pan-Canadian Pharmaceutical Alliance
Alliance pharmaceutique pancanadienne

pTAP Stakeholder engagement

In August 2023, the pan-Canadian Pharmaceutical Alliance (pCPA) engaged with clinicians, patient groups and industry to present and hear feedback on a set of principles and conditions for a pCPA Temporary Access Process (pTAP).

pTAP has been designed to inform the negotiation process with the pCPA and potential product listing agreements for pCPA jurisdictions for any drug products that follow the Canadian Agency for Drugs and Technologies in Health (CADTH) time-limited reimbursement recommendations (TLRs). Québec's participation is subject to the Institut national d'excellence en santé et en services sociaux (INESSS) recommendations.

TLRs are temporary reimbursement recommendations that are contingent on a future reassessment within a specific time period, where future evidence is expected to address any uncertainty identified during the initial CADTH assessment.

The pCPA retained the firm Pathway Strategies to coordinate the online stakeholder engagement sessions that took place on August 3 and 18, 2023. In addition to taking part in the online sessions, organizations had the opportunity to provide written feedback through the pCPA website, with a submission deadline of August 18.

What we heard

A total of 9 clinicians, 27 patient groups and representatives from 3 industry associations (BIOTECanada, Innovative Medicines Canada and RAREi) participated in the online stakeholder engagement sessions. In addition, we received written submissions from 31 parties, some of whom represented a multitude of members across Canada. Overall, clinicians, patient groups and industry indicated support for pTAP. There were, however, some concerns expressed over various proposed principles and conditions.

- For drugs that treat very small populations, it can be difficult for manufacturers to commercially justify a Phase III trial because of trial requirements. Stakeholders wonder whether real-world evidence and other types of evidence could be considered for pTAP.

- CADTH's cost-effectiveness measures can be unreasonable and unrealistic, making it challenging to reach pTAP deals with manufacturers.
- Risk sharing between payers and manufacturers should be better balanced.
- Flexibility in timelines for generating evidence may be needed to address unforeseeable disruptions or delays.
- TLRs and pTAP could create an unintended consequence whereby over time, manufacturers dispense with higher-quality clinical trials as they are no longer needed to secure public reimbursement.
- Stakeholders within the patient group and manufacturer communities are hoping for additional opportunities to inform the development and evaluation of pTAP, to ensure the process works for everyone.

Results

Building on this feedback, the pCPA and the three industry associations that participated in the engagement sessions continued to discuss specific negotiation details of the application of pTAP.

On September 28, 2023, CADTH announced the implementation of the TLRs. In March 2024, the pCPA introduced the finalized principles and conditions for pTAP, which have been posted on our website.