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Submitted e-mail to the Pan-Canadian Genomics Strategy Secretariat genomics-genomique@ised-isde.gc.ca

**Developing a Pan-Canadian Genomics Strategy: Innovative Medicines Canada Response**

Innovative Medicines Canada (IMC) is the national association of 49 biopharmaceutical and vaccine companies who are working steadfastly, with Canadian governments, to address the COVID-19 pandemic and bring a range of innovative cell and gene therapies and other precision medicines to Canadians. Guided by a strict Code of Ethical Practices, we work with governments, insurance companies, healthcare professionals and stakeholders to advance the field and enhance the wellbeing of Canadians. We are committed to being a valued partner within Canada's healthcare and innovation ecosystems.

IMC supports the creation of a Pan Canadian Genomics Strategy (PCGS) to help Canada advance its international leadership and increase capacity in genomics through commercialization and adoption. Innovation, Science and Economic Development Canada (ISED) notes the study of genomics is "the science that aims to decipher and understand the entire genetic information of an organism encoded in DNA and related molecules." Genomics research spans not only areas of disease treatment and public health but also food, agriculture and natural resources. Genomics is helping to advance precision medicine, improve the productivity and resiliency of forests, crops and livestock, create more sustainable energy and biomaterials, bioremediate contaminated sites, and protect the environment. Throughout the COVID-19 pandemic, genomics research has been instrumental in understanding the virus and vaccine development.

Developing a cohesive and impactful genomics strategy is one critical element of a broader and comprehensive approach that is needed for life sciences innovation in Canada. As noted in the 2021 Biomanufacturing and Life Sciences Strategy, Canada ranks fourth in global health and biosciences hubs but lags behind U.S., UK, and Germany. In order for Canada to utilize its expertise and grow into an international leadership role, the PCGS should promote and incentivize innovation and ensure that Canadian regulatory frameworks are aligned to this objective. A comprehensive approach to genomics and the broader life sciences can also support Canadian resilience in the context of potential future health emergencies.

The PCGS should align and build upon the five pillars of the Canadian Biomanufacturing and Life Sciences strategy:

1. **Strong and coordinated governance -** This should include alignment at the federal level (consistent objectives and policy between health and innovation portfolios), close cooperation with provinces to support their life science efforts, and productive partnership between governments, industry, and other stakeholders. Funding of new genomic testing infrastructure and equipment, outside of research, should be considered through dedicated budgets at the jurisdictional and institutional level.
2. **Laying a solid foundation by strengthening research systems and the talent pipeline –** Supporting and maintaining vibrant provincial pharmaceutical systems can help to attract talent and clinical trials. Human resource challenges remain due to the limited number of well-trained Canadian experts in molecular pathology. The establishment of formal, pan-Canadian programs to train doctors in this field, as well as investments in retaining Canadian talent are key to increase the pool of well-trained individuals in the medical and bio-informatics space. Canada can also support new innovation models through research infrastructure investments such as those related to enabling real world evidence generation. Integrating data across provincial borders and making data accessible to all stakeholders through a collaborative research network model will help to leverage and optimize the use of data.
3. **Growing business by supporting existing and emerging areas of strength -** The PCGS can build upon Canada's existing research strengths in genomics and artificial intelligence and build capacity in the area of precision medicine. Because much of the expertise in these areas resides in the private sector, multistakeholder communication and collaboration will be critical in these efforts.
4. **Building public capacity –** We note there is a significant gap and fragmentation of equity to genomic testing and screening in Canada that some provinces, such as Quebec and Ontario, have begun to address. Enhancing capacity for next generation sequencing testing for cancers and rare diseases is crucial to ensuring early and accurate diagnosis to support better health outcomes for patients and building a robust life sciences ecosystem.
5. **Enabling innovating by ensuring world class regulation** – We note that agile licensing, competitive and predictable price regulation, and timely access to medicines with fit for purpose reimbursement processes for precision medicines for rare diseases and acceptance of real-world evidence in decision making are all critical elements of world class regulatory processes.

As noted in the Biomanufacturing and Life Sciences Strategy, continued investment in emerging technology areas with high potential to solve current and future health challenges is

key to fostering a healthy and sustainable genomics ecosystem. Increased focus should be given to precision medicines, including cell and gene therapies, RNA and viral vectors and monoclonal antibodies, as well as timely and accurate diagnostic and testing infrastructure. Investment in these areas will allow for better, accurate targeting of rare diseases and cancers and better outcomes for patients, and are a crucial element of a comprehensive and effective rare disease strategy which should be complementary to the PCGS.

**Canada's genomics landscape –challenges and opportunities**

Challenges within the genomic landscape include fragmentation of resource availability, practices, and infrastructure across different provincial health care systems. Similarly, differences in authority and access to diagnostic screening and testing are challenges that should be addressed through a coordinated policy approach.

IMC & BIOTECanada have developed a joint policy position which highlights opportunities to enhance system-wide preparedness for innovative diagnostic testing to improve health, build health care infrastructure including reliable domestic supply, and position Canada to benefit from future research and development investments. The innovative biopharmaceutical industry recommends multistakeholder dialogue on the following six areas which are explored in more detail in the attached position:

1. Enhanced Publicly Funded Testing to Support all Canadians
2. Coordination and Anticipation of Future Needs
3. Transparency & Accountability
4. Context-Specific HTA
5. Priority Setting Driven by Patient and Health Systems Needs
6. Appropriate Role for Industry and other Stakeholders in Diagnostic Testing

In addition, there are a number of actionable opportunities that the PCGS should consider which require close cooperation with other health and innovation system partners:

- **Increased regulatory predictability for innovative products**. Impending regulatory changes to the Patented Medicine Prices Review Board (PMPRB) remain a significant risk to access to new medicines in Canada. The finalization of the PMPRB's Guidelines must be conducted carefully to support timely access to future precision medicines, including cell and gene therapies RNA and viral vectors and monoclonal antibodies.
- **Fostering continued regulatory and market access efficiencies.** Health Canada should continue to build upon its agile regulatory framework to enhance opportunities for rolling reviews and a streamlined pathway for drugs for rare diseases including an appropriate definition.

- **Integration of testing within the health system**. There remain inconsistencies due to the lack of resources for conducting tests and testing time requirement discrepancies between different testing locations within provinces. There is an urgent need to better incorporate testing into the health care system and have an education strategy to assist the workforce in this field if Canadians are to receive timely care, achieve optimal health outcomes, and have access to an efficient, sustainable and resilient health system.
- **Standardized newborn screening for all infants.** Standardized newborn screening can address current inconsistencies within provincial jurisdictions for many conditions including Spinal Muscular Atrophy (SMA).
- **Improved data infrastructure and data access for all stakeholders.** Canada would benefit from a more sophisticated and interconnected data infrastructure that can be accessed by researchers, stakeholders, and the innovative industry to inform better research, clinical and funding decisions. The federal government should consider targeted investments in this area (please see IMC's commentary in the context of consultations concerning a Canadian rare diseases strategy submitted in March 2021, and September 2021).

Thank you for your consideration of the points above. We would be pleased to answer any questions that you may have and look forward to further dialogue on the development and implementation of a Pan-Canadian Genomics Strategy.

With Kind Regards,

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