Submitted via PMPRB's Consultation Portal

Patented Medicine Prices Review Board Standard Life Centre
Box L40 333 Laurier Avenue West
Suite 1400 Ottawa, ON K1P 1C1

**RE: Scoping Paper for the Consultations on the Board's Guidelines, November 2023**

December 19th, 2023

We appreciate the opportunity to provide feedback on the Scoping Paper for the Consultations on the Board's Guidelines. Moderna Canada is a recently established biotechnology company and since the pandemic, have been working tirelessly to ensure that Canadians are protected against COVID-19. We have made significant efforts to ensure that Canada will be ready for the next pandemic and have secure supply of respiratory vaccines for the future. The success of our COVID vaccine has allowed Moderna to explore new therapeutic areas such as latent viruses, oncology and rare diseases that have the potential to revolutionize medicine in the years to come using our proven mRNA platform.

Domestic pricing environment makes the launch of any future medicines more challenging, with riskier pricing jurisdictions potentially getting delayed access. In the best-case scenario, pricing uncertainty leads to global de-prioritization of launch order amongst the launch countries. In the worst-case scenario, Canadian launch of new therapeutics may not happen at all which prevents Canadian patients from getting timely access to potentially life-saving therapies. Thus, any price review process, whether conducted in an expedited manner or not, should be thoroughly assessed to see how it will impact time to launch in Canada in the context of a global market.

We believe that the new PMPRB Guidelines should reflect PMPRB's legislative mandate to prevent "excessive" price. Thus, Highest International Price (HIP) of PMPRB11 should be used as an initial triage measure. As a manufacturer with several vaccines in the pipeline, we want to comment specifically on how vaccines should be viewed under the new Guidelines. Moderna Canada is aligned to the Vaccine Industry Committee's (VIC) position that given the low risk of excessive pricing for vaccines due to the procurement process, they should be managed by PMPRB through a "complaint" based approach.

As a member of BIOTECanada, we are aligned to it's position that new Guidelines must align with the current Canadian ecosystem and should reflect Canadian government's broader objective to grow the biotech and life sciences sector. If there is one thing we learned from the pandemic, it was that when the outcome, ambition and roles and responsibilities were clear, we were able to work together to achieve success. Thus, pricing reform presents an opportunity to review systems that currently exist in Canada and identify what is needed to achieve access to medicines for Canadians, foster innovation in Canada while protecting consumers from excessive pricing. We are hopeful that true collaboration between the right parties within the ecosystem can achieve this goal for the betterment of all Canadians.

In order to develop an operational, transparent and predictable framework, we request PMPRB to establish relevant technical working groups to fully assess the impact of any new Guidelines. All efforts should be made to assess both the intended and unintended consequences of any new Guidelines to the best of our ability.

Moderna Canada is excited to have partnered with Canadian federal and provincial governments to bring mRNA manufacturing to Canada. It is our hope that these new and innovative products will spur greater research partnering and be acknowledged for the groundbreaking work they represent, via a globally competitive and balanced pricing regime.

Sincerely,

Stefan Raos

Stefan Raos
General Manager, Moderna Canada