Vaccine Industry Committee
Le comité de l'industrie du vaccin

June 21, 2021

Dr. Mitchell Levine
Chair, Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

As previously expressed by the VIC during the consultation process, the Regulations and Guidelines create additional uncertainty and do not reflect the uniqueness of the vaccines industry. The new PMPRB Regulations may have unintended consequences as follows:

1. There will be high levels of pricing uncertainty for vaccines, which will complicate vaccine patentee decision making and encourage delays or deferred vaccine product launches. Global manufacturers may deprioritize Canada and choose other jurisdictions to launch vaccines where threshold economic factors and market size does not impede pricing. This would impact the reputation that Canada has withheld as being a leading country to launch vaccines, as well as hinder its access to vaccine clinical trials. For applicability to the Canadian public health context, if a new vaccine emerged for a global health threat, the uniquely Canadian requirements linking vaccine prices to market size, would result in issues of access and supply in Canada, thereby restricting availability for public health officials to manage potential future endemic and pandemic outbreaks.

2. In times of vaccine shortages or outbreak situations there are significant fluctuations in market size from one year to another, which could result in a vaccine moving from Category II to Category I. This would result in lower net pricing, which would demand rapid decisions from manufacturers regarding supply prioritization on a global scale. Because Canada may be competing with other countries for vaccine supply, delays in making these decisions (i.e. caused by the additional time required to obtain approval for exceptions from PMPRB, local authorities, or company's global pricing teams) can hold up supply allocations to Canada and negatively impact Canadian public health.

3. Since most Grandfathered vaccines are purchased through public contracts, the average transactional price (ATP) incorporates significant discounts and benefits to the provinces/territories, resulting in NEAPs being much lower than the MLP. As a result, most currently marketed vaccines will likely have to apply to request that the MLP remains at the level prior to the revised regulations and guidelines. This will result in additional workload for both the PMPRB and Industry. VIC has suggested

.../2

previously that if the list price is non-excessive, it would be simpler and less work to make a rule to use the current list price, instead of processing large numbers of applications for NEAP exceptions.

4. Vaccines are complaint-based only, and therefore will be unnecessary workload from both the industry and PMPRB with twice yearly submissions and assessments. It would be more efficient and practical that patented vaccines only submit data, if a complaint is received, once a MLP has been set.

Therefore, it will be important to monitor the impact of the new PMPRB Regulations for the following issues, over the next 5 years:

1. Timing of new vaccine launches compared to other countries with similar healthcare standards (e.g. US, UK, Western Europe, Australia) (as stated in the GMEP proposal)
2. Any vaccine shortages due to concerns of being classified as a Category I product, which VIC or an appropriated 3rd party will be monitoring.
3. Impact on workload of both the PMPRB and Industry (as stated in the GMEP proposal)

In addition, the PMPRB has stated in its Guidelines for Monitoring and Evaluation, that it will measure *"shifts in the proportions of total spending accounted for by individuals, public plans and private insurers. The spending on these medicines will also be evaluated in relation to macroeconomic measures of overall health expenditures and GDP".*
This is a shortsighted measurement for innovative medicines, and in particular for vaccines, since it is hoped and expected that the percentage of vaccine spend will increase vs total health expenditures. Vaccine's account for <1% of total annual health budgets despite vaccinations being one of the most cost-effective ways of avoiding diseases (as per the 2019 WHO declaration). In addition, the current COVID-19 pandemic has resulted in a significant increase in spend on COVID-19 vaccines in 2021 and which will no doubt continue for years to come.

Kind regards

J. McCarles

Jacqueline McCarles
Chair, Vaccine Industry Committee