

May 21, 2021

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

Subject: Request for a delay in the implementation of the *Patented Medicines Regulations*

Dear Prime Minister,

On behalf of the Canadian Forum for Rare Disease Innovators (RAREi), I am writing to request a delay in the implementation of the amendments to the *Patented Medicines Regulations*, which are now scheduled to come into force on July 1, 2021. RAREi is an informal network of 13 Canadian biopharmaceutical companies that develop and commercialize therapeutics for rare diseases. Several RAREi members are also producing innovative therapeutics for preventing or treating COVID-19.

Your government previously made the decisions to delay the implementation of these regulations during the first and second waves of the pandemic in an effort to avoid imposing additional burden on pharmaceutical companies and to allow our sector to focus on responding to the crisis. As we are still in the midst of a devastating third wave of the pandemic, the rationale to delay the regulations remains the same.

The entire pharmaceutical supply chain has been challenged to meet Canadian and global needs for sustainable and reliable access to needed treatments during a very uncertain time. These new regulations will add additional and unnecessary compliance challenges for our sector that will ultimately undermine our efforts to support Canadian patients and health systems during this critical period.

A delay would provide the government with an opportunity to take the time to rethink its approach regarding the pricing regulations because the current environment has significantly changed since the regulations were first devised in 2017. Specifically, the pandemic has demonstrated that having a strong biopharmaceutical sector is critical for Canada's ability to respond to health challenges and to ensure our economic security.

As well, we need to ensure that the federal pricing regulations do not derail efforts led by Health Canada to develop a national rare disease strategy. This strategy is key to helping improve access to new treatments for some of Canada's most vulnerable patients. However, it will be impossible to achieve this critical goal if the government moves forward with the implementation of the pricing regulations on July 1, 2021, as they will discourage or delay the commercialization of new treatments in Canada, especially for rare diseases. In fact, although the new pricing regulations are not yet in force, the uncertainty they

have generated since their adoption in 2019, have already cast a chill on the sector and delayed or prevented access to orphan medicines for Canadians.

In this context, RAREi members stand ready to work with your government to address the outstanding issues that prompted the regulations. We believe that a delay will present an opportunity for additional dialogue focused on how we can work together to achieve your government's medicine affordability objectives, while ensuring that Canadians, including those who suffer from rare diseases, have the most optimal access to medicines that can save or improve their lives.

Yours sincerely,



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c.c. The Hon. Chrystia Freeland, P.C., M.P., Deputy Prime Minister and Minister of Finance
The Hon. Jean-Yves Duclos, P.C., M.P., President of the Treasury Board
The Hon. Patty Hajdu, P.C., M.P., Minister of Health
The Hon. François-Philippe Champagne, 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 Akcea Therapeutics Canada, Alexion Pharma Canada Corp., Amicus Therapeutics, Inc., Biogen Canada Inc., Biomarin 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.