March 12, 2021

Hon. François-Philippe Champagne
Minister of Innovation, Science and Industry
C.D. Howe Building
235 Queen Street
Ottawa, Ontario K1A 0H5

Subject: Consultation on the creation of new biomanufacturing capacity for Canada

Dear Minister Champagne,

On behalf of the Canadian Forum for Rare Disease Innovators (RAREi), thank you for the opportunity to contribute to Innovation, Science and Economic Development Canada’s (ISED) discussions on building Canada’s biomanufacturing capacity.

RAREi is a group of innovators of rare disease treatments in Canada. Its members are biopharmaceutical companies that are committed to improving the lives of patients around the world living with rare disorders by researching, developing and commercializing rare disease treatments.

We would like to start by commending the Government of Canada for its tireless efforts throughout the COVID-19 crisis. We also support in principle what ISED is trying to achieve through the abovementioned initiative. Building Canada’s biomanufacturing capabilities will support this country’s response to the current crisis and, if done right, will make it better prepared for the health challenges of the future.

However, RAREi believes there is an opportunity to be more ambitious. Canada has very innovative rare disease development companies that have made remarkable advancements throughout the years. Given the chance, those companies can compete globally, but they need the right conditions to support growth.

From a rare disease perspective, it is important to note that the nature of biomanufacturing is changing. At the moment, some rare disease therapies, which involve reengineering or changing genetic samples, are being sent to the US to be finished. We can and should be able to do more of this in Canada. In this context, the focus of this initiative should not just be about building new factories – we need to have capacity to manufacture in a clinical environment where care is given. For the purposes of this initiative, this would require a much broader focus on the entire life sciences ecosystem.

Moreover, RAREi believes that an exclusive focus on this one aspect of the life sciences ecosystem in isolation will not produce the expected results. The discussion paper for this consultation notes that despite initiatives and investments in recent years in Canada’s life sciences sector, specific gaps remain within Canada’s biomanufacturing landscape.
The question we need to ask ourselves is why? For decades, Canada has been recognized as a top global destination to conduct research activities. It has excellent research infrastructure, top STEM graduates, and a history of scientific breakthroughs, including in the rare diseases space. Why then do we not already have a robust life sciences ecosystem in Canada with domestic manufacturing capabilities like those seen in other global jurisdictions?

While Canada certainly has all the right ingredients to become a global life sciences powerhouse, what has been missing, and what has prevented us from getting to where we need to be, is a competitive regulatory and procurement environment capable of unlocking the life sciences sector’s true growth potential.

While some of the initiatives outlined in the discussion paper may attract companies in the short-term, what will keep them here in the long run is a competitive policy environment that values innovation, attracts investment, supports the growth of domestic firms, and ensures early health system adoption of new health innovations. The government’s focus on building biomanufacturing capacity without addressing the many other underlying challenges facing our sector is like building a house without a foundation – it won’t last.

In this context, the current proposed reform of the Patented Medicines Prices Review Board (PMPRB) will continue to serve as an unnecessary obstacle that will significantly diminish Canada’s access to medicines, research investments and life sciences growth.

These reforms offer very little predictability in terms of price compliance for developers of new treatments, particularly those operating in the rare diseases space. The range of mandatory regulatory price decreases, compared to current levels, is very concerning and makes it almost impossible, in many cases, to develop a business case globally for the deployment of new treatments and research investments in Canada.

For this reason, and as part of ISED’s current efforts to build Canada’s biomanufacturing base, RAREi strongly recommends that the proposed PMPRB changes be reassessed. In particular, we strongly recommend that the new economic factors be repealed from the Patented Medicines Regulations until their effect on the life sciences ecosystem and access to treatments and clinical trials have been appropriately assessed.

At the same time, RAREi believes that a comprehensive pan-Canadian rare disease strategy is required in Canada in order to address the current policy limitations that exist. Even in the absence of the problematic federal pharmaceutical price review reforms, there is a gaping need for a new whole-of-government approach to managing and developing rare disease treatments in this country. Therefore, RAREi is very encouraged by your government’s intention to develop a national strategy for access by Canadians to rare disease treatments. However, we believe that effort should be co-led by your ministry and Health Canada and that the federal role should be to act as a facilitator for a true pan-Canadian strategy for rare diseases. The resulting strategy should be co-created by affected stakeholder
groups and address not just rare disease treatment access, but also early detection and prevention, provision of equitable care and support for innovative research.

Thank you for the opportunity to contribute to these important discussions. Please do not hesitate to reach out to our group for more information on its position.

Yours sincerely,

[Signature]

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