INNOVATIVE MEDICINES CANADA | MÉDICAMENTS NOVATEURS CANADA

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Mr. Brennen Young
Director, Regulatory Cooperation
Regulatory Affairs Sector
Treasury Board of Canada
140 O'Connor Street
Ottawa, ON K1A 0R5

Via email: rcd-dcmr@tbs-sct.gc.ca

RE: Canada-U.S. Regulatory Cooperation Council Consultation

Dear Mr. Young:

On behalf of Innovative Medicines Canada (IMC), thank you for the opportunity to provide comments on the Canada-U.S. Regulatory Cooperation Council (the RCC) and future opportunities for bilateral regulatory cooperation.

In February 2017, Prime Minister Trudeau and President Trump renewed the Canada-U.S. commitment to advancing bilateral regulatory cooperation. Canada's Treasury Board notes this commitment "provides a solid basis for regulators in both countries to continue the work of the Canada-U.S. RCC."

We are supportive of this renewed focus on regulatory cooperation and the RCC. We would also take this opportunity to congratulate Health Canada on its ongoing leadership and work towards full membership in the International Council for Harmonisation.

However, we have urgent concerns regarding recent regulatory developments in Canada that heighten business and regulatory uncertainty and could limit the viability of the Canadian market for many innovative products. New mandate changes and emerging Canadian regulatory divergences from the U.S. may impede meaningful regulatory cooperation, and we encourage Canada to reevaluate these policy initiatives given their potential impact.

Canadian Regulatory Divergence and Risks

Price Regulation and the PMPRB

Canada has recently proposed regulatory changes to the Patented Medicine Prices Review Board (the PMPRB) that would significantly expand the Board's regulatory mandate. The proposals lack clarity and introduce considerable uncertainty regarding the future path for bringing innovative medicines to Canadian patients.

For example, it has been proposed that the PMPRB would no longer be required to assess excessive patented medicine pricing with reference to a "basket" of nations that includes (together with six other nations) the U.S. Canada and the U.S. share similar mixed drug systems with significant private payer and public payer markets. Canada has proposed to remove the U.S. as a PMPRB pricing comparator country.

Instead, Canada would align its price regulation with South Korea, Spain and other countries that have much different pharmaceutical systems and, in some cases, different levels of economic development, than Canada and the U.S.

Canada is also proposing to institute price ceilings based on cost-effectiveness thresholds that would significantly diminish incentives for innovation and which may lead to fewer innovative medicines being launched in Canada. This could impact the future viability of numerous drugs in Canada – particularly those for rare diseases and for oncology treatments. This approach would also create a *sui generis* Canadian price ceiling criteria: while cost-effectiveness thresholds are used downstream in other nations, their utilization as part of an initial price setting mechanism would be unique in the world.

Taken as a whole, the proposed PMPRB changes will increase Canada-U.S. regulatory asymmetries. They may also create new border enforcement challenges by incenting inappropriate cross-border trade in innovative medicines. We encourage Canada to consider the implications of the proposed PMPRB changes to patients and to Canada's trading partners, and to reconsider how to proceed as part of a more balanced approach.

Blurring Health Canada's Regulatory Review Mandate

Canada has also initiated a reform effort regarding the regulatory review of drugs and devices that would seem to put it out of step with other international regulators, including the U.S. Food and Drug Administration (FDA). Canada's highly-regarded drug safety and efficacy regulator (Health Canada, Health Products and Food Branch, HPFB) faces increasing political pressure to base its activity on non-regulatory criteria, such as "healthcare system need" and "affordability." This blurs Health Canada's regulatory mandate with budgetary cost-containment. IMC is concerned this could lead to inappropriate cost-based prioritization within the regulatory system. "Healthcare system need" and "affordability" are indeed important factors for governments to address with respect to innovative medicines, but they are best addressed by Canadian public and private payers.

International regulators, including the European Medicines Agency, have consistently upheld the importance of a clear separation between regulatory review, and payer-related health technology assessment (HTA) functions. Canada should not depart from these important international norms, and should preserve clear and distinct roles for its national safety regulator and HTA agencies.

Health Canada can maintain a priority review capacity with the overriding criteria to address urgent unmet patient needs regarding the "treatment, prevention or diagnosis of serious, life-threatening or severely debilitating disease or conditions." In IMC's view, the most critical "healthcare system need" and appropriate basis for prioritization under Health Canada's regulatory mandate relates to patients suffering from diseases or conditions that are "not adequately managed by a drug marketed in Canada." [1]

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[1] *Health Canada, "Guidance for Industry - Priority Review of Drug Submissions"* https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/priority-review/drug-submissions.html

Incorporating measures to address perceived economic healthcare system needs into regulations or Health Canada guidance documents could also inappropriately alter HPFB's mandate. We urge Health Canada to clarify that it will not use cost or cost-effectiveness to prioritize regulatory reviews or otherwise limit the ability of its trading partners to access the regulatory system.

Orphan Drug Regulation

Canada recently discontinued plans for a regulatory framework for drugs for rare diseases (also known as "orphan drugs"). Since 1992, the U.S. Orphan Drug Regulation has accelerated the development of these drugs in the U.S., with benefits for patients internationally. For many years, Canada also considered a parallel framework that could have advanced orphan drug development and helped to achieve alignment with the U.S. However, this workstream has been discontinued with little explanation provided to patients suffering from rare diseases. This is a significant missed opportunity for Canada, and, with no orphan drug framework, makes the country an international outlier among developed nations. We would welcome an opportunity to work with government and the patient community to renew this important policy initiative.

Intellectual Property Regulation

As part of its treaty commitments under the Canada-European Union (EU) Comprehensive Economic and Trade Agreement (CETA), Canada recently implemented a version of patent term restoration by providing up to two years of intellectual property (IP) protection to offset some of the regulatory and other delays that erode patent life. While this marks modest progress on better IP protection, Canada is still well short of the U.S. and general international standard of up to five years of patent term restoration (granted by way of certificates of supplementary protection (CSPs), in the Canadian context). We encourage Canada to continue to bring its life sciences IP environment into line with those of our major trading partners. We also encourage Canada to remove onerous and unnecessary red tape, such as time-limited filing requirements for CSP eligibility, which are not a prerequisite for patent term restoration in the EU or the U.S.

Current RCC Workstreams

Innovative Medicines Canada encourages the acceleration of current RCC workstreams. IMC members note that the workstream on Common Electronic Submissions Gateway for Pharmaceuticals and Biologics has been successful, and is an example of expediting the process of regulatory filings. We encourage more attention and tangible progress on workstreams regarding Good Manufacturing Practices and mutual reliance on inspection-related activities. We would welcome ongoing technical dialogue with regulators in these areas.

New Technologies

We encourage Canada to align its regulatory approach regarding new technologies with emerging directions from FDA wherever possible. For example, the FDA has begun to review and has recently approved cellular

and gene-based therapies. We encourage Canadian regulators to consider how to leverage FDA experience in this regard and explore collaborative approaches to regulating and facilitating these important new technologies. More generally, we would encourage ongoing multi-stakeholder dialogue on future regulatory approaches in the context of precision medicine.

Thank you again for this opportunity to comment on Canada-U.S. regulatory cooperation efforts. We would welcome an opportunity to discuss these perspectives in greater detail and explore other opportunities to reduce regulatory burden and accelerate drug reviews. If you have any questions or wish to discuss our submission further, please contact me at (613) 236 0455, x 425 or by email at dhamill@imc-mnc.ca.

Sincerely,

Declan Hamill
Vice President, Legal, Regulatory and Compliance
Innovative Medicines Canada

c.c. Ambassador Kelly Craft, Ambassador of the United States to Canada
Ambassador David McNaughton, Ambassador of Canada to the United States
Cathy Parker, Director General, Biologics and Genetic Therapies Directorate, Health Canada
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