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Intelligence MEMOS

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From: Johanne Chambers and William Dempster

To: Pharma Policy Watchers

Re: Faster Deals or Faster Access? Evaluating the pCPA's New Drug Negotiation Pathways

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Canada's drug price negotiator for public drug plans is embarking on consultations about creating two new pathways to speed drug coverage. The goal of accelerating timelines is encouraging, and this initiative has the potential to reduce delays caused by protracted price negotiations after new medicines are approved. We outline some of the considerations that will be required.

The pan-Canadian Pharmaceutical Alliance (pCPA) negotiates drug prices on behalf of federal, provincial, and territorial public drug plans. Created in 2010, it combines the purchasing power of governments to **secure** better prices and ensure consistency in drug coverage decisions across Canada.

This joint approach has delivered significant **savings**, but also introduced **delays**: negotiations often continue for months after regulators and health technology assessment bodies finish evaluating a new medicine. The pCPA launched a **consultation** to accelerate negotiations and address the bottleneck. However, provinces will also need to speed up funding decisions post-pCPA deals to actually improve timelines for public access to new medicines.

Before a new drug reaches patients, it must clear several stages. Health Canada first reviews it for safety, efficacy, and quality. If approved, and often during regulatory evaluation, Canada's Drug Agency (CDA) and Quebec's Institut national d'excellence en santé et en services sociaux (INESSS) assess whether the drug provides good value for money compared to existing treatments and care protocols.

Then pCPA negotiates a national price on behalf of public drug plans. Each province or territory must then decide whether to list and fund the medicine. This means that even after approval and price negotiation, access can still take months, or not occur at all. On average, it takes nearly **two years** from Health Canada approval to public listing in one province. That lag has become increasingly controversial as patients **push** for faster access to new treatments.

In late October, the pCPA launched a **consultation** on two new "accelerated" negotiation pathways designed to speed this process: An Early Negotiation Process (ENP) for cancer drugs reviewed under Health Canada's **Project Orbis**, and a revised Targeted Negotiation Process (TNP) for simpler medicines similar to existing ones, formalizing a process that already exists.

Both are designed to deliver faster letters of intent – the preliminary pricing agreements between the pCPA and a manufacturer – by starting talks earlier and imposing tighter deadlines. Under the ENP, negotiations could begin as soon as Canada's Drug Agency releases its draft review report, potentially cutting several months from the current process. This is intended to make better use of the review period by overlapping assessments and price discussions rather than waiting for one to conclude before the next begins. For both the ENP and the TNP, there is a 65 business-day limit on the conclusion of negotiations after the pCPA issues a letter of engagement, or the file can be closed.

In this context, a couple of important issues emerge:

Speed vs. access: The ENP and TNP could shorten negotiation times, but whether they lead to faster patient access is uncertain. A letter of intent is no guarantee – it is only an "option to fund." Each public drug plan must still sign its own listing agreement with a manufacturer before patients can get the drug, and there are no timelines for that. In practice, the delay may just shift from negotiation to funding. Ontario's new **FAST** (Funding Accelerated for Specific Treatments) program was created to close this gap. FAST commits to fund some Project Orbis drugs when Canada's Drug Agency issues it recommendation. By contrast, the ENP only aims to reach a letter of intent by that stage. Unless provinces commit to reimbursing faster, the ENP risks offering speed on paper, not in practice.

More rigid framework, fewer deals? Both proposed new streams rely on a rigid structure with strict, short timelines for exchanges of offers between manufacturers and the pCPA. While the pCPA retains broad discretion over which drugs qualify and whether offers are acceptable, manufacturers have limited options and must comply or risk no negotiations or early termination. This approach may keep files moving but could restrict or even deny access. Tight timelines leave little room for nuanced discussions, especially for complex cancer medicines, many of which require hospitals and community healthcare to provide specialized diagnostics or other clinical interventions. In addition, the process also carries high expectations for deeper price reductions, and the **pCPA** is already aggressive in this regard. And if the pCPA process fails to secure a pricing agreement, public drug plans will not list, eliminating public access, undermining the goal of faster, broader availability.

The pCPA deserves credit for tackling a long-standing bottleneck. But real acceleration will require collaboration from every player. Without that coordination, Canada's new "fast lane" risks becoming another detour on the long road to timely, equitable access to new medicines.

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