Vaccine Industry Committee
Le comité de l'industrie du vaccin

September 11, 2024

Mr. Thomas Digby,
Chairperson Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario KI-P 7C1,

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

Dear Mr. Digby,

Following the release of the Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines, the Vaccine Industry Committee (VIC) wishes to submit the below response to: "**Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines."**

The VIC is aligned with the positions and recommendations contained in BIOTECanada's submission to the Discussion Guide.

Background

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 secure 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 available (2019, the World Health Organization (WHO)), 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. With the resurgence of measles in recent months, a vaccine-preventable disease, Canadians have been reminded 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.

Unique market characteristics already ensure non excessive pricing and support security of supply

It is important to note that the Canadian market for vaccines already has unique market conditions that ensure that prices are not excessive and support security of supply. There is minimal risk of excessive pricing 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 process through the National Advisory Committee on Immunization (NACI) and centralized procurement for public vaccination programs via the federal government on behalf of the Provinces and Territories.

The Canadian public tender process effectively prevents excessive pricing by design, with most tenders requiring Rights Holders to offer competitive bids discounted from the public list price. In limited instances where sole source contracts are signed, Rights Holders must certify prices are "not in excess of lowest price for similar quality & quantity" charged to any other customers. The market for privately sold vaccines is much smaller than the market for those funded by the government. When new patented vaccines are launched, the list prices are required to adhere to pricing guidelines set by the PMPRB to avoid complaints and investigations.

The value of vaccines is being realized through the use of these entities combining not only competitive tenders and negotiated prices but security and predictability of supply. The inclusion of a complaints-based process for vaccines for consideration by the Board signals a recognition of the unique nature of vaccines (tendering process, manufacturing complexity, global allocation, population health objectives, etc.).

It is important to note that the prices (including CPI) of Existing Medicines that were considered to be compliant prior to implementation of the new Guidelines should be presumed to be non-excessive moving forward. It is also important to clarify the rules regarding an in-depth review based on a complaint. The VIC believes it is important to establish guidelines on the principle of predictability, which includes a clearer definition of the review and settlement process for a complaint. Without predictability, list price management will have lots of uncertainties that might hinder the availability of new innovations.

For the above stated reasons, VIC requests the Board proceed with Option 2 in the Final Guidelines: The PMPRB will only open an in-depth review for vaccines when a complaint is received. Considering the unique Canadian tendering process for vaccines as well as competitive market conditions and PMPRB regulations in the private market, a complaints-based process is 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.

We appreciate the recognition of vaccines as a therapeutic category that may pose a lower risk of excessive pricing, expanding the list of medicines eligible for the complaint-based process. We look forward to further discussions with PMPRB and key stakeholders, ensuring that vaccination rate goals and the needs of Canadians are fully considered through the appropriate application of complaint-based mechanisms.

Sincerely,

Kevin Sauvé, Chair, Vaccine Industry Committee