**September 30, 2025**

*Consultation Response on Proposed Framework for the Assessment of Biomarkers used in Cancer Care*

Innovative Medicines Canada & BIOTECanada are the primary associations representing the innovative medicines industry in Canada. We thank Canada's Drug Agency (CDA-AMC) for the opportunity to provide feedback for the current consultation on the draft assessment framework intended to inform adoption or funding decisions on molecular, genetic, and genomic biomarker testing in cancer care. We commend the work already initiated by CDA-AMC, specifically in relation to convening a pan-Canadian panel with jurisdictional representation that has since demonstrated capabilities to provide a foundation for this and related initiatives.

There are clear opportunities to enhance system-wide preparedness for innovative diagnostic testing ensuring both improved health outcomes and greater equity in care, build health care infrastructure including reliable domestic supply, and position Canada to benefit from future research and development investments. The innovative medicines industry would like to reference our original 2022 Policy Position on Optimizing Patient Access to Precision Therapies for core principles to address assessment and implementation considerations for precision therapies. This existing IMC and BIOTECanada policy provides a grounding for what the framework should include: equity in access for all Canadians, system level coordination, transparency and accountability, identification of health system needs, and alignment between diagnostics and therapies.

The innovative medicines industry highlights that for the framework to succeed, it must be actionable. Many recommendations in the consultation depend on support from interested parties and jurisdictions must prioritize these policy areas. The framework must outline clear roles for all parties and timelines for all processes. The funding mechanisms need to be clearly outlined, with minimum disruption to existing services, and built-in accountability. A successful framework should be forward-thinking such that it anticipates upcoming innovations, plans for necessary infrastructure and workforce, and ensures that Canadian jurisdictions do not lag international best practices or each other. The framework should account for proper funding and workforce allocation to support validation and the implementation of tests. Incorporating patient perspectives, ensuring

fairness, and monitoring outcomes should continue to be central themes of this important work. The assessment framework should be equitable and patient centric.[1]

***Comments on the Advisory Panel's Recommendations***

The innovative medicines industry, knowing the many products coming through the pipeline require biomarker testing, would encourage interested parties to come together with a sense of urgency in developing an assessment process that promotes collaboration. The use of biomarker-driven approaches has become central to cancer drug discovery and is a growing trend for newly approved therapies. As such, the future scope of any assessment framework should extend beyond oncology - e.g. rare diseases and future precision medicines.

***Guiding Principles & Definitions***

The innovative industry is encouraged to see guiding principles which address sustainability, collaboration, transparency, accountability, equity, and foresight. Canada can become an international leader in this space if federal and provincial governments, health technology assessment (HTA) bodies, industry and other interested parties work together to ensure that the policy framework evolves with the pace of science.[2] The panel's scope included only two of the identified 4 stages of a comprehensive biomarker assessment process (topic identification and intake; evidence criteria and assessment; deliberation and consensus-based recommendation development; and implementation, monitoring and continuous evaluation). For an actionable framework, it is recommended for the panel to consider expanding their scope to include all four stages of the biomarker assessment process.

***Proposed Recommendations on the overall biomarker assessment process***

Understanding that there is currently no centralized or national governance structure for biomarker assessment in Canada, there are clear opportunities to enhance system-wide preparedness for innovative diagnostic testing to improve health, build healthcare infrastructure including reliable domestic supply, and position Canada to benefit from future research and development investments.

Increased adoption of advanced diagnostic testing enhances the treatment selection process for individual patients, potentially bringing the benefits of precision medicines seen in clinical trials to the real-world setting.[2] These more efficient and effective treatment approaches can improve patient health outcomes and enhance disease management.[3]

However, governments will need to expand upon existing and/or build robust public testing infrastructure if patients are to fully realize these benefits. This will require policy agility and the adoption of a multi-stakeholder, holistic system approach to the Canadian testing infrastructure which will pragmatically address real and potential barriers as well as capital and ongoing costs. It is of utmost importance that partners are engaged early and continuously throughout the design and implementation of this coordinated model. Additional guidance regarding the state of readiness for genomic testing in Canada and actionable recommendations can be found at https://accesstogenomictesting.ca/

The innovative medicines industry is encouraged to see the advisory panel recommend a submission process that distinguishes between companion diagnostic and non-companion diagnostic biomarkers. It is important that companion diagnostic biomarkers are assessed at the same time as the companion or biological treatment so that the timing for the funding recommendation of both the drug and associated companion diagnostic biomarker is aligned. To ensure equity and innovation, the framework should actively facilitate capability and capacity development within the Canadian market, alongside funding for diagnostic assays in conjunction with targeted therapies.

To address patient needs, funders need a holistic system view to health technology management with a focus on coordinating and ensuring appropriate resources for disconnected service pathways. Enhanced multi-stakeholder coordination of the processes around horizon scanning, presubmission (drug) meetings, diagnostic test assessment, medicine assessment, dedicated test funding and medicine funding is needed to deliver cohesive and timely patient access to both diagnostic testing and treatments.[4] In particular, given the time to develop and validate tests is often longer than the time required to assess treatments, there is a need to start planning and coordination work on diagnostic testing earlier, possibly through provincial early engagement processes.

Provincial Ministries of Health can create more transparent, connected, and accountable systems, transforming the testing adoption pathway to one that is transparent regarding access and funding of diagnostics and accelerates access to targeted therapies. We are encouraged to see a recommendation regarding a single accountable point of contact per jurisdiction and a published protocol for diagnostic decision making with meaningful stakeholder input and engagement.

***Topic Identification & Intake***

The innovative industry is encouraged to see a recommendation for coordination among various interested and impacted parties within jurisdictions to help ensure that both therapeutic and diagnostic components are assessed, funded, and implemented when appropriate in a coordinated, timely and equitable manner. We agree that a pan-Canadian inventory of biomarkers in cancer care that are being assessed, as well as the outcomes (e.g. funded, not funded, de-funded) is needed along with targeted test turnaround times, and notes about test validation or optimization, ideally catalogued by jurisdiction, and that a pan-Canadian organization such as CDA-AMC can maintain such a database.[5]

***Proposed Evidence Criteria***

The innovative industry agrees with the three core (i.e., clinical utility, analytical validity and clinical validity) and three cross cutting (i.e., harms, equity, and patients', clinicians' and public perspectives and preferences) evidence criteria for the assessment of biomarkers.

We also note the panel's recommendation that these standardized evidence criteria be implemented within existing jurisdictional processes. While HTA plays an important role, given the diversity of funding mechanisms and local health system considerations, this should continue to be addressed or implemented, at the individual jurisdictional level, ideally in a harmonized manner in consideration of aligned best practices with other jurisdictions. Establishing HTA processes for diagnostic testing requires the consideration of numerous technical, logistical, and biologic factors that are highly context specific.

As such, useful evaluation will require HTA processes that are closely linked to communities of practice and consider local care pathways, data availability and other factors. As suggested in the proposed framework, CDA-AMC could play a role to help convene timely and appropriate interprovincial dialogue and coordination, for example, through a diagnostic testing policy advisory committee of provincial funders and laboratory leaders (see terms of reference for the similar Drug Policy Advisory Committee).

This can help to address the interprovincial variability that currently exists in funding and operational process affecting adoption and patient access to diagnostics, while maintaining provincial leadership in this area. The Québec synchronized evaluation process for companion diagnostic tests initiated by INESSS is an exemplary practice since it allows a test to be added to the list of covered medical acts at the same time as the medicine's indication becomes listed on the provincial list of medications.[6]

***Proposed Evidence Submission Process***

Though the innovative industry is generally aligned with the proposed process for evidence submission, we would recommend that submission requirements be reevaluated as needed to ensure that evidence requirements are aligned with clinical advancements in this field. Adequate lead time for adoption of evolving requirements should be permitted.

***Proposed Evidence Review Process***

The innovative industry is aligned with the recommendation that an evidence review process be inclusive of appropriate experts and those with lived and living experience. We are also encouraged to see that the panel agreed on timeliness as an essential consideration such that the time for an evidence review should not unduly postpone recommendations for access to valuable biomarker testing. Clear criteria, methods, and rationale used in biomarker assessments should be transparently published.

The committee's recommendation regarding contributing to a pilot of a centrally coordinated assessment model with interested jurisdictions while prioritizing collaboration with patients, patient groups, clinicians and clinical societies should include industry and other partners. Industry can aid in supplementing information on global practices and provide input on timely implementation solutions. Laboratories also require sufficient lead time to onboard test before the health technology assessment (HTA) review for funding, to ensure smooth and timely adoption, We agree that a proof-of-concept exercise will help evaluate the feasibility and refine processes before a pan-Canadian roll out and would encourage timely establishment of such an exercise as we see an urgency given the current landscape of future precision medicines in the pipeline.

***Additional Considerations***

The innovative industry would like to add that decisions to introduce new diagnostic technologies often seem to follow fiscal and technology management policies of hospital- and clinical program-based care, guided by expenditures rather than capturing health system value in a vertically integrated manner. Indeed, the need to move beyond traditional budget silos to align resources is apparent within provincial health ministries (e.g., between drug plans & diagnostic funding). Decision makers can move away from these ad hoc "one test, one biomarker" approaches driven by the current finance model and toward a more strategic "one test, many biomarkers" solution. For example, multitarget assays are tests that simultaneously provide multiple relevant patient insights, and hold the potential

to deliver efficiencies, reduce the cost of testing and permit more patients to be tested and at earlier stages for preventative and treatment purposes.[7]

With respect to the appropriate role for industry in diagnostic testing, the funding of medically necessary public diagnostic services should be driven by public health objectives that are covered by public budgets and not be left primarily to medicine manufacturers, who do not typically supply testing technology directly. While treatment manufacturers are often willing to assist with testing considerations, provinces should develop sustainable funding mechanisms for independent testing capacity and related resourcing that can be more resilient over the long run than one-off approaches.[8] Collectively, we can adopt a more coordinated public approach with the goal of simultaneous public funding of diagnostic tests and precision medicines, along with clarity on the integrated and supportive role that medicine manufacturers could play in the process.

[1]There is a lack of real-world evidence (RWE) in the diagnostic space — data such as case volumes, positivity rates, and mutational profiles in the Canadian population. This gap is even more significant when it comes to underrepresented patient populations, such as Indigenous patients, where there is a lack of sufficient understanding of mutational profiles and cancer risk. To address this, provincial-level datasets or, ideally, national registries should be built that can serve as a robust RWE resource and guide more equitable cancer care.

[2] Critically important to have more detail on how transparency is operationalized in the long-term vision (i.e., how evidence is weighted, appraised, and translated into recommendations so all stakeholders can understand the rationale behind decisions)

[3]Targeted treatment through advanced diagnostic testing (including molecular, cytogenetic, and immunohistochemical tests) hold promise for meaningful improvements in patient outcomes from new medicines, including improved response rates, reduced toxicity, and improved survival. i [3]Leifer BP. Early Diagnosis of Alzheimer's Disease: Clinical and Economic Benefits. J Am Geriatr Soc 51:S281–S288, 2003. Brooks BR. Earlier is better: the benefits of early diagnosis. Neurology. 1999 ;53(8 Suppl 5):S53-4; discussion S55-7. PMID: 10560640.Beyond improved health outcomes, patients and their caregivers value timely and accurate diagnoses because such knowledge provides the opportunity to learn about the disease, enable future planning for financial and legal needs, and can enhance management of chronic conditions.

[4] Public plans do not always have the same priorities as private insurers. In particular, private drug insurers and their beneficiaries tend to place a higher importance on patient choice and rapid access compared to public drug plans. In scenarios where private coverage is broader than public coverage for precision medicines, there will be a gap in access to diagnostic testing that only the private insurer can fill. In addition, there will frequently be a time-limited gap in private access to precision medicine and public access to diagnostic testing which the private insurer can fill. vii Stakeholders include but are not limited to provincial governments, public drug plans, patients, laboratory networks, and manufacturers. viii Considering a host of biomarkers at once instead of assessing, reviewing, and implementing them one-by-one introduces a number of efficiencies, including: the administrative burden of scoping, assessing and implementing; the workflow at the point of care; and the delay in patient access to novel precision medicines, diagnostic technologies or both.

[5] It is important to also note that some labs send their testing to the U.S. because of limited local capacity in certain provinces (e.g. NGS cases in Newfoundland are sent to Miami). This can happen despite Canadian labs — both public and private — having the capability to absorb the volume. Often, these labs are in other provinces, but cases don't get referred there because there isn't an integrated system to support reimbursement across jurisdictions. Considering the current political climate, it could be valuable to repatriate these cases to Canadian labs. There should be clear and specific pathways which expedite patient access to biomarkers—particularly for priority review drugs or tumour types with high unmet need.

[6] As part of this framework, a national body could support regular pipeline updates in collaboration with lab leaders to stay informed about emerging biomarkers and to prioritize those that need validation in anticipation of coverage. In practice, labs usually require a 12–18 month lead time to onboard a new genomic test if the biomarker is not already available locally, yet this process is currently unfunded. A best practice could be to identify provincial or regional centers of excellence to lead the onboarding, with the number of labs offering the test expanded once reimbursement is in place.

[7] Considering a host of biomarkers at once instead of assessing, reviewing, and implementing them one-by-one introduces a number of efficiencies, including: the administrative burden of scoping, assessing and implementing; the workflow at the point of care; and the delay in patient access to novel precision medicines, diagnostic technologies or both.

[8] Medicine manufacturers often step in to support development and validation of new tests to help ensure their adoption is timed with treatment availability. However, relying on drug manufacturers to finance tests may create risk to the stability and sustainability of domestic supply chains for diagnostic services—testing technologies are developed and sold by diagnostic test developers, not by the developers of the medicines. In some cases, solutions are sought using out-of-country providers. And while some pharmaceutical developers may be willing to fund the public operation of diagnostic services, it is not a guarantee that all will. For those that do fund, there is no obligation they continue funding public services indefinitely. The result is that arrangements by private entities could lead to suboptimal test delivery, and ultimately could be unsustainable as circumstances – unstable market conditions, competition, regulations, and other factors– may quickly disrupt the ability of a pharmaceutical developer to finance the public delivery of diagnostic services.