

August 31, 2021



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

Subject: Notice and Comment - On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions

As leaders of organizations in the field of cancer research, we are writing to share our concerns regarding the indirect downstream impacts of the Patented Medicine Prices Review Board (PMPRB) regulation changes and the abovementioned proposed Guideline changes on the quality of Canada's biomedical research ecosystem.

We would like to note that we are not taking a position on medicine pricing. We fully support government efforts to improve medicine affordability and access for Canadians. However, we believe that the PMPRB changes could have inadvertent harmful impacts on the health research ecosystem and it is critical that these impacts be further examined.

To provide background, over the last thirty years Canada has built an enviable and globally recognized health research ecosystem. We have world-leading research institutes, hospitals, universities, start-ups, multinationals, and individual scientists working together here and with global partners to advance medical discoveries.

Through matched funding programs, public-private partnerships form the critical core of Canada's investment in, and the advancement of, medical research. Every year, the private sector provides hundreds of millions of dollars in research investments and nearly \$2 billion worth of free medicines used in clinical research.¹ Over the years, these collective efforts and partnerships have led to vast health and socioeconomic benefits for Canadians.

However, we are concerned that continued and unpredictable changes to the regulatory environment and increasing efforts to achieve significant price reductions for pharmaceuticals in Canada could be impacting pharmaceutical company decisions about whether to continue investing in Canada's health research ecosystem.

¹ Tran, D.T. et al, The Costs of Industry-Sponsored Drug Trials in Canada, PharmacoEconomics Open (2020) 4: 353- 359: https://www.researchgate.net/profile/Dat_Tran13/publication/334373055_The_Costs_of_Industry-Sponsored_Drug_Trials_in_Canada/links/5d26033f92851cf44077adco/The-Costs-of-Industry-Sponsored-Drug-Trials-in-Canada.pdf

Importantly, some of our members have seen a significant reduction in research investments from the private sector in recent years. For instance, BioCanRx, a network of Canadian researchers working to accelerate the development of immune oncology therapies in Canada, has seen a 50% reduction in the in-kind contributions of approved drugs from the private sector (which only they can provide). This is concerning.

In these challenging times, we need a lot more research to help get us through the pandemic and prepare us for imminent health challenges, such as the forthcoming tsunami of cancer that we are expecting in the coming years.

In this context, the CHRF was encouraged by the recent announcement of a federal Biomanufacturing and Life Sciences Strategy. This is an initiative that will greatly support our country's health and economic objectives in the years to come.

However, to support the success of this initiative, it would be irresponsible to move forward on these regulatory changes without first conducting a proper impact assessment. This assessment needs to be carried out by credible, independent experts (e.g., the Auditor General of Canada, Canadian Institutes of Health Research, etc.) in a transparent and open manner, and subject to peer review – ideally international peer review, which is standard practice in the research field, and which can help mitigate any potential conflicts of interest.

As an immediate first step, we recommend that the PMPRB halt its planned changes to its Guidelines and avoid any additional regulatory initiatives until this impact assessment has been conducted.

Thank you for the opportunity to provide our feedback on this important issue.

Sincerely,

The Canadian Health Research Forum

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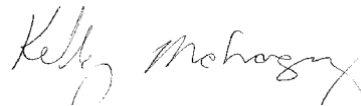
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