

CANADA

Recent and planned developments in pharmaceutical policies 2025/2026

CHANGES IN PRICE REVIEWS

New Guidelines

The Patented Medicine Prices Review Board (PMPRB) reviews patented medicine prices to protect Canadians from excessive prices. The PMPRB published new guidelines in June 2025.

Staff uses a patented medicine's first semi-annual price filing to conduct an Initial Review against the highest international price ("HIP") filed by the Rights Holder for the Schedule Countries. These countries are Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden and the UK.

Patented medicines whose prices are above the HIP threshold are subject to an In-Depth Review. Once Staff has finished the In-Depth Review, they will inform the Chairperson whether they recommend that a hearing into the price of a patented medicine be held. The Chairperson decides whether to issue a Notice of Hearing. Following a hearing, if the Board finds that a Rights Holder is selling a patented medicine in any market in Canada at an excessive price, the Board may order the Rights Holder to reduce the maximum price at which the Rights Holder sells the medicine.

CHANGES IN REIMBURSEMENT

pan-Canadian Pharmaceutical Alliance (pCPA)

The pCPA negotiates drug prices with manufacturers on behalf of publicly funded drug plans.

This includes all 14 provincial, territorial, and federal governments. As of December 31, 2025, pCPA reached 768 agreements. Of these drugs, 270 were for oncology drugs, 92 were biosimilars, and 91 were for rare diseases. The savings reported by pCPA were of CAN\$4.9 billion 2024-25

pCPA has instituted several initiatives to both speed up the time of negotiation and provincial listing.

2024 Temporary Access Process (pTAP) Designed for innovative drugs that show early promise and have been given conditional regulatory approval while confirmatory trials are in progress. Drugs can be negotiated sooner, allowing public drug plans to offer temporary coverage earlier.

2025 Early Negotiation Process Established in support of Project Orbis drugs in Canada, high-priority cancer therapies reviewed concurrently with the US FDA and other international partners to speed up access. Negotiation process begins when the Canada's Drug Agency (CDA-AMC) or the Institut national d'excellence en santé et services sociaux (INESSS) accepts a submission. Expected to save up to 6 months compared to the standard negotiation process.

Federal, Provincial and Territorial Initiatives

2026 Ontario FAST Program: Ontario is fast-tracking public funding for six specific cancer drugs (Tagrisso, Scemblix, Nubeqa, Calquence, Opdivo+Yervoy) approved through this, aiming for access up to a year earlier.

OTHER CHANGES

In 2024, the Canadian Agency for Drugs and Technologies in Health (CADTH) became the Canada's Drug Agency (CDA-AMC) with an expanded mandate. The new agency will continue CADTH's important work of health technology assessment and monitoring of post-market safety and effectiveness.

Key changes

- **Expanded Mandate and System Role:** CDA-AMC evolved from a traditional HTA body (CADTH) into a broader national drug agency with an explicit role in improving patient health and system sustainability by advancing appropriate medication use, strengthening pan-Canadian data collection and real-world evidence to inform decision-making and analytics, and reducing duplication and coordination gaps that drive inefficiencies across the drug system.
- **Modernized Reimbursement Review Processes:** Major procedural reforms introduced proportionate review pathways (including PACES), clearer distinctions between standard and complex reviews, unified deliberative frameworks, and shorter, more predictable review timelines for appropriate submissions.
- **Shift to Managed and Conditional Access:** CDA-AMC normalized time-limited and conditional reimbursement recommendations, particularly for drugs with evidence uncertainty, enabling managed access models linked to post-listing evidence generation and reassessment rather than binary list/do-not-list decisions.
- **Greater Transparency, Equity, and Early Engagement:** Decision-making now more explicitly integrates equity, unmet need, and lived experience; engagement with sponsors occurs earlier and more systematically; and recommendation reporting is clearer and more transparent, supporting faster and more consistent provincial uptake.

The goal of these changes is a faster, more flexible public reimbursement process. CDA-AMC's reforms have shortened and stabilized HTA timelines and enabled provinces to rely on conditional, criteria-based, and reassessment-linked funding decisions, supporting earlier patient access while managing clinical and economic uncertainty.

SPECIAL TOPIC:

Regulation, pricing and reimbursement of pharmaceutical combination products

Canada does not have explicit, standalone pricing or reimbursement rules for pharmaceutical combination products in its public drug plans. Combination products and combination therapies are managed using existing regulatory, HTA, pricing, and formulary mechanisms originally designed for single products. Public drug plans focus on value for money, avoidance of double payment, and management of cumulative costs. These principles are applied through HTA recommendations, price negotiations, and jurisdiction specific formulary restrictions.

Jurisdictional observations

- Across provincial public drug plans (e.g., Ontario, Quebec, Western provinces), fixed dose combinations are generally assessed as a single Drug Identification Number and follow HTA recommendations (CDA-AMC or INESSS) for reimbursement and price negotiations.
- Co-packaged products are typically reimbursed at the component level, with kits rarely listed as standalone reimbursable products.
- Most policy attention in Canada relates to combination regimens composed of separate products, rather than fixed dose or co packaged combination products as such.
- At the HTA level, there is no dedicated pathway for combination therapies; recommendations commonly focus on ensuring that total costs do not exceed the aggregate costs of individual components for the public plans.