CANADA

Recent and planned developments in pharmaceutical policies 2025

Role of the pCPA

The pCPA, an alliance of all 14 provincial, territorial and federal governments, negotiates lower drug prices to improve public drug coverage. It works with Health Canada; the two Canadian health technology assessment (HTA) bodies, Canada's Drug Agency (CDA) and the Institut national d'excellence en santé et en services sociaux (INESSS); and public drug plans.

Brands and biosimilars: Negotiations occur per drug indication, after regulatory approval and positive HTA reimbursement recommendation, and end in a listing agreement.

Generics: A negotiated master agreement uses the Tiered Pricing Framework with three pricing tiers, setting discounts from 15% to 75% based on market competition and brand-name reference pricing.

Unique negotiation mechanisms

For brand and biosimilar negotiations, the pCPA has two unique negotiation pathways that complement the regular one:

Targeted Negotiation Process: Expedited pathway with limited offer exchanges and a specified timeframe for the negotiation to conclude.

pCPA Temporary Access Process (pTAP): Early pathway for drugs that show promise and have received conditional regulatory approval while ongoing confirmatory trials are in progress. It allows for an interim agreement, with a requirement for additional evidence to be submitted to HTA bodies within three years, followed by a re-negotiation to confirm long-term pricing and coverage conditions.

HTA developments

Time-limited recommendations: In 2024, the CDA issued its first time-limited reimbursement (TLR) recommendation, requiring manufacturers to address evidence gaps through further clinical studies. A final decision follows reassessment of this new data. Eligible drugs need a Notice of Compliance with Conditions (NOC/c) from Health Canada, a phase III trial plan within three years, and a commitment to reassessment. The pCPA's pTAP handles negotiations for drugs under this pathway.

Societal perspective in HTA reviews: The CDA is broadening its economic evaluations to include the societal perspective in complex drug reviews. Traditionally, assessments focused only on public payer costs (e.g. drug expenses, hospitalizations). The new approach considers patient productivity loss, missed work for treatment, and costs to other government sectors. This pilot project aligns with practices at INESSS, which requires both healthcare payer and societal perspectives.

Broad policy considerations

National pharmacare: In 2024, the federal government introduced the *Pharmacare Act* as a first step toward a national drug coverage program. The initial phase provides universal access to essential medications, beginning with diabetes and contraception drugs. Bilateral agreements are currently being signed between the federal government and provinces and territories. The pCPA welcomes the opportunity to negotiate drug prices for national pharmacare.

Tariffs and drug shortages: The pCPA is monitoring the potential impact of tariffs on drug pricing and availability to ensure reasonable pricing and stable supply.

National Strategy for Drugs for Rare Diseases (NSDRD): Canada has launched NSDRD committing $1.4 B to drugs and treatments over 3 years to improve access, affordability and innovations for rare diseases.

Learn more about the pCPA

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