

VIA EMAIL (pm@pm.gc.ca) AND AVAILABLE AT WWW.RAREI.CA

November 9, 2020

The Right Honourable Justin Trudeau, P.C., M.P.
Prime Minister of Canada
80 Wellington St,
Ottawa, ON K1P 5K9

Subject: Revisions need to be made to the *Patented Medicines Regulations* to improve and save lives

Dear Prime Minister,

On behalf of the Canadian Forum for Rare Disease Innovators (RAREi) – a group of twelve global biopharmaceutical companies with a specific focus on researching, developing, and commercializing treatments for rare diseases – I am writing to request that you revisit the amendments to the *Patented Medicines Regulations* scheduled to come into force on January 1, 2021.

I want to start by commending your government's response to the unprecedented public health crisis created by the COVID-19 virus, and your plan to move forward on a rare disease strategy. RAREi members are committed to supporting your efforts to combat the pandemic, and some members are currently testing their therapies to see if they could be useful in treating COVID-19 or developing vaccines that will allow Canadians work and socialize with our colleagues, friends and families once again. We are also pleased that your government reiterated its commitment to adopt a national rare disease strategy in its recent Speech from the Throne. We look forward to engaging with your government on this strategy and hope that it can be implemented in the very near term to ensure that Canadians have access to the rare disease treatments they need.

However, we remain gravely concerned about your government's intention to implement the amendments made to the regulations, in part because the Canadian market will not include many new rare disease medicines to fund when the planned \$500 million budget for rare disease treatments comes online in 2022. In fact, the amendments are already negatively affecting patient access to medicines,¹ clinical trials² and the life sciences industry and the biopharmaceutical sector as a whole³ during a critical time for Canada's health care system and economy given COVID-19.

Our concerns regarding your government's new price control regime are shared by a wide array of stakeholders, including provincial governments and agencies, clinicians, researchers and patients. Almost 90% of stakeholder submissions provided in the context of the Patented Medicine Prices Review Board's (PMPRB's) most recent consultation were either opposed to or raised serious concerns with the revised guidelines, which will be used to implement new regulatory measures.⁴

The most problematic aspect of the pending regulatory changes is **the new economic factors included in the August 2019 amendments (i.e., pharmaco-economic value, market size, and GDP/GDP per capita)**. They create a complex and unpredictable pricing framework that will block reasonable pathways to commercialization of new treatments, thereby depriving Canadian patients of access to important new medicines. We encourage you to work with your cabinet colleagues to **remove the new economic factors from the *Patented Medicines Regulations***.

We want to emphasize the urgency of this issue given there are less than two months left to implement a more balanced approach.

We hope we can count on your leadership and support to change the regulations so that all Canadian patients, including those with rare diseases, can receive timely access to the medicines they need to survive and get better.

Yours sincerely,



Bob McLay

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c.c. The Hon. Chrystia Freeland, P.C., M.P., Deputy Prime Minister and Minister of Finance
The Hon. Patty Hajdu, P.C., M.P., Minister of Health
The Hon. Navdeep Bains, P.C., M.P., Minister of Innovation, Science and Industry

About RAREi

RAREi is an informal network of research-based bio pharmaceutical innovators committed to monitoring, responding and shaping policy issues in the Canadian rare disease environment. The members of RAREi are Alexion Pharma Canada Corp., Amicus Therapeutics, Inc., Biogen Canada Inc., Biomarín Pharmaceutical Inc., Horizon Therapeutics Canada, Ipsen Biopharmaceuticals Canada Inc., Mitsubishi Tanabe Pharma Canada Inc., Recordati Rare Diseases Canada Inc., Sanofi Genzyme, Sobi Canada Inc., Ultragenyx Pharmaceutical and Vertex Pharmaceuticals (Canada) Inc. For more information, see www.rarei.ca.

REFERENCES

¹ Life Sciences Ontario Webinar : *New Medicine Launches: Canada in a Global Context*, June 2020 : https://lifesciencesontario.ca/wp-content/uploads/2020/06/EN_LSO_Global-Launch-Benchmarking_Webinar-June22-20_Final.pdf

² Rawson, Nigel SB (2020). *Clinical Trials in Canada Decrease: A Sign of Uncertainty Regarding Changes to the PMPRB?* Canadian Health Policy, April 2020. Toronto: Canadian Health Policy Institute: https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada-decrease--a-sign-of-uncertainty-regarding-changes-to-the-pmprb-.html?buy_type=

³ Survey conducted by the research firm Research Etc. for Life Sciences Ontario, February 2020: <https://lifesciencesontario.ca/news/new-federal-drug-pricing-rules-are-already-delaying-medicine-launches-and-costing-jobs-in-canada-survey-reveals/>

⁴ PMPRB website, feedback received in response to its revised draft guidelines consultation: <https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html>