November 24, 2025

Perspectives on timely access to medications and policy approaches for consideration

Overview:

- The process for new drugs and related treatments to move through review, approval, assessment and decision-making processes is complex and lengthy. In many cases it takes an extended period for patients to be able to access the medications they need. This is a critical issue with implications for patient care and outcomes, sometimes with dire consequences, especially for those with unmet needs and life-threatening illnesses.

- National leadership, with cooperation from all jurisdictions and at all levels, along with stakeholders, is necessary to streamline infrastructure, including review, assessment, negotiation and decision-making processes, reducing timelines at every step, including at Health Canada, the Patented Medicine Prices Review Board (PMPRB), Canada's Drug Agency (CDA-AMC), the pan-Canadian Pharmaceutical Alliance (pCPA) and at drug programs.

- All relevant departments, agencies and programs, both collaboratively and independently, must be mandated and resourced to take on and prioritize the important goal of delivering effectiveness and modernization to improve timeliness. Redundancies and inefficiencies need to be addressed along with greater accountability, transparency and parliamentary oversight.

What is the problem?

- In recent years, numerous studies have examined how long it takes for drugs and related treatments to move through review, approval, assessment and decision-making processes. Estimates vary, but it is generally concluded that it takes approximately two years from Health Canada approval for medications to be available on a public drug plan.

- In contrast, those who have access to private health insurance, through an employer or other group, also wait for approvals but these wait times are far less than for those who rely on public plans. According to data collected by Telus Health, private plans take an average of about eight months to list drugs and related treatment on their formularies. This is inherently inequitable and goes against the ethos of the Canadian public healthcare system where it is expected that care is received based on need, not on ability to pay.

Relevant reports and studies:

- **Patented Medicine Prices Review Board:** **Factors delaying the public listing of drugs in Canada**
    - On average, new drugs are added to a Canadian public formulary 906 days (approximately 30 months/2.5 years) after receiving a notice of compliance from Health Canada.

    - It takes longer for drugs to move through the process from regulatory approval to reimbursement on public programs in Canada than in any other G7 country.

- **Conference Board of Canada:** **Access and Time to Patient: Prescription Drugs in Canada—January 2024 - The Conference Board of Canada**
    - The time between regulatory approval for new drugs and their listing on public provincial formularies averaged 736 days (25 months) in 2022. This is double the average time reported in comparable Organisation for Economic Development (OECD) countries.

    - After initial listing, it took 90 days on average for drugs to be available to half of public drug plan beneficiaries in Canada, for a total time of 825 days from regulatory approval to patient.

    - Overall time to patient in 2022 varied considerably by province, driven mainly by delays surrounding completion of the individual provincial product listing agreements (e.g. 44 days in Quebec and 662 days in Prince Edward Island after pan-Canadian Pharmaceutical Alliance [pCPA] negotiation).

- **Mood Disorders Society of Canada:** **System Broken: How Public Drug Coverage is Failing Canadians with Mental Illness**
    - For drugs used to treat mental illness, it takes at best 2.5 years, and at worst up to six years to become accessible on public drug plans, compared to the average time to patient of two years for all publicly reimbursed medications.

How can this be fixed? Potential solutions for consideration

Streamline and improve processes including facilitating concurrent reviews

- The submission process for the several bodies involved in approvals, assessments and reviews in Canada largely runs consecutively, often creating bottlenecks and delays as drugs work through the entire process, hindering the ability to get drugs to patients in a timely fashion.

- Streamlining the system would allow for either all or some of the processes to run concurrently to speed up the process. Ideally, submissions would be made to Health Canada, Canada's Drug Agency (CDA-AMC), and the pan-Canadian Pharmaceutical Alliance at the same time. As such, Health Technology Reviews (HTA) would be undertaken by CDA-AMC while Health Canada is evaluating a submission, contributing to moving drugs and related treatment through the system faster.

- Significant work has been done to facilitate concurrent reviews but, by some reports, this is often underutilized. Since 2018, drug developers have been able to submit to the CDA for reviews 180 days before they receive a notice of compliance or a notice of compliance with conditions from Health Canada, but on average, drug developers submit to the CDA only 13 days before a Health Canada approval. It is imperative that Health Canada work with stakeholders, including drug developers, to conduct analysis on the extent of underutilization of concurrent review pathways and, where possible, work with stakeholders to develop policies and tools to address delays.

- Further understanding is needed on the role of drug developers who are seeking approvals in Canada in delaying and extending review times, including factors such as responsiveness, providing requested data and other measures.

- All involved in the process, must work together to analyze and develop a shared understanding on the causes and contributors to bottlenecks in the system. In addition, all players must acknowledge and embrace the objective of addressing barriers and contributing to improving timeliness, working cooperatively towards shared goals.

- In addition, there is a need for coordinated, transparent and easily accessible reporting and tracking of progress on the full review through reimbursement journey for each drug under consideration.

Increase reliance on comparator countries to reduce the need for full reviews in Canada

- Jurisdictions like the United States and the European Union have standards for the approval of medications which are like those in Canada. In some cases, this resource intensive, time consuming and duplicative effort may not contribute or be necessary to ensuring safety standards are met.

- A potential option for reducing the time to listing for pharmaceuticals is having Canada formalize stronger partnerships with countries with rigorous regulatory standards comparable to those in Canada to reduce, or eliminate, the need for Canada to conduct its own full review for some drugs.

- A cost-effective approach to streamlining the domestic review process could be to seek formalized partnerships with comparable countries such that drugs could receive approval in Canada once approved in a partner country. This would contribute to alleviating strain on the Canadian system and reduce processing time while contributing to ensuring that patients in Canada are able to benefit from the same treatment options as soon as patients in comparable countries.

- Importantly, there must be assurances that transparency and safety standards will not be compromised as measures to harmonize internationally and increase reliance on comparator countries are adopted. In addition, international cooperation and reliance must be coupled with efforts to implement processes and systems to ensure that Canada is a preferred site for clinical trails. This could include streamlining ethics reviews and other measures to address barriers.

Measures to accelerate price negotiations and post-negotiation listing consistently

- Timelines for the pCPA and drug developers to complete negotiations on behalf of public payers are unacceptably lengthy and are a significant roadblock to timely access. It takes an average of eight months to complete negotiations and, subsequently, it takes an average of 3.5 months for public payers to finalize decisions regarding listing drugs on their formularies post-pCPA. It must be noted that some provinces/public payers take even longer and, in some cases, drugs which have gone through the pCPA negotiation process successfully are then not included in some provincial formularies. In addition, there is a general lack of transparency as drugs move through these processes.

- Specialized initiatives to accelerate access to some drugs, such as through Project Orbis for select cancer drugs, and expedited negotiation pathways, including the Early Negotiation Process (ENP) and the Targeted Negotiation Process (TNP) by the pan-Canadian Pharmaceutical Alliance (pCPA), are welcome. Decision makers are urged to prioritize evaluation of these and other initiatives and pursue rapid expansion and broadening of scope to deliver benefits to a greater proportion of patients awaiting access.

- There is an urgent need to create tailored reimbursement processes, not just broad lists of drugs, that align with the need for patients to get the personalized care they need, especially for those with severe and difficult to treat conditions. Efforts must be made to ensure that for all patients, especially those with unmet needs, the specific drug or related treatment deemed necessary is available as quickly as possible without barriers such as policies at the drug program reimbursement decision stage which require trial and failure on other options before qualifying for advanced therapies.

- Measures must be pursued to eliminate, or significantly reduce, delays such that drugs move to formulary listing immediately following successful negotiations. For example, processes in Quebec lead to formulary listings in 44 days on average, largely achieved by listing drugs immediately after CDA-AMC's health technology assessment reviews versus waiting for the pCPA to conclude negotiations. As another example, the practice in Germany for many orphan drugs is to automatically list following an assessment with the difference between a list price and the negotiated price reconciled retroactively.

Measures to encourage developers to identify Canada in early launch plans

- In addition to improving access for patients, overall improvements to efficiency and timelines will contribute to a more positive operating environment for drug developers and, in turn, encourage earlier initiation of submissions for approval in Canada.

- Challenges related to capacity at small and medium sized drug developers to undertake submissions to a series of review bodies must be considered. This burden is particularly relevant to makers of orphan drugs for rare disorders with significant unmet needs.
  Drug developers may be receptive to incentives to encourage early introduction of drugs in Canada. Such incentives could be coupled with drug developer requirements such as post-market surveillance on special populations like pediatrics, and research and disease community investments.

- In addition, Canada's intellectual property and data protection rules for drug developers should be reviewed and compared against those in OECD countries to ensure that Canadian frameworks are in line with best practices which would potentially improve Canada's position for earlier introductions by developers and contribute to more timely access to safe and effective drugs and related treatments.

About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 32 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 comprised 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
Fighting Blindness Canada
Health Coalition of Alberta
Huntington Society of Canada
Kidney Cancer Canada
Lung Health Foundation
Lymphoma Canada
Medical Cannabis 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
the cancer collaborative