vaccin

BIOTECanada

November 21, 2019

Karen Reynolds
Health Canada
Executive Director
Office of Pharmaceuticals Management Strategies
Strategic Policy Branch
Ottawa ON K1A 0K9

[Email: karen.reynolds@canada.ca]

Dear Ms. Reynolds,

BIOTECanada and the Vaccine Industry Committee are writing to you to clarify changes to the patented medicine regulations described in the Regulatory Impact Analysis Statement (RIAS) published on August 21, 2019 and vaccine regulation. This change in Regulations removed the reduced reporting obligations to vaccines which was inconsistent with the communication you provided to BIOTECanada (on behalf of Health Canada) on December 15, 2017, which stated "vaccines that are not on the Prescription Drug List described in Canada Gazette, Part 1 would be exempt from reporting of price, sales, identify information and information on the new price regulatory factors. As the majority of vaccines are not on this List, the proposal as currently written would exempt patentees of these types of medicines from having to report this information unless requested by the Patented Medicine Prices Review Board (PMPRB)".

BIOTECanada is the national industry association for Canada's health, industrial and agricultural biotechnology sectors. The Vaccine Industry Committee members are the leading vaccine manufacturers serving the Canadian market as well as early stage Canadian companies developing advanced vaccine technologies. BIOTECanada and the Vaccine Industry Committee conveyed the Industry's concerns about the proposed regulatory changes in letters delivered in February 2018 calling on Health Canada to ensure that the regulations clearly state that vaccines will be managed with limited regulatory oversight on a "complaint" based approach similar to OTC products. Increasing unnecessary regulatory burden on the vaccine manufacturer to satisfy new pricing controls is not necessary given the competitive tendering process of Government controlled procurement that delivers low vaccine prices.

The industry was assured by Health Canada in 2017 that vaccines would not be regulated to the full extent under the Regulations. However, the Patented Medicines Regulations and RIAS stated the opposite, placing an undo level of burden on the manufacturer, price uncertainty and may unnecessarily negatively impact vaccine availability, vaccine supply and public immunization programs.

The industry is requesting a meeting to clarify the changes to vaccine price ceiling regulation and the reversal of direction that Health Canada communicated prior to Gazette Part II.

Sincerely,

Andrew Casey
President and CEO
BIOTECanada

Catherine Paquette
Chair
Vaccine Industry Committee