



**Neighbourhood
Pharmacy**
Association of Canada

Association canadienne
**des pharmacies
de quartier**

Office of the Chief Executive Officer

1205-3230 Yonge Street
Toronto, ON M4N 3P6
T: 416.226.9100
F: 416.226.9185
info@neighbourhoodpharmacies.ca
neighbourhoodpharmacies.ca

Government of Canada

**Submission Regarding
New requirements proposed for the Food and Drug Regulations**

(additional regulations intended to prevent, mitigate, and respond to drug shortages)

**Canada Gazette, Part I, Volume 158, Number 52: Regulations Amending Certain
Regulations Made Under the Food and Drugs Act (Shortages and Discontinuation of Sale
of Drugs and Medical Devices)**

March 26, 2025

Neighbourhood Pharmacy Association of Canada

**Submitted to
Health Canada
(via email)**

Introduction

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 12,200 pharmacies and their teams, that serve as integral community health hubs in urban, suburban, rural, remote and First Nations neighbourhoods. Canada's pharmacies employ more than 185,000 Canadians, including 38,000 licensed pharmacy professionals, who dispense more than 847 million prescriptions per year valued at \$36 Billion. The sector generates an estimated \$9.5 Billion in GDP, while its total economic footprint is more than \$18.7 Billion.

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 on Health Canada's proposed amendments to the *Food and Drug Regulations* aimed at enhancing the tools available to prevent, mitigate, and respond to drug and medical device shortages. We value our continued engagement with Health Canada and thank you for convening a Drug Shortages Regulatory Package Listening Session for our Association on March 18, 2025, as well as for allowing additional time to submit this more detailed written response.

This submission reflects our sector's front-line experience in the medication access pathway and builds upon the input shared during our in-person consultation. We offer targeted feedback on the proposed regulatory elements and provide additional recommendations intended to strengthen Canada's drug supply resilience, particularly through the role pharmacies play in supporting the resilience, efficiency, and sustainability of drug supply management in Canada.

Context and Background

Canada's pharmacies and their teams represent the final drug distribution access point in the entire medication supply chain, are the medication experts advising on how to safely and effectively manage a patient's drug supply and are a key source of education and information to the public. Representing our members nationwide, Neighbourhood Pharmacies offers recommendations grounded in this unique and critical role.

We recognize that the proposed regulations will impose new obligations on Market Authorization Holders (MAHs) intended to prevent, mitigate, and respond to drug shortages. While we do not represent the MAHs, we have consulted with supply chain partners and support many of their recommendations. Our feedback reflects pharmacies' real-world experience and the downstream impacts these regulatory changes may have on medication access for patients

1. Consider a Temporary Pause in Regulation Implementation

Since the launch of this consultation, escalating trade tensions with the United States have created significant uncertainty. At the time of this submission, the Canadian government is

considering imposing a second wave of tariffs on a wide swathe of American products being imported into Canada. A number of pharmaceutical products, including brand name, generic and OTC medications, are being considered. The total value of these imported medications under deliberation is estimated at \$4.4 billion; which is over 50% of all US-imported prescription drug products dispensed by Canada's pharmacies.

We strongly urge Health Canada to pause any further implementation of these regulatory changes and new manufacturer obligations in light of the ongoing tariff dispute between Canada and the U.S., which threatens to destabilize the entire pharmaceutical supply chain. With increased uncertainty around drug pricing, availability, and market access, introducing additional regulatory changes at this time could further disrupt supply and jeopardize patient access to essential medications.

While we support the country's need to mount a strong retaliatory response to US-imposed tariffs, and we and other stakeholders have recommended the removal of any pharmaceutical products from Canadian counter-tariffs, the situation is still uncertain. A temporary pause would allow for a clearer assessment of the potential economic and healthcare impacts, ensuring that any future regulatory decisions support, rather than further strain, Canada's pharmaceutical landscape.

2. Expansion of scope of drugs subject to regulatory obligations, and information to be provided.

Our understanding is that Health Canada has proposed specific regulatory changes that will

- *“allow the Minister to expand the scope of drugs that would be subject to regulatory obligations related to shortages, such as reporting, to additional drugs or classes of drugs, including certain over-the-counter drugs” and*
- *“allow the Minister to require information to be provided, in certain circumstances, about a shortage of any drug that could present a risk of injury to human health if in shortage rather than only those drugs in scope of shortage reporting;”*

We support, in principle, the proposed amendments that grant the Minister authority to expand the scope of drugs subject to regulatory obligations related to shortages, including the extension of reporting obligations to additional drugs or classes of drugs, such as certain over-the-counter (OTC) products. As demonstrated during the COVID-19 pandemic, OTC medications can experience significant shortages, highlighting the critical need to incorporate these products into broader shortage mitigation strategies. This flexibility and nimbleness in regulatory oversight is essential to maintaining medication availability and ensuring public confidence in Canada's drug supply system.

However, we urge Health Canada to approach these expanded requirements with caution, particularly regarding the impacts they may impose on the pharmaceutical supply chain. Specifically, any new obligations must provide clear predictability and adequate advance notification to supply chain stakeholders, including pharmacies, to ensure effective planning and response.

3. Shortage Prevention and Mitigation Plans, including use of Critical and Vulnerable Drugs List

Our understanding is that Health Canada has proposed specific regulatory changes that will *“set new requirements for drug market authorization holders to develop and maintain shortage prevention and mitigation plans for drugs where a shortage could present a serious risk of injury to human health”*

We support the development of a Critical and Vulnerable Drugs list that will guide the identification of drugs for which shortages could present a series risk of injury to human health. In previous submissions to Health Canada, we have advocated for the thoughtful creation of such a list which should include factors such as drug safety, effectiveness, cost, as well as a robust assessment of risks to Canadians and the healthcare system overall if these medications are not available. The list should be designed to be reviewed on a regular cadence, and flexible enough to respond to emerging challenges in the healthcare ecosystem.

However, we wish to highlight the importance of clearly articulating the purpose of the CVDL, to ensure it is for appropriate policy decisions. The CVDL should not, for example, be confused with the development of a minimum national formulary, one of the building blocks of implementing national pharmacare.

We also wish to acknowledge the potential benefits of requiring Market Authorization Holders (MAHs) to develop and maintain shortage prevention and mitigation plans for drugs listed on the Critical and Vulnerable Drugs List (CVDL). However, we are concerned about the potential financial and operational burden these requirements may place on MAHs, that will result in increased costs that will cascade through the supply chain. MAHs and other supply chain stakeholders will inevitably seek ways to offset their increased expenses, which could ultimately translate into higher costs for pharmacies to carry and support their medications. Unlike other supply chain participants, pharmacies cannot pass increased costs on to patients. Instead, they must absorb these financial pressures while striving to maintain service levels.

We urge Health Canada to take a cautious, phased approach to implementation, supported by frequent, meaningful consultation. This need for careful consideration is heightened by current global economic volatility and ongoing international trade disruptions, including tariff uncertainties with key trading partners. Introducing extensive regulatory changes amid this context significantly elevates the risk of destabilizing the pharmaceutical supply chain, which could lead to severe disruptions in patient care and healthcare delivery.

4. Maintenance of Safety Stocks

Our understanding is that Health Canada has proposed specific regulatory changes that will *“set new requirements for drug market authorization holders to maintain safety stocks for select drugs that could present a serious and imminent risk of injury to human health if in shortage;”*

We acknowledge and support the underlying rationale for requiring Market Authorization Holders (MAHs) to maintain safety stocks for select drugs identified as presenting a serious and imminent risk of injury to human health if shortages occur. This measure could significantly enhance Canada’s pharmaceutical resilience, especially in the face of global supply disruptions or tariff-related uncertainties.

However, we remain cautious regarding the immediate operational and financial implications associated with the implementation of these requirements. Health Canada's own estimates indicate initial setup costs at approximately \$71 million—an expense that will undeniably place substantial financial pressures on industry stakeholders. As noted above, manufacturers and other supply chain stakeholders will inevitably seek ways to offset these expenses. This could lead to cost pass-throughs, which could inadvertently escalate operational costs at the pharmacy level; and negatively impact patient affordability and access to both prescription and OTC medications.

The additional financial burden on MAHs could also trigger possible re-negotiation of pricing norms and contracts or even loss of products for Canadians if manufacturers decide to withdraw products from the Canadian market. Well-intentioned safety stock requirements could inadvertently exacerbate, rather than prevent, medication shortages in Canada.

To avoid these negative downstream consequences on Canadian's ability to access their medications we recommend that Health Canada consider establishing economic incentives to offset compliance costs for implementation of shortage mitigation strategies by supply chain stakeholders. Effective incentive structures could better facilitate regulatory compliance without compromising the financial sustainability of stakeholders throughout the supply chain.

5. Extension of Expiration Dates

Our understanding is that Health Canada has proposed specific regulatory changes that will *“allow the Minister to increase the supply of a drug available to address a shortage by extending the expiration date for the drug in certain circumstances;”*

We support the proposed regulatory amendments permitting the Minister to increase the available supply of a drug by extending its expiration date under certain circumstances when addressing a drug shortage. We recognize this as a pragmatic approach that has been successfully employed in past shortage scenarios to ensure continued patient access to critical medications.

However, this approach should always be accompanied by clear, timely, and transparent communication. Effective dissemination of information regarding changes to expiration dates is essential to healthcare providers, pharmacies, and patients alike. Adequate communication ensures confidence in the safety and efficacy of medications and allows pharmacies and healthcare professionals to manage patient expectations appropriately. Open communication channels are essential to avoid confusion, ensure patient safety, and maintain trust in Canada's pharmaceutical supply system during shortages.

6. Strengthen Pharmacy Scope & Therapeutic Substitution Capabilities

The ability of pharmacists to independently substitute therapeutically appropriate medications in response to shortages is one of the most immediate and effective tools to mitigate supply disruptions. However, in many jurisdictions, pharmacists remain restricted from making such substitutions without physician involvement, which creates avoidable delays and inefficiencies in patient care.

We urge the federal government to take a leadership role in facilitating national and PT dialogue on scope expansion, working collaboratively with provinces and territories to allow regulatory frameworks that empower pharmacists to make informed therapeutic substitutions. This will ensure continuity of care, reduce administrative burden, and improve patient outcomes during times of supply constraints.

Furthermore, appropriate funding mechanisms must be implemented to remunerate pharmacists for their expanded role in drug shortage management. Pharmacy teams report spending up to 20% of shift time managing drug shortages, which can equate to more than 400 hours annually per Canadian pharmacist.

Pharmacy teams are carrying the burden of identifying and addressing shortages at the patient level, but without structured compensation models that support existing and expanded scope activities, this work remains unsustainable in the long term.

7. Leverage Pharmacy Information Systems for Real-Time Drug Supply Monitoring

Canada's pharmacies are at the frontline of the medication supply chain, yet their existing digital infrastructure remains underutilized for shortage detection and response. We recommend that Health Canada explore mechanisms to integrate pharmacy data into a real-time national drug utilization and inventory tracking system.

By leveraging existing digital platforms, such as pharmacy dispensing and inventory management systems, Health Canada can gain timely insights into prescription trends, demand spikes, and potential shortages before they escalate into crises. However, any new reporting requirements must be carefully structured to prevent additional administrative burden on pharmacy teams. This initiative should be developed in consultation with pharmacy stakeholders to ensure feasibility and effectiveness.

8. Enhance Public Communication & Education Strategies

Public perception and behavior play a significant role in worsening drug shortages. During past crises, panic buying and misinformation led to artificial supply constraints, as seen during the pandemic with OTC medications. We urge Health Canada to proactively engage in public education campaigns that:

- Provide clear, evidence-based communication on drug supply stability.
- Discourage hoarding behaviors that disrupt supply chains.
- Educate Canadians on the risks of purchasing medications from non-legitimate online sources, particularly during shortages.
- Educate Canadians on any specific shortage mitigation strategies such as extension of expiry dates (if implemented).

A strong public information strategy will prevent unnecessary disruptions and ensure that drug supply remains stable and accessible for those who truly need it.

Conclusion

Neighbourhood Pharmacies appreciates the opportunity to contribute to this important consultation. We support Health Canada's intent to strengthen Canada's pharmaceutical supply chain, but stress that implementation must be measured, collaborative, and sensitive to current

geopolitical and economic realities. We look forward to continued dialogue and partnership in advancing policies that protect patients' ability to access their medications, and promote a resilient, sustainable drug supply system.