

**August 4, 2020**

**RE: Feedback on the amended Patented Medicines Regulations**

*High Risk of Negative Impact on Canadian bio-Medical Research*

As leaders of organizations in the bio-medical research fields, we are deeply concerned by the recent trends Canada is experiencing both in levels and the availability of funding for medical research activity. We are of the opinion that the detrimental impact of the proposed changes to the PMPRB regulations on the R&D ecosystem have not been adequately considered and that Canadian bio-medical research institutes, clinician-scientists, researchers and Canadian patients will be increasingly adversely impacted through the indirect downstream effects of the proposed changes on research funding in Canada. We strongly urge that the proposed policy amendments be independently studied and modelled on their potential impact on R&D expenditure and activities prior to their adoption, given the unique nature of the R&D ecosystem and the beneficial long-standing public/private funding programs. This work should be conducted by credible, independent experts in a transparent manner and open to peer review.

The proposed amendments to the Patented Medicines Regulations and ensuing dispute with the bio-pharmaceutical sector has created uncertainty impacting the development of new medicines in Canada. Numerous publications have raised concerns about the declining R&D activity in Canada. A publication by the Canadian Health Policy Institute assessed the relationship of R&D with drug prices. This review of 44 studies from the US and EU noted "...the claim that there is no link between price and R&D or access to medicines is not supported by the evidence from the scientific literature" (Labrie, 2020). The review implied a reduction to R&D expenditure of \$1 for every \$2 decrease in price and a reduction in the number of compounds entering clinical phase of research of 50-60% related to a 40-45% decrease in prices. Commentaries by the MacDonald Laurier Institute (Rawson, Adams, 2020) and the Fraser Institute (Aciri, 2020) have noted a decline in research activity in Canada that may point to a declining R&D attractiveness at a time when Canada is poised to make greater strides in drug development and commercialization as a critical area for the future economy. The number of clinical trials registered in Canada between November 1, 2019 and March 15, 2020 fell by 52 percent compared with the same period in previous years as shown in Figure 1 (Rawson, Adams, 2020). The effects of the COVID-19 pandemic on Canada has reduced this even more and we may not adequately recover from these losses.

Significant financial and infrastructure commitments by both Federal and Provincial governments to Canadian bio-medical research has spawned numerous and important research institutes, partnerships and consortia, each significantly contributing to Canadian innovation and improvements in health care. Past programs such as the Networks of Centres of Excellence (NCEs), Business-led NCEs (BL-NCEs), Centres of Excellence for Commercialization and Research (CECRs) and Networks of Centres of Excellence - Knowledge Mobilization (NCEs-KM) focused on building infrastructure and collaborative networks to stimulate the economy and improve the quality of life of Canadians by driving public and private sector R&D. All of the aforementioned mechanisms rely on a healthy private sector willing to invest in strategic

research partnerships and funding (Halliwell J., Centers of Excellence as a Tool for Capacity Building, Case Study: Canada, OECD 2013).

Significant public funding for infrastructure, consortia and research initiatives over the years forms our R&D legacy investment. The down-stream effects of these proposed amendments may well have direct, negative impact on Canada's ability to maintain bio-medical funding and continued utilization of existing capacity in critical therapeutic areas such as cancer. Research in these fields demands a stable and healthy R&D ecosystem encompassing both public and private enterprises. For these reasons we reiterate the need for an independent and peer reviewed analysis of the effects of the amendments to the PMPRB Regulations prior to any changes being adopted and taking effect.

We welcome the opportunity to engage the PMPRB committee to discuss these concerns and further clarify the gravity of the issues under consideration. We believe that a more balanced way forward is possible that better meets the needs of Canadian patients, the research and clinical community, as well as benefitting the Canadian economy.

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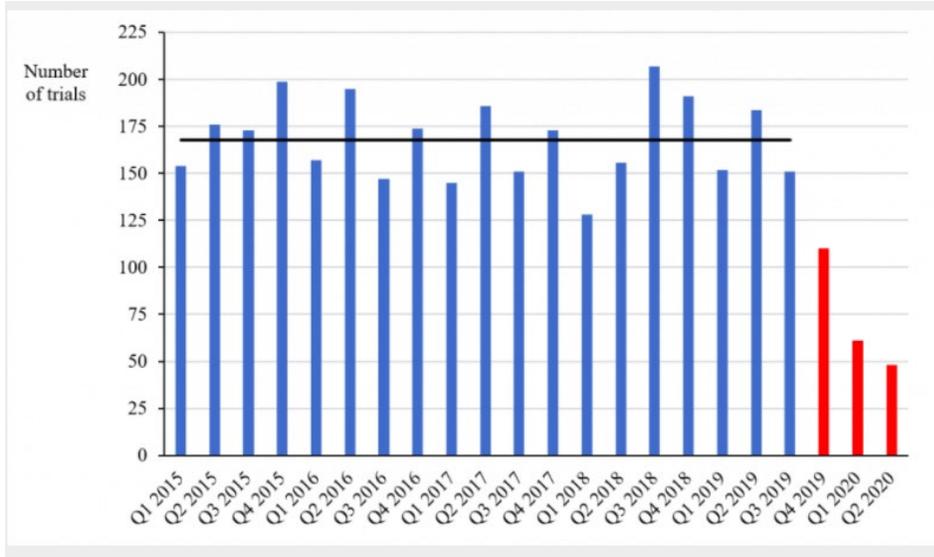
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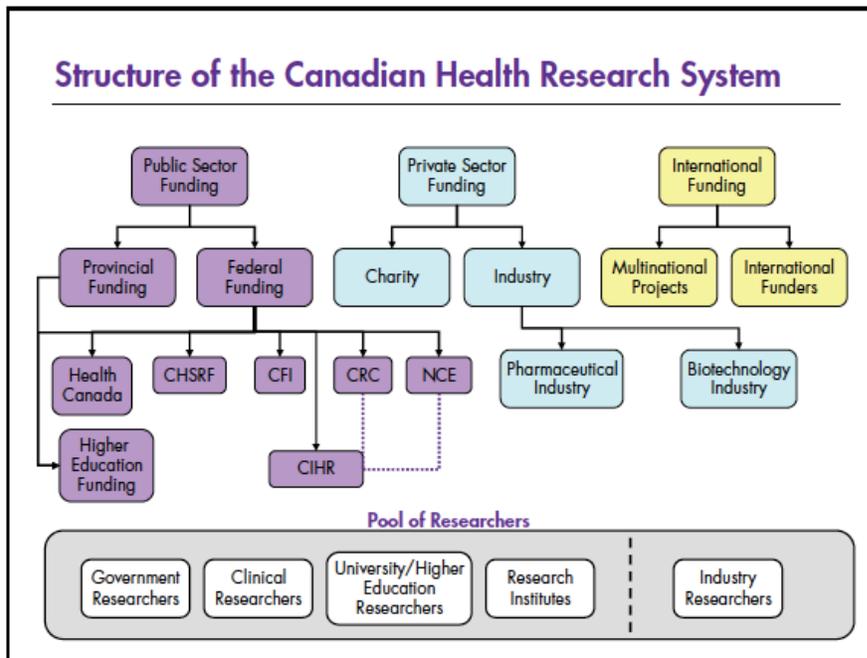
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Figure 1: Phase I, II and III Trials Approved between 2015 and 2020, by quarter



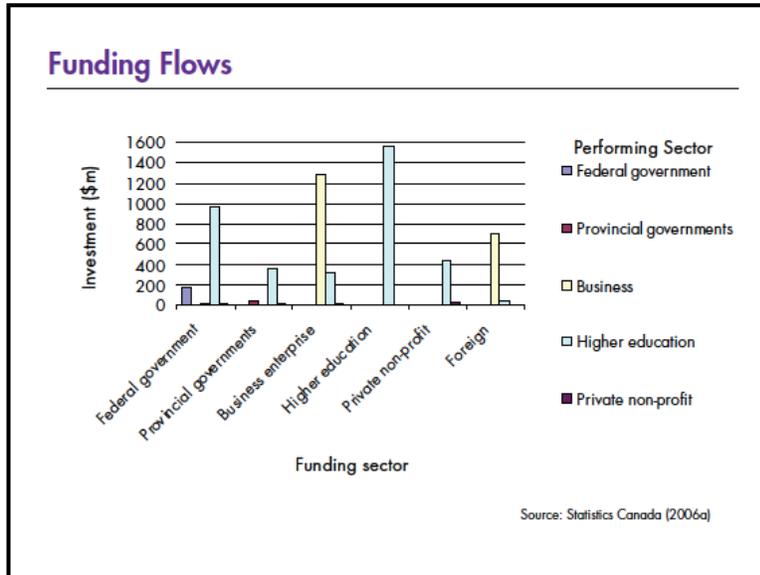
Nigel S.B.Rawson, MacDonald Laurier Institute, July8, 2020

Figure 2: Canadian Health Research Structure, 2008



Health and Medical Research in Canada: Observatory on Health Research Systems, Edward Nason, RAND Corporation, 2008.

Figure 3: Sources of Research Funding 2005



Health and Medical Research in Canada: Observatory on Health Research Systems, Edward Nason, RAND Corporation, 2008.

The major funders of health research are business enterprise and higher education (in 2005, providing \$1.5 billion (0.11% of GDP) and \$1.6 billion (0.12% of GDP), respectively), with government providing around \$1.6 billion (0.12% of GDP) between federal and provincial branches. These three funding bodies provide around 80 percent of the Canadian health research funds (around 27 percent each).

## References

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Nigel S. B. Rawson and John Adams, Access to New Medicines: What Should Ottawa Learn from COVID-19? MacDonald Laurier Institute, June, 2020