June 12, 2023

Tina Green
Assistant Secretary, Regulatory Affairs
Regulatory Policy and Cooperation Directorate
Treasury Board of Canada Secretariat
90 Elgin Street
Ottawa, ON K1A 0R5
By email: regulation-reglementation@tbs-sct.gc.ca

Dear Ms. Green,

On behalf of Innovative Medicines Canada (IMC) and its membership, I am writing with respect to the consultation for the upcoming *Annual Regulatory Modernization Bill*, launched March 27, 2023.

IMC is the national association representing the voice of Canada's innovative pharmaceutical industry. The association advocates for policies that enable the discovery, development, and delivery of innovative medicines and vaccines to improve the lives of all Canadians and supports the members' commitment to being a valued partner in the Canadian healthcare system. The association represents companies which support 107,000 high-quality, well-paying jobs in Canada and invest $2.4 billion in R&D every year. Collectively, our members contribute $15.9 billion per year to Canada's knowledge-based economy.

IMC supports the Government of Canada's efforts to improve how federal regulatory systems keep pace with rapid innovation and evolving regulatory environments, while maintaining protections for Canadians' health and safety. We also welcome a whole-of-government approach to granting all federal regulatory organizations the authority to 1) create regulatory sandboxes; and 2) incorporate by reference internal government documents. Cohesive and consistent action will serve to support regulatory agility in a manner which reduces unnecessary or duplicative administrative burden, improves competitiveness, and supports innovation.

IMC is already deeply engaged in Health Canada's initiatives to create an agile regulatory system. Most recently, in response to the COVID-19 pandemic, Health Canada successfully piloted tailored regulatory approaches to safely bring new products to market and respond quickly to the public health crisis. Subsequently, we welcomed Health Canada's recent consultation with respect to the *Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Agile Licensing)* which seeks to embed authorities under the COVID-19

interim orders into regulation. This initiative is necessary and welcomed, and we are committed to ongoing dialogue with Health Canada as it considers stakeholder input with respect to its regulatory reform proposals.

1. **Proposal to set up regulatory sandboxes**

The creation of regulatory sandboxes allows for the testing of new regulatory frameworks that provide the flexibility to address emerging innovations in life sciences. In June 2019, Health Canada created a regulatory sandbox to authorize Advanced Therapeutic Products (ATP) through the utilization of a regulatory sandbox. IMC remains engaged with Health Canada as it defines controls for ATPs.

Looking ahead, Health Canada needs to think beyond the current frameworks and be prepared for innovations that will be developed following, among other factors, the use of Artificial Intelligence (AI) in research, the development of digital health solutions, and the advancement in diagnostic testing. Additionally, Health Canada should develop an approach to ensure an efficient and fast review and approval of new innovative therapies, such as precision medicines, that are not easily managed using the current regulatory framework. Unless regulatory frameworks are created or modified to address new technologies, access to new treatments for Canadian patients will be precluded or significantly delayed.

In addition, while regulatory sandboxes create an agile framework to address innovation in a manner outside of the conventional regulatory process, regulators must still be transparent about their decision-making and outcomes when utilizing these sandboxes so that stakeholders, the public, and the broader system can hold regulators accountable for decisions impacting them. Furthermore, regulators must also engage with stakeholders during their decision-making and consult with them when contemplating changes to how a particular sandbox will operate, all while protecting confidential business information and trade secrets.

2. Proposal to grant all federal regulatory organizations the authority to incorporate by reference (IBR) internal government documents

IMC and its members welcome the use of IBR by Health Canada in situations where technical information or requirements are expected to change over time. While there are benefits to utilizing this policy tool to create agility outside of the regulatory process, it will remain critical to consult with key stakeholders from the life sciences sector, such as IMC, to ensure that controls introduced through IBR are clear, accurate and produce their intended effect.

To this end, IMC recommends that Health Canada consider designing and implementing a multi-stakeholder consultation process specific to each document to measure the costs, benefits and results against the policy intent of the department's proposals. This will facilitate

an inclusive and considered approach to the creation of any internal government documents on the basis of collective experience.

Conclusion

IMC supports the Government of Canada's efforts to improve how the regulatory system keeps pace with rapid innovation and evolving regulatory environments by utilizing policy tools such as regulatory sandboxes and IBR of internal documents.

While building on Health Canada's leadership at the regulatory level, IMC notes that other steps in Canada's Health Technology Assessment, negotiation and listing processes are also critical to bring innovative treatments to Canada. IMC believes that much more must be done to ensure faster and more predictable access to innovative medicines for Canadians. Of the new medicines that are already available internationally, Canadian patients wait twice as long (732 days) as patients in most peer countries for public plan access to those medicines following Health Canada approval. Canada ranks last in the G7 and 19th out of 20 peer OECD countries in respect of the time it takes for patients to get access to new medicines following regulatory approval.

Innovative responses to the COVID-19 emergency provide us with important insights into how agility can be incorporated into regulatory processes in a manner which responds to innovation while protecting the health and safety of Canadians. Advancements in science and research over the next decade will need to be anticipated and accommodated. Looking ahead, Canada can be progressive and forward thinking by systemically undertaking horizon-scanning and scenario analyses to anticipate and monitor high-impact innovations in the life science sector.

IMC recommends the continued strengthening of institutional foundations which enable co-operation and joint approaches with the provinces, territories, and international regulators through tools such as the use of foreign decisions, parallel review mechanisms, and mutual recognition agreements. Further, strengthened multi-jurisdiction collaboration, particularly with respect to the use of digital tools, can facilitate the utilization of high-quality data available across Canada and internationally to inform decision-making.

In conclusion, IMC believes that Canada needs to continue to be a welcoming and supporting environment for innovative medicines, vaccines and medical devices that enhance the health of Canadians. Canada must continue to be at the forefront of regulatory innovation and agility, and IMC remains committed to support these efforts. We support the use of agile tools such as regulatory sandboxes and IBR of internal documents to help keep pace with medical innovation.

IMC thanks the Government of Canada for the opportunity to respond and looks forward to continued dialogue to ensure the development and implementation of such regulatory changes are successful in achieving Government priorities.

Please do not hesitate to contact IMC should you have any questions or comments.

With Kind Regards,

Declan Hamill
Vice President, Policy, Regulatory and Legal Affairs