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Dr. Mitchell Levine, Chairperson
Patented Medicine Prices Review Board
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Submitted electronically: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Dear Dr. Levine

CATALIS Quebec Clinical Trials ("CATALIS") would like to offer a number of important perspectives on the PMPRB's proposed Guidelines, particularly from the perspective of the current and projected impacts on the Province of Quebec.

CATALIS is a non-profit partnership, co-funded by the Quebec Ministry of Economy and Innovation and private industry. Our mission is to optimize the clinical research environment in Quebec in order to maximize private investment and accelerate the development of innovative patient care. Our vision is to create a provincial environment that allows all patients easy access clinical trials in Quebec. In addition to leveraging Quebec's exceptional base of scientific and medical talent, CATALIS strategic objectives are to accelerate the start-up and conduct of clinical trials, facilitate patient recruitment and referrals throughout Québec, and increase Québec's international influence to attract more clinical trials.

In 2019, Quebec hosted over two thousand (2000) active clinical trials focusing on advancement of medical knowledge and the improvements of treatments for patients in Quebec and beyond. This has benefitted Quebec patients through access to cutting-edge treatments. Quebec's healthcare system also benefits from the substantial, sustained contribution to patient care in conjunction with the publicly funded aspects of care delivery.

Quebec's strong clinical research position has evolved due to the substantial efforts of the Government of Quebec, research institutions, and the wider life sciences industry to unite around a common strategy. Significant steps have been taken to align various public policies, regulations, and other key requirements in order to ensure that Quebec continues to offer a globally competitive environment for clinical research. Importantly, great care has been taken to ensure that policies are complementary and coherent wherever feasible, given that clinical investment decisions depend upon a range of individual factors in a given jurisdiction. This policy platform has allowed Quebec to attract and retain clinical research funding from both public and private sources – an exemplary model of collaboration in service of a societal objective. CATALIS wishes to see these efforts continue.

CATALIS welcomed the most recent Quebec Budget (2020-21) which included $118 million directed to the Quebec life sciences sector including $15 million directly allocated to CATALIS to increase the number of clinical trials conducted between private companies and research centres

in the public sector , in order to facilitate collaboration between the various players in the life sciences sector and accelerate the development of innovative treatments.

Having reviewed the proposed PMPRB Guidelines and consulted with the members of our network, CATALIS has identified serious deficiencies with the PMPRB's approach. We understand that prior to the coming into force of the new PMPRB regulations in July 2020, the PMPRB Board and staff members still have an opportunity to make adjustments to their administrative Guidelines in order to promote clarity and regulatory stability to all market participants – most notably patented pharmaceutical manufacturers, a key partner for clinical research in Quebec and across Canada.

We strongly encourage the PMPRB Board to revisit the overall approach in the Guidelines against the reality of Canada's competitive position with respect to attracting and retaining research, timely new product launches, and sustaining access to global standards of care. This demand is all the more important because, although Quebec and Ontario are working to accelerate the start of clinical trials, our average time to start a trial is between 6-7 months, compared to the 2 months expected by pharmaceutical companies. Our current performance seriously impacts our ability to recruit the targeted number of patients and capitalize on available investments. It is important that Canada offer an attractive market until we can solve this problem and increase our international competitiveness.

The overriding purpose of early-stage clinical research is not just to advance medical knowledge as a goal in itself but to generate useful, later stage product candidates suitable for submission to regulatory agencies and eventual appropriate use by patients on the advice of healthcare professionals. Any policies which impact later-stage research directly impact the entire R&D enterprise, including the earlier-stage areas of most direct interest to CATALIS.

As currently configured, the Guidelines represent a major source of destabilization and uncertainty for Quebec's life sciences research community. We are particularly concerned about the application of a subjective, highly variable pharmacoeconomic test to approved products at the regulatory level. Pharmacoeconomics has been used in Quebec and Canada for some time at the reimbursement level, particularly in the context of negotiating product access and criteria. However, we are unaware of any jurisdiction which utilizes these tools in a regulatory context, especially one so disconnected from and separate to wider health system and other public policy considerations.

This fundamental uncertainty will cause a "chill" on not just new products being delayed for Quebec and Canada in favour of other more predictable and favourable markets. It will also limit the ability of Quebec and Canada to offer a competitive climate for new investments in clinical research. The approach offered by the PMPRB Guidelines undermines the objectives of the Quebec 2017-2027 Life Science Sector Strategy, specifically its goal of attracting a further $4 billion to the Province in new investment.

The availability of new therapies in Canada is an important basis for subsequent phases of clinical research and product innovation. CATALIS is concerned that the PMPRB Guidelines will cause Quebec and Canada to not receive new therapies as quickly as in prior years, or not at all. The conduct of clinical research often relies upon the availability of a given standard of care in a therapeutic area. It is of interest to both the medical community and civil society not just whether

a given intervention delivers an improved health outcome for the patient, but whether it does so in comparison with other available treatment options and their relative effectiveness and expected clinical outcome. If Quebec can no longer offer a standard of care in a given area of therapy, that gap will have a negative impact on our ability to attract clinical trials in the same area of medicine.

Our private sector partners have also raised significant concerns about the ethics of commencing trials and recruiting patients for a given therapy for which the company may not have any reasonable confidence in a future launch in the same jurisdiction. Clinical trials generate close to $2.2 billion annually to the health care system, and therefore we benefit from the conduct of clinical trials, whether they generate licensed or unlicensed products. But the balance and long-term sustainability depends on our ability to integrate new treatments into the overall system in a timely and predictable way.

On behalf of the wider Quebec clinical trials community, CATALIS strongly urges the PMPRB to revisit its approach to its Guidelines in the spirit of not disturbing the progress made in Quebec and Canada on growing our clinical research enterprise. Additional consultation and consideration of other approaches to price regulation is clearly required as soon as possible. With a different approach, we are optimistic that the PMPRB will be able to fulfill its mission within its jurisdiction without harming the interests of Quebec research institutions, scientists, and Quebec patients.

Sincerely,

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cc

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