Vaccine Industry Committee
Le comité de l'industrie du vaccin

October 31, 2016

Mr. Doug Clark
Executive Director, Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Mr. Clark,

Re: PMPRB Guidelines Modernization

On behalf of the Vaccine Industry Committee, thank you for the opportunity to provide input in the context of consultations on the proposed modernization of the Patented Medicine Prices Review Board (PMPRB) Compendium of Policies, Guidelines and Procedures (Guidelines). In particular, we are interested in sharing our perspectives on how the Guidelines could be modernized in a way that best aligns with how vaccines are currently procured and used by Canada's health systems.

The Vaccine Industry Committee (VIC) members are the leading vaccine manufacturers serving the Canadian market as well as early stage Canadian companies developing advanced vaccine technologies. The Committee partners with stakeholders to help secure Canada's public immunization programs (e.g., supply continuity, licensing of new vaccines), 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.[1, 2]

Based on the PMPRB Guidelines Modernization Discussion Paper (Discussion Paper) and the PMPRB industry information session held on September 30, 2016, VIC members are pleased that the PMPRB is considering applying a different regulatory approach for products that have a "low risk" of potential abuse of statutory monopoly.

We believe that vaccines are a prime example of a class of patented products for which there is low risk, and therefore should be managed with limited regulatory burden including adoption of a "complaint" based approach similar to OTC products. Our members' have been exceptionally compliant with the current PMPRB guidelines, which can be expected to continue under a complaint-based approach due to the nature of the market forces operating in the vaccines sphere.

Indeed, the need for PMPRB regulatory oversight has long been discussed and in the vast majority of cases, patented and non-patented vaccines are procured through competitive tenders.

Specifically, the VIC believes that strict regulatory oversight is not necessary for vaccines given the competitive bid process that establishes a fair market price and represents the vast majority of doses dispensed in the Canadian market.[3]

Key features of the government procurement process for vaccines include:

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- **Contracts:** Most vaccines are sold under multi-year contracts negotiated between the manufacturer and the provinces/territories. These contracts are under the administration of Public Services and Procurement Canada (PSPC). The provinces/territories and PSPC are sophisticated, knowledgeable, and have the purchasing power to negotiate contracts that provide optimal arrangements in terms of price, quality and supply.

- **Tender process:** Vaccine procurement policy is often based on a competitive tendering process, whereby the lowest bidder is granted a majority share of the contract to supply the customer with a specific vaccine. This federal tendering system ensures that patented vaccines are fairly priced within the Canadian marketplace. The tender process also results in limited price discrepancy and facilitates the adoption of vaccines across Canada.

- **Commercialization pathway complexity:** The current market access process for vaccines includes strict Health Canada reviews, then evaluated by the National Advisory Committee on Immunization (NACI), Canadian Immunization Committee (CIC) and multiple layers of procurement processes. Additional PMPRB regulatory oversight for vaccine prices adds an unnecessary barrier to patients and health system for access to therapies that are highly cost-effective to prevent diseases.

We also note that the Discussion Paper raises concerns about how the current system allows patentees to discriminate between different classes of consumers (i.e., differential pricing). In the case of vaccines, as mentioned above, it is important to note that the tender process limits price discrepancies. It is important to preserve the wide variety of procurement processes that currently exist in the country, as these processes were developed to meet the specific needs of funders and users in various jurisdictions.

We thank you again for the opportunity to provide a submission on how Canada can modernize its federal pricing review process. As we move forward in this consultation process, it will be important to consider how any specific proposed changes to the Guidelines could impact vaccines, as the reimbursement process for vaccines differs significantly from the reimbursement process for pharmaceutical products.

We look forward to discussing these important issues with you and other health system stakeholders, and hope that this dialogue can occur early in the consultation process, before any proposed changes are submitted for review to PMPRB decision-makers and before revised Guidelines are developed.

Sincerely,

Truong Ta, Chair, Vaccine Industry Committee

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References

1. Bulletin of the World Health Organization, 2008, Volume 86, Number 2, 81-160
2. World Health Organization, *State of the world's vaccines and immunization. Third edition*, 2009
3. Public Health Agency of Canada, *National Immunization Strategy: Final Report 2003,* 2004