Canadian Organization for Rare Disorders

Strengthening Canada's Innovative Medicines Strategy: From Receptivity to Implementation

Follow-up reflections for the Pharmaceutical and Life Sciences Sector Task Force

Purpose of this note

This note summarizes key reflections following a consultation with the Co-Chairs of Canada's Pharmaceutical and Life Sciences Sector Task Force. We appreciated the openness of the discussion and the clear indication that the Task Force is already thinking beyond narrow questions of drug approval and industrial competitiveness. In particular, it was encouraging to hear recognition of the need for better integration of data, improved coordination across systems, and a more coherent clinical trials environment.

At the same time, many of the themes raised — including integrated data, a single or streamlined clinical trials process, better coordination across jurisdictions, and more timely access to innovative medicines — have been discussed in Canada for many years. The challenge is not only identifying the right issues. The challenge is ensuring that the recommendations lead to concrete, measurable changes in how patients actually access medicines.

The purpose of this document is to reinforce the importance of moving from consensus to implementation, with particular attention to patient access, federal leadership, provincial and territorial delivery responsibilities, and accountability for results.

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1. Overall response to the Task Force direction

We welcome the creation of the Task Force and its mandate to consider both Canada's life sciences competitiveness and timely access to innovative medicines. These two goals should not be treated as separate agendas. A strong life sciences sector should ultimately serve patients and the health system, while a health system that can adopt innovation responsibly and equitably is itself an important part of Canada's competitiveness.

Our consultation suggested that the Co-Chairs understand many of the concerns raised by patients, clinicians, researchers, and other stakeholders. In particular, we heard openness to a broader view of access — one that goes beyond Health Canada approval and considers the full pathway from research and evidence generation to reimbursement, prescribing, dispensing, administration, monitoring, and patient outcomes.

That broader framing is essential. A medicine is not truly accessible simply because it has been approved. It becomes accessible when patients can be diagnosed, prescribed,

covered, dispensed or administered the therapy, monitored appropriately, and supported through the treatment pathway without unreasonable delay, cost, administrative burden, or geographic inequity.

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2. The key implementation challenge: Canada often knows what needs to change

Many of the ideas under discussion are not new. Canada has been discussing for at least a decade the need for:

- Better integration of health data;
- A more coordinated clinical trials system;
- Reduced duplication across regulatory, ethics, institutional, and provincial processes;
- Faster movement from approval to reimbursement and patient access;
- More consistent adoption of innovation across provinces and territories;
- Better use of real-world evidence;
- Improved coordination among federal, provincial, territorial, public, private, and research actors.

The recurring problem has not been a lack of ideas. It has been a lack of implementation mechanisms.

Canada often produces thoughtful reports, frameworks, strategies, and recommendations, but too few are attached to binding deliverables, timelines, funding conditions, or public accountability. This is especially true when responsibility is divided across federal, provincial, and territorial systems.

The Task Force therefore has an opportunity to do more than restate the need for coordination. It can recommend mechanisms that make coordination actionable.

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3. The federated system cannot be used as a reason for inaction

Canada's federated system is a real and important constraint. Provinces and territories are responsible for much of health care delivery, including many decisions about formulary listing, service delivery, pharmacy practice, hospital-based access, diagnostic capacity, and implementation of care pathways. Any national medicines strategy must respect this reality.

However, the federated system should not become a reason for limited federal ambition. The federal government still has important levers, including:

- Regulation through Health Canada;
- Convening power across jurisdictions;
- Federal funding;
- National data standards;
- Support for pan-Canadian infrastructure;
- Alignment of drug review, health technology assessment, and evidence requirements;
- Support for clinical trials capacity;
- Funding agreements with specific deliverables;
- Public reporting and accountability requirements;
- Federal programs serving specific populations;
- Support for Indigenous health priorities in partnership with Indigenous peoples and governments.

The federal government may not directly implement every element of medicines access, but it can provide clearer direction, stronger incentives, and more disciplined accountability.

A purely voluntary approach is unlikely to be sufficient. Where federal funding is provided, it should be linked to specific outcomes, timelines, reporting requirements, and measurable improvements in access.

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4. Federal funding should be tied to deliverables and accountability

One of the strongest opportunities for the federal government is to use funding not only to support innovation, but to require implementation.

Federal investments in data infrastructure, clinical trials, health-system innovation, access programs, domestic manufacturing, or life sciences capacity should include clear conditions. These should specify what will be delivered, by whom, by when, and how success will be measured.

Examples of possible deliverables include:

- Adoption of common data standards across participating jurisdictions;
- Timelines for ethics and institutional approvals for multi-site clinical trials;
- Public reporting on time from Health Canada approval to first reimbursed patient access;
- Provincial and territorial reporting on formulary listing timelines;
- Commitments to reduce duplication in trial start-up processes;
- Transparent reporting on access gaps by geography, payer, and population;

- Integration of patient-reported outcomes and real-world evidence into post-market evaluation;
- Requirements for patient and caregiver participation in governance structures;
- Specific improvements in diagnostic, dispensing, infusion, or specialty pharmacy capacity where relevant to innovative therapies.

Funding should not simply support activity. It should support measurable change.

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5. Access must be measured at the patient level

A central recommendation should be that Canada measure medicines access from the patient perspective, not only from the system perspective.

Current discussions often focus on milestones such as:

- Regulatory submission;
- Health Canada approval;
- Health technology assessment recommendation;
- pCPA negotiation;
- Provincial or territorial listing;
- Private plan coverage.

These are important, but they are intermediate steps. The most meaningful access measure is whether and when a patient actually receives the medicine.

Canada should therefore develop and publicly report access metrics such as:

- Time from Health Canada approval to HTA recommendation;
- Time from HTA recommendation to price negotiation conclusion;
- Time from negotiation to public formulary listing;
- Time from listing to first prescription;
- Time from prescription to first dose;
- Time from diagnosis to treatment initiation;
- Access differences by province or territory;
- Access differences between public and private coverage;
- Out-of-pocket costs for patients;
- Denial and appeal rates;
- Wait times for required diagnostic or biomarker testing;
- Travel distance or time to treatment site;
- Availability of dispensing, infusion, administration, and monitoring infrastructure.

If Canada only measures approval and reimbursement milestones, it will miss many of the barriers that patients experience.

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6. The access pathway includes dispensing, administration, and delivery

Innovative medicines are often discussed as if access ends with approval and reimbursement. In practice, many of the most important barriers occur later in the pathway.

For many innovative therapies, access may depend on:

- Specialist referral;
- Genetic or biomarker testing;
- Prior authorization;
- Public or private payer approval;
- Hospital or cancer agency funding;
- Community or specialty pharmacy access;
- Cold-chain distribution;
- Infusion or injection capacity;
- Home-care support;
- Monitoring requirements;
- Renewal criteria;
- Patient navigation;
- Travel and accommodation support;
- Digital systems that allow information to move across providers and payers.

This is especially important for biologics, oncology drugs, rare disease therapies, cell and gene therapies, high-cost chronic therapies, and medicines that require specialized monitoring or administration.

A national strategy for innovative medicines should therefore include the delivery infrastructure needed for patients to receive those medicines. Otherwise, Canada may approve therapies that remain practically inaccessible to many patients.

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7. Clinical trials reform needs implementation discipline

We were encouraged to hear discussion of a more coherent clinical trials process. This is a long-standing and important priority.

Canada needs a clinical trials environment that is easier for patients, researchers, sponsors, institutions, and health systems to navigate. Multi-site trials should not be

slowed by duplicative processes that add cost and delay without improving ethics, safety, or scientific quality.

However, this issue has been discussed for many years. The Task Force should avoid simply recommending another commitment to streamline clinical trials. It should recommend a concrete implementation plan.

Such a plan could include:

- A common national approach to ethics review for multi-site trials;
- Harmonized contract and budget templates;
- Standardized institutional start-up processes;
- Clear timelines for review and activation;
- Digital infrastructure to support trial identification and recruitment;
- Better inclusion of community-based, rural, remote, and under-represented populations;
- Patient involvement in trial design and feasibility;
- Public reporting on trial start-up timelines;
- Incentives for provinces, territories, and institutions to adopt common processes.

The goal should not only be more trials. It should be faster, more inclusive, more patient-centred trials that generate evidence relevant to Canadian decision-making and access.

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8. Data integration must move beyond aspiration

Similarly, the need for integrated data is widely recognized. Better data are essential for regulatory learning, health technology assessment, post-market surveillance, real-world evidence, outcomes-based agreements, pharmacovigilance, appropriate prescribing, and evaluation of access equity.

But Canada has repeatedly identified data integration as a priority without achieving the level of interoperability needed.

The Task Force should therefore recommend specific actions, including:

- Common national data standards;
- Clear governance for privacy-protective data linkage;
- Patient consent and trust frameworks;
- Interoperability requirements tied to federal funding;
- Infrastructure to support real-world evidence;
- Inclusion of patient-reported outcomes and experience measures;
- Mechanisms for linking prescribing, dispensing, administration, outcomes, and adverse-event data;

- Public reporting on access and outcomes while protecting privacy.

Data integration should not be framed as a technical project alone. It is an accountability tool. Without better data, Canada cannot know whether innovative medicines are reaching patients equitably, whether they are producing real-world benefit, or where the system is failing.

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9. Patient and community role should be embedded, not peripheral

Patients and patient organizations should not be treated only as consultation participants. They should be part of governance, implementation, and evaluation.

Patients bring evidence that is often missing from system-level discussions, including:

- Where delays occur in real life;
- How administrative burden affects access;
- Whether therapies are practically usable;
- What outcomes matter most;
- How travel, cost, disability, language, work, caregiving, and geography affect treatment;
- Where public and private coverage fails;
- How access differs across communities;
- Whether patient support programs are helping or masking system gaps.

Patient advocates can also help translate access barriers into actionable policy recommendations. For example, rather than simply saying that patients wait too long, advocates can help identify the specific point in the pathway where the delay occurs: diagnosis, testing, referral, reimbursement, prior authorization, dispensing, administration, or renewal.

The Task Force should recommend formal patient and caregiver involvement in any implementation structures that follow its report. Participation should be supported, compensated, accessible, and representative of diverse communities.

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10. Recommendations for the Task Force

We respectfully suggest that the Task Force consider the following recommendations:

Recommendation 1: Define access as patient receipt of therapy

The Task Force should define access not only as regulatory approval or reimbursement, but as the ability of patients to obtain, use, and benefit from medicines in a timely, affordable, equitable, and clinically appropriate way.

Recommendation 2: Create an end-to-end access pathway framework

Canada should map the full pathway from research and clinical trials to diagnosis, approval, HTA, negotiation, listing, prescribing, dispensing, administration, monitoring, and outcomes. This framework should identify where responsibility lies and where delays occur.

Recommendation 3: Attach federal funding to specific deliverables

Federal investments should include measurable deliverables, timelines, and public reporting requirements. Funding should be used to encourage provincial, territorial, institutional, and system-level adoption of agreed reforms.

Recommendation 4: Establish national access metrics

Canada should publicly report on time from approval to actual patient access, including time to first dose and differences across provinces, payers, and populations.

Recommendation 5: Move clinical trials reform from principle to implementation

The Task Force should recommend a concrete plan for harmonized, efficient, patient-centred clinical trials processes, including common ethics review, standardized agreements, clear timelines, and patient involvement.

Recommendation 6: Make data integration an accountability mechanism

Data integration should be tied to clear standards, funding conditions, privacy-protective governance, and public reporting on access, outcomes, safety, and equity.

Recommendation 7: Include dispensing and delivery infrastructure

Innovative medicines strategy should include the practical infrastructure needed for access, including pharmacy, specialty distribution, infusion capacity, diagnostics, monitoring, home care, and rural and remote delivery.

Recommendation 8: Embed patients in implementation governance

Patients and caregivers should be included not only in consultation, but in governance, implementation planning, monitoring, and evaluation.

11. Suggested implementation approach

The Task Force could recommend a staged implementation model:

First 6 months

- Establish a federal-provincial-territorial implementation table with patient representation;
- Agree on a national definition of patient access;
- Identify priority access metrics;
- Select initial therapeutic areas or medicines to test end-to-end access tracking;
- Begin work on clinical trials harmonization deliverables;
- Identify federal funding streams that can be tied to implementation requirements.

6 to 18 months

- Launch public reporting on access timelines;
- Implement common clinical trial start-up standards in participating jurisdictions;
- Develop data standards for linking approval, reimbursement, prescribing, dispensing, and outcomes;
- Pilot patient access pathway mapping in selected areas;
- Report on provincial and territorial adoption of agreed reforms.

18 to 36 months

- Expand access reporting across more therapeutic areas;
- Link federal funding to demonstrated adoption of reforms;
- Evaluate whether reforms reduce time to first patient access;
- Publish annual progress reports;
- Adjust policy based on real-world evidence, patient experience, and equity data.

This staged approach would help ensure that recommendations do not remain aspirational.

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12. Concluding message

The consultation with the Task Force Co-Chairs was encouraging. There appears to be recognition that Canada needs a more integrated and patient-centred approach to innovative medicines. That is an important starting point.

However, Canada's history in this area shows that good ideas are not enough. Integrated data, streamlined clinical trials, faster access, and better coordination have been discussed for many years. The opportunity now is to make these commitments concrete.

The Task Force can add significant value if its recommendations focus not only on what should change, but on how change will be implemented, funded, measured, and publicly reported.

For patients and communities, the test is simple: will these recommendations make it easier for people in Canada to receive the right medicine at the right time, regardless of where they live, how they are insured, or how complex their treatment pathway may be?

That should be the central accountability measure for Canada's innovative medicines strategy.