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Members of the Standing Committee on Health
Standing Committee on Health
House of Commons
Ottawa ON K1A 0A6

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Re: Medicago's Brief on the PMPRB Guidelines issued on October 23, 2020

Dear honourable members of the Standing Committee on Health:

We appreciate the opportunity to participate in the Standing Committee on Health (HESA) study about the changes to the Patented Medicine Prices Review Board (PMPRB) Guidelines set to come into force on July 1, 2021.

Medicago is a Canadian biopharmaceutical company that has been developing a manufacturing platform throughout the past two decades that can be key in the preparation and fight against pandemic threats and other emerging diseases. During the current COVID-19 pandemic, Medicago has allocated nearly all its resources to develop a vaccine against COVID-19 and to accelerate its path to increasing Canada's domestic vaccine manufacturing capacity.

In addition to the significant scientific advancements made by Medicago, we are contributing substantially to the Canadian economy with direct investments having already reached more than $500 million in Canada, despite not having generated any product sales to date. Our new manufacturing complex, currently under construction in Quebec City, is estimated to generate direct and indirect benefits in the order of $500 million over the course of its five-year completion, according to the Quebec Institute of Statistics.

As stated in our feedback on PMPRB Guidelines during the consultation period this past summer, Medicago is concerned about the proposed changes. As we approach the launch date of our first products, including potentially a vaccine against COVID-19, the new PMPRB regime has created unprecedented uncertainty for our development and commercialization efforts in Canada. We have summarized below our three main points of concern for your consideration.

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1. **Exceptions for the market size adjustments and new tests create unfair market dynamics**

Grandfathered, Line Extension and Gap patented vaccines will not be subject to market size adjustments (i.e., 25 to 35% price discounts depending on the market size). However, innovative vaccines that will be competing with these products in public tenders will be subject to market size adjustments, creating unfair market dynamics and discourage companies like ours from even competing for business in Canada. This rule, combined with ceiling prices limited by the Domestic Therapeutic Class Comparison (dTCC), will hinder the launch of new vaccines in Canada.

Although PMPRB has recognized in the latest Draft Guidelines that vaccines subject to tendering need a different pricing methodology, vaccines were only mentioned as an example in the "Investigations" section (item 94). This leaves a significant uncertainty about how prices will be assessed by PMPRB, posing a challenge to manufacturers currently selling or planning to sell vaccines in Canada as they would have to wait for an investigation to learn how prices will actually be assessed.

2. **New thresholds for Category I medicines would limit vaccine manufacturers' ability to secure supply of vaccines to the Canadian market during supply shortages caused by manufacturing issues, pandemics, or outbreaks**

Global manufacturing issues impacting large manufacturers, pandemics, or outbreaks cause significant fluctuations in market size from one year to another. During these public health crises, manufacturers with available capacity must allocate their doses among different countries and price sustainability may be one of the allocation criteria. Although these crises may be short, they can also last several years when, for instance, large manufacturing plants halt operations due to unexpected events.

The proposed guidelines disregard these market fluctuations by imposing price reductions based on market size and other new tests that reference a larger basket of countries during times of higher demand, discouraging manufacturers to allocate doses to Canada. In these situations, manufacturers would need to supply additional doses at a significant discount – at potentially unsustainable prices that will be based on the price of older vaccines (Domestic Therapeutic Class Comparison – dTCC) with additional 25 to 35% price discounts depending on the market size.

3. **Guidelines discourage investments in R&D and domestic production in Canada**

In a discussion paper issued in 2016 about the need for modernization of the PMPRB Guidelines, the PMPRB reported that one of the reasons to initiate a consultation process was that since 2003 the pharmaceutical industry in Canada has failed to meet the commitment to invest 10% of revenues in R&D and that the average ratio was standing at 5% in 2016[1]. However, the recently issued Guidelines do not provide any incentive for companies that are currently investing more than the 10% target to continue do make these investments in Canada.

Medicago's R&D ratio was 1,254% in 2018[2] and reached 1,931% in 2019 with the increased investments in our new facility and clinical trials. Despite the significant investments in R&D and domestic production, local companies such as Medicago are subject to the same rules as other companies that do not invest in R&D in Canada.

These three points will be especially harmful to local manufacturers given that large multinationals can opt to leave the Canadian market or postpone their product launches in Canada, which represents only a small fraction of their global sales.

In its 2017 Regulatory Impact Analysis Statement published in the Canada Gazette, Health Canada states: "*It is not anticipated that these amendments would generate adverse impacts on industry employment or investment in the Canadian economy.*"

The reality is that Medicago – the only Canadian vaccine manufacturer with a vaccine in late stages of development – will be negatively impacted not only in the short-term if we prioritize product launches in our home country, but also in the long-term. As global markets may use Canadian prices as a reference, the new PMPRB guidelines will have cascading effects in other markets where Medicago expects to launch its products, negatively impacting the company's global revenues. This will adversely impact the Canadian economy in many ways, from possible cuts in local investments and highly qualified jobs to the reduction of corporate sales taxes based on global sales generated by companies headquartered in Canada.

Therefore, we ask that the committee make a clear recommendation to the Minister of Health and her colleagues to amend the regulations and for the PMPRB substantively amend its Guidelines to ensure they foster the growth of Canadian life science companies, stimulating domestic research and production to contribute to our economy and to help protect our country from infectious diseases. We welcome any opportunity discuss these important changes to the PMPRB, as well as any other related topics. This includes the current pandemic and Medicago's contributions to help the Canadian health system, economy and citizens return to work and social endeavours that are so important to all of us.

Sincerely yours,

Nicolas Petit
Vice-President, Commercial Operations

cc. The Hon. Patty Hajdu, Minister of Health (hcminister.ministresc@canada.ca)

[1] PMPRB (http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines/discussion-paper)
[2] Canada's Top 100 Corporate R&D Spenders 2019, Research Infosource Inc. (https://researchinfosource.com/top-100-corporate-rd-spenders/2019)