June 7, 2019

The Honourable Chantal Petitclerc  
Chair, Standing Committee on Social Affairs, Science and Technology (SOCl)  
Senate of Canada  
Ottawa, ON K1A 0A4  
Via email: Chantal.Petitclerc@sen.parl.gc.ca

Re: Bill C-97, Subdivision C of Division 9 (amendments to the Food and Drugs Act)

Dear Senator Petitclerc:

Innovative Medicines Canada (IMC) sincerely appreciates the invitation from the Committee to participate in its public hearings on the above noted Bill. We regret that we could not appear at the Bill c-97 hearing but offer the following comments for consideration by the Committee.

IMC is the national voice of Canada’s innovative pharmaceutical industry. We advocate for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our members’ commitment to being valued partners in the Canadian health and regulatory system. Furthermore, IMC members play an important role in Canada’s health sector ecosystem and overall economy. The Canadian pharmaceutical industry supports 34,000 high-quality, well-paying jobs in Canada. Our industry creates an overall economic impact of more than $3 billion a year on Canada’s economy.

We were pleased to see the “regulatory roadmaps” announced in Budget 2019. Specifically, it was important that the roadmaps would address stakeholder issues and irritants, as outlined in the Health and Biosciences Economic Strategy Table Report. It was encouraging that the concept of aligning regulations with industry realities is to be embedded in government approaches.

However, IMC would like to express its disappointment in the approach that has been taken given these draft changes were proposed without meaningful consultation with stakeholders. It is therefore of the utmost importance that stakeholders are consulted when implementation strategies are developed (whether in the form of amendments to regulations, development of policy or guidance documents, or other means).

Proposed Amendments to the Food and Drugs Act in Bill C-97

Subdivision C of Division 9 of Bill C-97 contains several significant additions to the Food and Drugs Act (FDA). While some of these changes had been discussed notionally with Health Canada, the specific changes and how they might be operationalized have not been discussed with any significant detail. The fact that these changes are included in a broad budget implementation bill effectively forecloses on any real opportunity to discuss the merits of the provisions.
Classification of products
The FDA regulates various product classes including food, drugs, cosmetics, and devices, each of which is defined in the Act. The proposed amendments introduce two changes in this regard: the power to designate classification; and the creation of a new class – “advanced therapeutic products”.

IMC is encouraged that Health Canada is intent on modernizing its regulatory framework to support the approval and introduction of advanced therapies in Canada. These proposed changes provide the Minister with significant new powers. It is true that the current classification system creates some difficulty in assessing some novel therapeutic technologies.

However, it is unclear how these powers will be operationalized. IMC will work with Health Canada to operationalize these new authorities. It is very important that Health Canada’s classification approach is aligned with, and harmonized with international regulators, particularly the U.S. Food & Drug Administration and European Medicines Agency.

Clinical Trials
The proposed amendments would prohibit clinical trials for drug, device, or prescribed food for a special dietary purpose unless an authorization has been issued, and the study is conducted in compliance with any terms and conditions imposed by that authorization. The purported goal of these changes is to introduce a flexible, risk-based oversight of the conduct of clinical trials in Canada.

Clinical trials make a major contribution to Canada’s research capability and the economy. They build expertise among healthcare professionals and ensure that we have strong research programs in our hospitals and universities. They also provide access to new and experimental treatments for patients, making them an important part of a physician’s practice. At any given time, there are more than 3,000 clinical trials underway in Canada, representing an investment worth in excess of $1.8 billion.

Canada’s clinical trial environment is complex, with many stakeholders: patients, academic researchers, independent research sites, industry, and government. This complexity has an impact on efficiency, costs and can slow the clinical trial process.

These amendments represent a significant change in Health Canada’s framework, and IMC will work with Health Canada to operationalize these changes. However, since Canadian clinical trials are typically part of global development processes, any new requirements should closely align with the U.S. and Europe to help maintain Canada’s global competitiveness as a destination for clinical trials.

Inspection Powers
The proposed amendments would replace the current “powers of inspector” provision. The new provisions provide that Inspectors will be formally granted powers to inspect relevant electronic documents and data. The bill also clarifies rules around physical site visits.

1 http://www.cctam.ca/about/history/
IMC members are subject to a high degree of regulatory scrutiny and are highly compliant with all regulatory requirements. Any changes should be made in such a way that inspections are more efficient and can be better aligned and coordinated between jurisdictions.

Thank you again for this opportunity to comment on the FDA amendments in Bill C-97. We look forward to further consultation with Health Canada on the implementation of these changes. In the meantime, if you have any questions or wish to discuss our submission further, please do not hesitate to contact us.

Sincerely,

Declan Hamill
Vice President, Legal, Regulatory & Compliance

cc: Daniel Charbonneau, Committee Clerk, SOCI