Medicago Inc.
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February 12, 2021

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

Submitted electronically: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: Medicago's Response to Proposed Consequential Amendments to the January 1, 2021 Guidelines

Dear Dr. Levine:

In response to the PMPRB's invitation to comment on two proposed consequential amendments to the new Guidelines resulting from the decision to delay the coming-into-force date of the Regulations Amending the Patented Medicines Regulations ("Regulations") January 1, 2021 to July 1, 2021, Medicago would like to share its comments on the proposed changes.

As the world faces a major public health crisis brought the COVID-19 pandemic, and vaccines are not expected to be widely available in Canada until September 2021, our position is that it is not the appropriate time for the PMPRB to bring additional uncertainties to the healthcare sector. More importantly, as stated in previous communications from Medicago to the PMPRB, the uncertainties brought by the new Guidelines are especially harmful to local companies given that large multinationals can easily opt to postpone their product launches in Canada, which represents a small fraction of their global sales.

Medicago – the only Canadian vaccine manufacturer with vaccines in late stage 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. 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, such as Medicago.

Therefore, we continue to ask the PMPRB to 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.

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Regarding the proposal to revise the definition of Gap medicines as having a date of first sale from January 1, 2021 to July 1, 2021, Medicago proposes that the definition of Gap medicines be revised to a date of first sale of at least January 1, 2022 when the COVID-19 pandemic will hopefully be under control. This will avoid creating two classes of COVID-19 vaccines – one for first generation vaccines approved prior to July 1, 2021, and another for vaccines launched after that date. The delay would also provide more time for companies to implement the substantial changes being proposed.

Regarding the proposal to reduce the timeline to comply with MLP for Grandfathered and Gap medicines from 2 reporting periods (July 2021 for a July implementation) to 1 reporting period, Medicago disagrees with it as it would not provide sufficient time for companies to manage the administrative work required to comply with all the changes, and proposes the PMPRB to keep the original plan.

We welcome any opportunity to discuss our position as well as any other related topics. This includes the current pandemic and Medicago's contributions to help Canada's 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)