May 5, 2026

Submission to the Standing Committee on Health's Study on Canada's Pharmaceutical Sovereignty

Executive Summary

The Best Medicines Coalition (BMC) welcomes the opportunity to contribute to the Standing Committee on Health's (HESA) study on Canada's pharmaceutical sovereignty. Canada's ability to ensure reliable, timely, and equitable access to medicines is a foundational element of both public health and economic resilience.

From a patient perspective, pharmaceutical sovereignty must be understood not as isolation or domestic self-sufficiency, but as strategic resilience. This means the committee must consider how to protect access to medically necessary drugs across therapeutic areas, ensure continuity of supply, attract innovation and early launches, and deliver equitable access for all patients in Canada. This includes medicines for common chronic conditions, cancer and rare cancers, and therapies for rare diseases, which can be sensitive to market uncertainty, regulatory delays, and pricing instability.

Pharmaceutical sovereignty is particularly consequential for Canadians living with cancer, rare cancers, and rare diseases, where treatment timelines are often narrow and therapies increasingly personalized. Delays in regulatory approval, clinical trial start-up, or reimbursement decisions can result in missed treatment windows, poorer health outcomes, and premature death. For patients with rare diseases, including rare cancers, where standard-of-care options may be limited or non-existent, access to innovative medicines and trials are often the only viable therapeutic pathway. A sovereignty framework that does not explicitly include a strategy to improve the development of and early access to innovative therapies – including innovative oncology and rare disease therapies - risks further entrenching existing inequities for some of Canada's most vulnerable patients.

This submission outlines how sovereignty strategies should be designed to strengthen access for all patients. In particular, the needs of those relying on high-volume medicines for common conditions, those awaiting therapeutic innovations for unmet needs, and low-volume therapies for cancer and rare diseases must be embedded in the strategy. This should be done in concert with reinforcing Canada's broader health system sustainability, research capacity, and biomanufacturing abilities.

The Best Medicines Coalition, which represents more than 30 patient groups across Canada, thanks HESA for inviting us to provide testimony to its study on pharmaceutical sovereignty. We encourage further engagement with patients and patient groups to ensure the study is inclusive and has integrity.

Pharmaceutical Sovereignty: A Patient-Centered Definition

The COVID-19 pandemic exposed Canada's heavy reliance on global pharmaceutical supply chains and limited domestic manufacturing capacity. Subsequent global disruptions and trade tensions have reinforced the reality that medicines are essential to national security and social stability.

Much of the public discourse on pharmaceutical sovereignty has focused narrowly on essential medicines and generics. Essential medicines and generics are critically important, but this narrow focus is incomplete from a patient perspective. Innovative medicines, including biologics, oncology therapies, and drugs for rare and ultra-rare diseases are equally important to modern health care. Therefore, they must be considered in pharmaceutical sovereignty initiatives.

Pharmaceutical sovereignty should focus on four patient-centered outcomes:

1. Reliable and continuous supply of medicines across all therapeutic areas.
2. Timely access to innovation, including earlier regulatory approval and launch of new medicines.
3. Equitable coverage across provinces, territories, and payer types.
4. System resilience, ensuring Canada remains an attractive jurisdiction for research, trials, and life-sciences investment.

Risks posed by global drug policy and trade pressures

Recent and proposed U.S. drug policy reforms such as the Most Favored Nation (MFN) pricing approaches and the threat of tariffs, pose significant risks to Canada's access to innovative medicines. For example, evidence presented to HESA and in related analyses shows that Canada's relatively small market size may be deprioritized when manufacturers reassess global launch sequencing, investment, and supply decisions.

These risks must continue to be assessed with patient access – not just market access - in mind. Bringing a product to market is just one aspect of patient access. Ensuring there are consistent, equitable and reliable reimbursement strategies in place to cover innovative therapies that are in market is a true test of pharmaceutical sovereignty. What is the point of bringing products to market if patients can't access them?

Even when pharmaceuticals are not formally subjected to tariffs, policy uncertainty alone can disrupt supply chains, discourage investment, and delay submissions to Health Canada. For patients with cancer or rare diseases, these disruptions are not abstract economic concerns: they can translate into lost treatment windows, disease progression, irreversible harm and premature death.

The BMC aligns with patient and industry stakeholders who have called for:

- Explicit and permanent tariff exemptions for pharmaceuticals, vaccines, diagnostics, and medical supplies.
- Proactive federal monitoring of drug supply risks.
- Ongoing engagement with manufacturers, regulators, pricing and reimbursement bodies, and patient groups to protect Canadian patients from downstream access disruptions.

Strategic interdependence, not isolation

The BMC supports the growing consensus before HESA that full pharmaceutical self-sufficiency is neither realistic nor desirable. Instead, Canada must pursue strategic interdependence by strengthening targeted domestic capabilities while maintaining diversified and reliable international partnerships.

From a patient perspective, this means:

- Investing in domestic capacity where it is strategically critical, including biologics, advanced therapeutics, and clinical trial supply.
- Ensuring Canada has secure access to global manufacturing networks that underpin modern medicines.
- Avoiding policies that unintentionally deter bringing clinical trials to Canada, product launches or that reduce access to innovative therapies.

Many drugs used to treat cancer, rare cancers, and rare diseases involve small-batch or highly specialized manufacturing. This means access to these treatments depends on predictability, regulatory efficiency, and collaborative global integration, all objectives of strategic interdependence that Health Canada is working toward through its clinical trials modernization initiatives and through use of the reliance order, among other regulatory enablers.

Build on efforts that make Canada a destination for clinical research and innovation

Canada's ability to attract biomedical research and clinical trials is a cornerstone of pharmaceutical sovereignty. Early-phase and late-phase trials provide patients with early access to promising therapies while building national expertise and infrastructure.

Patient organizations across BMC's membership have consistently emphasized that regulatory modernization is essential to maintaining Canada's competitiveness. This includes:

- Reducing unnecessary duplication across jurisdictions.
- Supporting decentralized and multi-provincial trials.
- Enabling innovative trial designs, including small-population and N=1 studies.
- Ensuring appropriate frameworks for gene and cell therapies, including long-term follow-up.

Established disease-specific trial networks such as those operating in oncology, and rare diseases should be recognized as national assets that can and should leveraged to generate RWE and track and report on patient health outcomes. Policy frameworks that recognize and leverage these networks can significantly strengthen Canada's position as an early-launch jurisdiction for trials and innovative medicines.

Patient-focused drug review and Health Technology Assessment (HTA)

Pharmaceutical sovereignty must extend beyond supply and manufacturing to include how medicines are evaluated and adopted within the health system. Delays or restrictive decisions at HTA and/or reimbursement stages can undermine sovereignty because they can create an unpredictable investment environment.

The BMC supports ongoing reforms at Canada's Drug Agency (CDA) and INESSS that aim to strengthen patient engagement and modernize evidence standards. However, patients continue to raise concerns about:

- Rigid reliance on outdated cost-effectiveness thresholds used in HTA assessments, such as the CDA's non-official **($50,000) per quality-adjusted life-year (QALY)** to assess the cost-effectiveness of new drugs, including those for rare diseases.
- Insufficient collection and use of real-world evidence, including patient registries

For rare diseases and many cancers, traditional evidence models are often ill-suited to small populations and evolving standards of care. Sovereignty requires HTA approaches that are scientifically rigorous and responsive to lived experience and societal value.

Fragmented coverage undermines sovereignty

Even when drugs are approved and reimbursed at a pan-Canadian level, Canada's fragmented mix of public and private drug plans creates inequitable access across jurisdictions and plans. Patients face inconsistent timelines, eligibility criteria, and administrative barriers depending on where they live or how their coverage is structured.

From a sovereignty perspective, this fragmentation sends a negative market signal. Unpredictable and sequential reimbursement pathways can discourage manufacturers from choosing Canada as a first-to-launch country for new products, which can reduce Canada's attractiveness for investment.

Pharmaceutical sovereignty must not stop at our regulatory frameworks: we must also build strategic interdependence among our public and private drug plans to ensure that Canadians can get the same drug at the same price in the same time frame regardless of where they live. Sovereignty demands that we put our people first.

From a patient perspective, inequitable access undermines fundamental principles of fairness and universality. The BMC urges HESA to recognize that:

- Predictable, coordinated access pathways are essential to health outcomes and economic participation.
- Better federal-provincial alignment can reduce duplication and delay.
- Greater consistency across public and private plans would strengthen both equity and system resilience.

Policy recommendations

To strengthen pharmaceutical sovereignty in ways that prioritize patients while supporting innovation and economic resilience, HESA should recommend the federal government:

1. Adopt a patient-centered definition of pharmaceutical sovereignty, grounded in access, equity, and system resilience.
2. Protect medicines, vaccines, supplements, supplies and equipment from trade and tariff risks through permanent exemptions and proactive supply monitoring.
3. Strengthen strategic interdependence, investing in targeted domestic capacity while maintaining global partnerships.
5. Build on efforts that make Canada a destination for clinical research and innovation. Modernize HTA and drug review processes to reflect patient-driven evidence and real-world outcomes.
6. Improve predictability and equity of drug reimbursement across Canada through strengthened federal-provincial coordination and consistency of coverage.

Conclusion

Pharmaceutical sovereignty is not an abstract economic policy objective; it is a lived reality for patients who depend on timely and reliable access to medicines. A sovereignty strategy that fails to account for patient access, equity and engagement risks entrenching vulnerabilities rather than resolving them. It is therefore essential that patients and patient groups are at the table to give testimony so that HESA's study has the inclusion and integrity it needs to move its recommendations forward.

The Best Medicines Coalition appreciates HESA's leadership in examining these issues and urges the Committee to ensure that patient experience and access remain central to its final recommendations.

For more information contact Kim Steele, Chair at chair@bestmedicines.ca.

BEST MEDICINES COALITION
COALITION POUR DE MEILLEURS MÉDICAMENTS

About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 33 patient organizations. The BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and related treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. The BMC's areas of interest include drug approval, assessment, and reimbursement, as well as patient safety and supply issues. As an important aspect of its work, the BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC's core activities include issue education, consensus-based position development, and advocacy, making certain that patient-driven positions are communicated to decision makers and other stakeholders. The BMC was formed in 2002 as a grassroots alliance of patient advocates. In 2012, the BMC was registered under the federal Not-for-profit Corporations Act and operates under the direction of a Board of Directors composed of representatives of member organizations and elected annually.

Asthma Canada
Brain Tumour Foundation of Canada
Canadian Arthritis Patient Alliance
Canadian Breast Cancer Network
Canadian Cancer Survivor Network
Canadian Council of the Blind
Canadian Cystic Fibrosis Treatment Society
Canadian Epilepsy Alliance
Canadian Hemophilia Society
Canadian PKU & Allied Disorders
Canadian Skin Patient Alliance
Canadian Spondyloarthritis Association
CanCertainty
Crohn's and Colitis Canada
Cystic Fibrosis Canada
Eczema Society of Canada
Family Alliance on Severe Mental Illnesses
Fighting Blindness Canada
Health Coalition of Alberta
Huntington Society of Canada
Kidney Cancer Canada
Lung Health Foundation
Lymphoma Canada
Medicines Access Coalition – BC
Migraine Canada
Millions Missing Canada
Mood Disorders Society of Canada
Ovarian Cancer Canada
Parkinson Canada
Platelet Disorder Support Association
Psoriasis Canada
Pulmonary Hypertension Association of Canada (PHA Canada)
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