



**Neighbourhood  
Pharmacy**  
Association of Canada

Association canadienne  
**des pharmacies  
de quartier**

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## **RE: Consultation on the Controlled Distribution Program (CDP) for Clozapine**

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) represents leading pharmacy organizations across the country, including chain, banner, grocery chains, specialty pharmacies, mass merchandisers and independent pharmacies. Nationally, we advance the delivery of care through more than 12,000 pharmacies and their teams, that serve as integral community health hubs in urban, suburban, rural, remote and First Nations neighbourhoods.

As the only pan-Canadian association representing pharmacy operators, we act to support policy makers with the development of innovative solutions that allow pharmacies to support primary care while advocating for fair and sustainable funding for community pharmacies.

Neighbourhood Pharmacies appreciates the opportunity to provide feedback to Health Canada regarding its evaluation of the effectiveness and safety of the existing registry-based Clozapine controlled distribution program (CPD).

While there are still explicit monitoring requirements in product labelling, the best available clinical evidence and global regulatory changes, most notably the recent U.S. Food and Drug Administration decision to remove the clozapine Risk Evaluation and Mitigation Strategy program, suggests that registry infrastructure is not required to ensure patient safety. The existing registry system can hinder patient access and places a heavy administrative burden on prescribers and pharmacies. We believe that removing the closed distribution requirement and shifting to clinician-led monitoring will remove unnecessary administrative burden while still supporting continuity of safe and effective care.

Below we have provided a series of **operational, economic, and workflow impacts for Health Canada to consider as it continues to assess the current distribution model for Clozapine**

### **Patient Access and Continuity of Care Risks**

- Patients face **stressful, disruptive experiences** when asked to register or re-register, or when treatment is delayed due to registry or lab result issues.

- These interruptions create anxiety, confusion, and potential **treatment gaps** in a vulnerable population requiring continuity of therapy.
- A streamlined, clinician-led monitoring system could reduce these barriers while maintaining safety.

### Administrative Burden on Pharmacies

- The closed, manufacturer-specific registry model creates a **fragmented system** with duplicative paperwork, re-registration requirements, and brand-switch complications driven by hospital formulary decisions rather than patient choice.
- Pharmacies must navigate multiple registries without transparency, stock all brands to accommodate patients across programs, and manage significant clerical work (bloodwork verification, documentation, reporting, re-enrollment).
- This leads to **increased costs, inventory risk, and staff workload** without commensurate funding.

### Inadequate Funding and Reimbursement Structures

- Pharmacists provide critical services to support patients taking Clozapine—lab verification, ongoing monitoring, counselling, documentation, and coordination with prescribers—but in most provinces, these services are **unfunded**.
- For example, in Ontario, clozapine is reimbursed only through the **Special Drugs Program (SDP)**, designed as a hospital-only model. Community pharmacies dispensing clozapine must do so under binding agreements that:
  - Shift clinical responsibility onto pharmacies,
  - Deny payment of mark-ups or dispensing fees,
  - Require zero-dollar claims submission.
- This results in pharmacies **absorbing both the clinical workload and financial liability**. Moving clozapine into regular public formularies would enable fair reimbursement.

### National Guidelines and Standards

- Pharmacists are trained and competent in all areas of medication management, and can safely and effectively manage their patients clozapine therapy, including monitoring, addressing and preventing adverse events.
- To support an effective transition and communication, and uphold explicit absolute neutrophil count monitoring requirements in product labelling, national guidelines could be created in collaboration with provinces, colleges, clinicians and other stakeholders, such as
  - Lab monitoring frequency and stop/hold rules
  - Definition of “non-rechallengeable” patients
  - Brand-switch protocols
  - Potential for a limited pan-Canadian registry for severe neutropenia cases

### Enable pharmacist access to lab results across all provinces:

- Ensuring that all pharmacists have the authority to access and interpret laboratory tests would further support the safe removal of the closed distribution model.

- Several provinces already grant this authority, demonstrating pharmacists' competence.
- Pan Canadian implementation would promote consistency, reduce barriers, and enhance patient safety.

**Conclusion:**

The closed distribution model for clozapine imposes **unnecessary administrative burdens, disrupts patient care, and unfairly shifts costs and liability to community pharmacies.** Neighbourhood Pharmacies is in favour of changes that lessen the administrative load while maintaining patient safety and fair access to clozapine. We value Health Canada's initiative in reviewing the CDP and anticipate working together going forward to make sure that patients, prescribers, and pharmacy teams have a safe and easy transition.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Hanna', with a stylized flourish at the end.

Sandra Hanna, RPh. LLM. ICD.D  
Chief Executive Officer  
Neighbourhood Pharmacy Association of Canada