Vaccine Industry Committee
Le comité de l'industrie du vaccin

February 14, 2018

Karen Reynolds, Executive Director
Office of Pharmaceuticals Management Strategies
Strategic Policy Branch
Health Canada
Brooke Claxton Building, 10th Floor
70 Colombine Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9

Re: Vaccine Industry Committee Response to Canada Gazette, Part I published December 2, 2017, Regulations Amending the Patented Medicines Regulations

Dear Ms. Reynolds,

I am writing in regards to the **Regulations Amending the Patented Medicines Regulations** published in Canada Gazette, Part I on December 2, 2017. The proposed regulations and its ramifications are a significant concern for the Canadian vaccine industry as it invests heavily in research, development and manufacturing to support government public health programs which Canadians rely upon.

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 Health Canada regulations proposal and the Health Canada industry information session held on December 13, 2017 and January 10, 2018, VIC members were informed that Health Canada will apply a different regulatory approach for products that have a "low risk" of potential abuse of statutory monopoly and those not listed on the Prescription Drug List. The Vaccine Industry Committee believes that strict PMPRB 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. Therefore, vaccines are a perfect example of a class of patented products that belongs in the "low risk" category. The inclusion of vaccines in the "low risk" category will reduce regulatory burden on both industry and government. Health Canada should ensure that the regulations clearly states that vaccines will be managed with limited regulatory oversight on a "complaint" based approach similar to OTC products. The VIC is requesting a meeting with Health Canada to ensure the regulations are modernized in a way that best aligns with how vaccines are currently procured and used by Canada's health systems.

Vaccine procurement is 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.
- limits price discrepancies for all provinces and territories.

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 volume. The competitive nature of the tendering process and the bulk purchasing of vaccines by provinces/territories results in affordable vaccine prices.

The current market access process for vaccines includes strict Health Canada reviews, and evaluation by the National Advisory Committee on Immunization (NACI), the 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 proven cost-effective disease and illness prevention tools. These proposed regulations may negatively impact vaccine R&D investments, vaccine availability, vaccine supply and public immunization programs.

Thank you for this opportunity to provide input into Health Canada's modernization of PMPRB. We look forward to discussing these important issues with you and hope that a meeting can occur as soon as possible.

Yours truly,

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Chair, Vaccine Industry Committee

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