MINISTRY OF FOREIGN AFFAIRS OF DENMARK
THE TRADE COUNCIL

September 14, 2018

Lindsay Wild
Director, Regulatory Reviews
Regulatory Affairs Sector
Treasury Board of Canada Secretariat

Subject: Regulatory modernization — Request for stakeholder comments

Dear Ms. Wild,

On behalf of the Danish Life Sciences Forum (the Forum), thank you for the opportunity to provide input on the Treasury Board Secretariat's regulatory modernization initiative.

The Danish Life Sciences Forum was created earlier this year as a way for Danish life sciences companies to collaborate around shared opportunities and challenges in the Canadian marketplace, and build on their foundations in Denmark and experience globally. With the support of the Danish Trade Council, which acts as the forum secretariat, the group currently consists of Novo Nordisk Canada Inc., Leo Pharma Inc., and Lundbeck Canada – all foundation owned companies that are beholden to all societal stakeholders, and with a long-term mission to find cures in their therapeutic areas. Ultimately, the Forum hopes to work with government partners to increase trade in life sciences services, R&D and ensure everyone has equitable access to medicines.

Our submission is complementary to that of our industry association, Innovative Medicines Canada (IMC), and focuses on one of the three key sectors that have been targeted for the three-year regulatory review process: health and bio-sciences. **We would like to use this opportunity to draw your attention to one specific and emerging regulatory irritant that runs contrary to your efforts to streamline regulation in our sector: Health Canada's proposed reform of the Patented Medicine Prices Review Board (PMPRB).**

Issue summary

The PMPRB is an independent, quasi-judicial, federal agency that regulates the prices of patented drugs in Canada. Specifically, the agency sets maximum prices for new drugs entering the Canadian market based on their therapeutic value and their prices relative to a basket of seven other comparator countries (currently France, Germany, Italy, Sweden, Switzerland, the UK and the US).

In December 2017, Health Canada issued draft regulatory amendments to change the PMPRB pricing framework with the objective of improving the affordability, accessibility and appropriate use of prescription drugs. Key proposed changes include modifying the current basket of comparator countries by removing the US and Switzerland, while adding seven new countries. In addition, new economic criteria have been proposed for calculating maximum prices, including cost-effectiveness criteria, Canadian gross domestic product, and market size. The new system will apply to both new medicines entering the market as well as existing medicines already sold in Canada. In addition, the PMPRB will be able to continually reassess maximum prices based on a broad range of discretionary factors.

Potential impacts of PMPRB reform efforts

The biopharmaceutical industry is one of the most regulated industries in Canada. Companies must navigate through a litany of regulatory obstacles and a long and complicated drug review process that delays market access and imposes significant compliance costs. The proposed new price control regime adds an unprecedented layer of red tape and uncertainty to an industry already impacted by a challenging business and policy environment.

To illustrate the compliance burden, under the current system the PMPRB requires manufacturers to submit a variety of data, including semi-annual sales, revenue data, and international prices from seven countries for all patented products. Generating this information is already onerous and time-consuming. Under the new system, the new semi-annual reporting regime will require manufacturers to report five additional countries, along with reporting of health-economic models and market forecasts, and non-transparent sales and revenue data, split by payer type. This level of sophisticated data reporting may require substantial changes to companies' financial reporting systems. In addition, some countries don't have formularies written in English, requiring costly and time-consuming translation on a regular basis.

The government predicts a 10% gradual drop in industry revenues as a result of the new pricing system[i]; however, other estimates predict a sharp revenue drop of approximately 30%[ii], and potentially higher now that we have learned how Health Canada intends to operationalize the regulations. The proposed changes to the PMPRB are overly complex, burdensome, and largely unnecessary to achieve Health Canada's stated objectives. Moreover, they will create an unstable and unpredictable regulatory framework that will severely stunt the industry's long-term growth and competitiveness. This would be unfortunate as Canada has a robust life sciences industry, with significant growth potential.

The sector already supports over 30,000 jobs, drives over $19 billion in annual economic activity, and ranks 3rd in the country in terms of combined total research and development (R&D) spending.[iii] When combined with its emergence as a world leader in artificial intelligence (AI) and other disruptive technologies, Canada has an important opportunity to use its life sciences industry to become a global hub for research and innovation in health.

However, the steep decline in industry revenues resulting from Health Canada's proposal will hurt the industry's ability to invest and expand its presence in the Canadian market. It will also require significant cost-cutting measures. Companies will be forced to downsize workforces and scale back their investments in Canada. This means less investment in research and development, fewer clinical trials, and reduced health sector partnerships.

The proposed changes will also lead to reduced access to new and existing medicines for patients. At the moment, Canada is one of the first countries in the world where companies decide to launch new

medicines. A significant decrease in pharmaceutical industry revenues, along with the increased uncertainty and regulatory burden that will result from the proposed reform, will make Canada a less attractive place for launching new therapies. This means potential delays in new drugs coming to Canada or some new drugs not coming at all. The decision to apply the new rules retroactively to medicines already on the market could also mean that some medicines are removed from the Canadian market entirely. This will have dire consequences for patients and the health system.

Solutions

To ensure Canada remains a premier location for life-sciences companies to invest, innovate and operate, the federal government should consider taking steps to improve the ease of doing business by removing unnecessary regulatory barriers across the entire value chain of the industry, including research, regulatory approval, pricing, evaluations, and funding decisions. **As a matter of priority, Health Canada's proposed price control system for patented medicines should be paused and reconsidered.**

Moving forward, better alignment between government initiatives will help lead to better policy outcomes. Trying to grow the health and bio-sciences sector by removing red tape, while simultaneously adding an unprecedented layer of red tape to the industry is like stepping on the gas and breaks at the same time – it will not help us move forward.

There are ample opportunities for regulatory experimentation in our sector that can help achieve the dual objective of making medicines more affordable while attracting innovation. To that end, we welcome the federal government to:

- Work with our industry association, IMC, to find a novel approach to achieving its stated aims of improving the affordability, accessibility, and appropriate use of medicines;
- Learn from the regulatory approaches of other countries, including best practices and lessons learned. Based on our experiences in Denmark, innovation is an important economic growth and trade driver that should be cultivated through creative and market-based approaches to regulation and health system innovation.

We would welcome the opportunity to meet in person should you wish to hear about Denmark's system, which seems to have found a balanced approach between stimulating innovation, improving affordability and access of medications, and growing the life sciences sector.

On behalf of the Danish Life Sciences Forum, thank you once again for considering our input on the Treasury Board's regulatory modernization initiative.

Sincerely

Kerry

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[i] Health Canada's Regulatory Impact Analysis Statement on the proposed regulations: http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html

[ii] PDCI Market Access, Proposed Amendments to the Patented Medicines Regulations: A critical appraisal of the cost-benefit analysis, 2018: http://www.pdci.ca/pdci-critical-assessment-pm-regs-amendments/.

[iii] Ernst & Young, Innovative Medicines Canada Data Analytics and Members' Economic Footprint and Impact in Canada, 2017: http://innovativemedicines.ca/wp-content/uploads/2017/10/20171030_ EY-REPORT_IMC_FINAL.pdf.