Vaccine Industry Committee
Le comité de l'industrie du vaccin

November 6, 2020

Mr. Ron McKinnon
Chair, Standing Committee on Health
House of Commons
Ottawa ON K1A 0A6

Submitted online via portal.

RE: Vaccines Industry Committee Brief in Response to Standing Committee on Health's Study Regarding the Patented Medicine Prices Review Board's Final Guidelines

Dear Mr. McKinnon,

The Vaccines Industry Committee (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 available, and expands Canadian vaccine innovation and manufacturing capacity.

Given the current public health context, we're pleased that HESA is looking into this important topic, and we encourage the committee to include a policy assessment moving forward given the unprecedented level of uncertainty imposed by the Patented Medicine Prices Review Board (PMPRB's) Guidelines changes that are scheduled to come into effect on January 1, 2021.

As the VIC has noted in our prior public submissions to the PMPRB during their recent consultations, we would like to reiterate at this time that patented 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. As we are all witnessing first-hand today, innovative vaccines can and do play a critical role in addressing some of the most pressing public health, social and economic challenges of our time.

This submission from the Vaccines Industry Committee pertains only to those aspects of the new August 2019 federal regulations, and the new PMPRB Guidelines that specifically concern patented vaccines.

As result of the consultation process, and input from the VIC and its members, it is noteworthy that the PMPRB has made the decision in its new Guidelines to regulate Vaccines on a complaints-only basis. (In other words, the final Guidelines provide that vaccines would remain subject to the reporting requirements set forth in the *Patent Act* and the *Patented Medicines Regulations* but

going-forward would only be subject to a price review and investigation if a complaint is received by the PMPRB. COVID-19 vaccines would also be subject to a complaints-basis only, with slightly different parameters.)

This adjustment in the PMPRB's go-forward regulatory approach comes in response to feedback from individual vaccine manufacturers, and the VIC, and acknowledges the unique market dynamics surrounding vaccine procurement in Canada (i.e. Canada's longstanding and well-functioning public tendering system for vaccines). This change by the PMPRB also appears to be broadly consistent with statements made by Health Canada in late 2017 and early 2018 during several industry consultation sessions where, VIC members were informed that Health Canada may be open to taking a different regulatory approach for products that have a "low risk" of potential abuse of statutory monopoly.

However, the VIC notes that the complaints-based system for vaccines outlined in the new PMPRB Guidelines differs from how it will approach complaints based for biosimilars and generics. In cases where a complaint is made to the PMPRB regarding a patented vaccine, if the vaccine in question meets the Category I criteria (including market size adjustment) it would be assessed accordingly, whereas biosimilars and generics would never be subject to the category I pricing tools.

PMPRB's market size adjustment is, by nature, counter to the Public Health Agency of Canada objective of increasing vaccination rates, as manufacturers are negatively impacted once a product's revenues hit a certain threshold. This may disincentivize companies from providing higher volumes of vaccines even in the event of a stock out or urgent public health need; resulting in market conditions which conflict with the public health mandate to achieve herd immunity to protect the population. Therefore, we look forward to receiving further information from the PMPRB as to why this distinction is made.

Nevertheless, while VIC members remain concerned with the new PMPRB Guidelines in their entirety (as outlined below), we acknowledge that the PMPRB has taken at least one important step in the right direction by indicating that vaccines will now be subject to a similar complaints-based investigation criteria as patented biosimilars and generics.

Impact of the PMPRB Guidelines on Canadians

Several aspects of the new Guidelines remain highly problematic and if implemented as drafted they would have a profoundly negative impact on Canadian patients. Specifically, innovative new medicines and vaccines will not launch in Canada, depriving patients of potentially life-changing and life-saving new medicines. Canada could also see further reductions in the number of clinical trials in this country, and our life sciences sector will lose out on critical investments and jobs.

Since the amendments to Canada's *Patented Medicines Regulations* were introduced in August of 2019, the Vaccines Industry Committee is aware that, according to Conference Board of Canada data, there have been over 30% fewer new drug submissions made in Canada within 12 months of the drug being submitted for approval elsewhere in the globe , compared to the previous 3 years (24%).

There has also been a significant drop in Canada over this period in both the number of new drug launches and in the share of global launches – to less than half the figures seen in recent years. These trends regarding access to innovative patented medicines in Canada are very concerning to members of the VIC.

With this in mind, the members of the VIC would echo the call from Innovative Medicines Canada (IMC), as well as other Canadian life sciences industry associations, various patient groups and other health system stakeholders in calling for the suspension of the pending changes to the Patented Medicines Regulations (which are scheduled to take effect on January 1, 2021) until after the current pandemic has subsided. Suspending their implementation would not only reassure patients, but it will allow vaccine and therapeutics manufacturers to focus more directly at this time on developing and delivering COVID-19 treatments and vaccines, which is of paramount importance to all Canadians at this challenging time.

Recommendation:

Where novel infectious diseases emerge, our industry will continue to work to mobilize the full scope of our scientific and manufacturing resources to respond. The focus of the VIC and its member companies is to safeguard public health through innovation, and we will continue to work urgently to remove any needless barriers, regulatory or otherwise, which may negatively impact achieving that critical objective. Specifically, we will continue to advocate for clear ("bright line") regulatory regimes in Canada that maximize Canadians' access to vaccines supply and maintain our status as a priority launch country.

In the meantime, we would (1) respectfully submit to the members of the HESA Committee that a global pandemic may not be the right time to bring forward regulatory changes of this scale for patented medicines and vaccines, and we call for a pause on implementation until after the current pandemic has subsided. We would also (2) request that the HESA Committee – and indeed all Canadian parliamentarians at the federal, provincial and territorial levels – continue to play an active role in monitoring the implementation of these new regulations and Guidelines and questioning their impact on vaccines in this country.

Respectfully,

On Behalf of the VIC