RAREi
THE CANADIAN FORUM FOR
RARE DISEASE INNOVATORS

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

December 16, 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,

Thank you for acknowledging RAREi's letter of November 9, 2020 (see a copy below) requesting your support in reconsidering recent amendments to the *Patented Medicines Regulations* and in particular the new mandatory economic factors tests to be applied to patented medicines. A copy of the original letter is attached for ease-of-reference.

While we understand your inclination to defer this request to the minister of health, we ask that you reconsider that approach for two reasons.

First, Health Canada and the minister's office have demonstrated a persistent unwillingness to engage in any meaningful dialogue with stakeholders regarding their legitimate concerns with the new regulations. This lack of dialogue has particular concern for the Canadian rare disease community in the context of the promised national rare disease strategy that will determine how your government's $500 million per year investment will be directed. There is a very real question regarding whether the pricing reforms will undermine that strategy by dissuading new innovations from coming to Canada.

Second, we believe that a whole-of-government approach is needed given the broad impact of the new regulations. They will have repercussions that go beyond the health care system. Your government will also need to ensure that its new regulations do not undermine the growing biomedical and life sciences ecosystem that has been painstakingly built across Canada in recent decades and that represents a key pillar for the economic recovery of our country post-COVID.

Moreover, the public policy rationale underlying the reforms has been the need to improve the affordability of medications in Canada. Yet, a recent Canadian Health Policy Institute analysis of patented medicines spending data in Canada indicated clearly that their share of total national health spending, national gross domestic product (GDP), and per capita spending in 2018 was either the same as, or lower than, they have been historically.[1] The report demonstrates emphatically there has been nearly no real

[1] Canadian Health Policy Institute, *Patented Medicines Expenditure in Canada 1990-2018*, December 2020: https://www.canadianhealthpolicy.com/products/patented-medicines-expenditure-in-canada-1990-2018.html.

growth in patented medication expenditure during the past 16 years despite the numerous benefits pharmaceutical innovation offers.

We want to stress as well that the life sciences ecosystem has a large economic footprint across the country, as it encompasses academic research centres, offshoot health research institutes and early-stage medical technology discovery companies, contract research and manufacturing and a variety of other enterprises that rely heavily on innovative pharmaceutical companies to sustain them.

Another big concern is the impact of the new regulations on clinical trials in Canada. Given pharmaceutical companies' ethical obligation to ensure that patients continue to receive a treatment following a clinical trial when the medicine is effective, companies need reasonable assurance that there will be a viable commercial pathway for this medicine in Canada. However, the new federal regulations create unreasonable business uncertainty and make it very challenging for companies to commercialize their new medicines and therefore also to conduct clinical trials in this country.

The new regulations are putting the Canadian clinical trials infrastructure at risk and consequently the health of Canadians and our life sciences sector that depend on them. In addition, we anticipate a substantial reduction in the number of new product launches in Canada, depriving patients of potentially life-changing new treatments. The cumulative impact of the regulations on health care, the life sciences sector and the economy as a whole will be dire. That is why we believe that Health Canada's approach to pharmaceutical pricing needs more oversight, consideration and leadership from you, your office and central agencies within the federal government. This is the only way that the wider implications can be properly assessed, and hopefully lead to a reconsideration of the regulations.

As we stated previously, we hope we can count on your leadership and support to change the regulations by removing the new economic factors – the most problematic aspect of the reform – 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
Chair of the Canadian Forum for Rare Disease Innovators and General Manager, Sobi Canada Inc.
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c.c. The Hon. Chrystia Freeland, PC, MP, Deputy Prime Minister and Minister of Finance
The Hon. Patty Hajdu, PC, MP, Minister of Health
The Hon. Navdeep Bains, PC, MP, 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.

Copy of Email Correspondence from R. Dix, Executive Correspondence Officer, November 23, 2020

-----Original Message-----
From: Prime Minister/Premier Ministre <PM@pm.gc.ca>
Sent: Monday, November 23, 2020 1:06 PM
To: Bob Mclay <Bob.Mclay@sobi.com>
Cc: Patricia A. Hajdu <Hcminister.ministresc@canada.ca>
Subject: Office of the Prime Minister / Cabinet du Premier ministre

Dear Mr. McLay:

On behalf of Prime Minister Justin Trudeau, I would like to acknowledge receipt of your letter of November 9, 2020, regarding the Patented Medicines Regulations.

Thank you for taking the time to write to the Prime Minister. You may be assured that your comments, offered on behalf of the Canadian Forum for Rare Disease Innovators, have been carefully reviewed.

I note that you have also sent a copy of your correspondence to the Honourable Patricia A. Hajdu, Minister of Health. While the Prime Minister appreciates being made aware of your concerns, he will leave the matter you raise to be considered by Minister Hajdu.

Once again, thank you for writing.

R. Dix
Executive Correspondence Officer
for the Prime Minister's Office
Agent de correspondance
de la haute direction
pour le Cabinet du Premier ministre