



**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: Consultation on improving access to drugs and other health products in Canada

**Submitted by: Neighbourhood Pharmacy Association
of Canada**

August 30, 2023

**Submitted to:
Health Canada
Drug Shortages Task Force**

Introduction

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) represents leading pharmacy organizations across the country, including chain, banner, long-term care, grocery chains, specialty pharmacies, and mass merchandisers with pharmacies. We advance the delivery of care through more than 11,500 pharmacies and their teams, that serve as integral community health hubs in urban, suburban, rural, remote and First Nations neighbourhoods. As the association representing pharmacy operators across the country, we act at a pan-Canadian level to support policy makers with the development of innovative solutions that allow pharmacists to support primary care while advocating for fair and sustainable funding for community pharmacies.

We are pleased to support Health Canada's Drug Shortages Task Force to develop a long-term strategy to improve the availability and accessibility of drugs and other health products for Canadians. We have provided a series of recommendations and considerations to the Government from the unique perspective of the pharmacy sector, that reflect our members' pivotal role in the medication access pathway. Community 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.

Community Pharmacy Role in Managing Drug Shortages

Pharmacies and their teams dedicate many hours to managing drug shortages for their patients at the pharmacy counter, with some estimates suggesting up to 20% of every shift. Activities can include:

- Educating the public and healthcare professionals about drug shortages.
- Serving as a conduit for any public service information and minimizing 'hoarding' of drugs.
- Advising patients and healthcare providers on suitable substitution options to ensure continuity of treatment.
- Recommending therapeutic alternatives during shortages or (where enabled) making therapeutic substitutions.
- Managing medication supplies by implementing responsible dispensing practices, include limiting quantities.
- Compounding where possible or necessary.
- Helping patients access medications at other pharmacies if their pharmacy is out of stock, by referring or transferring prescriptions.
- Communicating with drug manufacturers, wholesalers, and distributors to enhance supply chain resilience and identify potential vulnerabilities.

These activities are reactive, short-term mitigation and management strategies, not preventative or long-term solutions. While necessary and critical, the time pharmacy teams spend on drug shortage activities detracts from the time they can spend on direct patient care. Moreover, these essential prevention and mitigation activities are not recognized or funded by the healthcare system. **We recommend the Government promote dialogue with provincial and territorial**

stakeholders to support and implement the funding of pharmacy services and activities to manage drug shortages at the frontline.

1. Recommendations to Foster Better Supply Chain Visibility:

Canada's pharmaceutical supply chain is under considerable stress due to a confluence of factors. Labour shortages have hindered efficient production and distribution, while manufacturing challenges and rising inflation have escalated costs and constrained availability. Even vulnerabilities uncovered by severe weather incidents have further compounded the strain on the country's pharmaceutical system. A better line-of-site of across the entire supply chain will help protect Canada's medication supply from these ongoing stresses.

- **Foster a better understanding of global pharmaceutical supply trends.** Drug shortages are having a global impact. By developing a comprehensive understanding of global pharmaceutical supply trends, Health Canada can proactively identify potential risks to the Canadian drug supply. There are many lessons to be learned from our colleagues in other countries. Collaborating with international partners and monitoring supply trends in key regions will help anticipate and prepare for any disruptions, be they due to geopolitical events, manufacturing challenges, or natural disasters. This foresight will help minimize the impact of drug shortages on Canadians.
- **Optimize the drug shortage database:** A comprehensive domestic drug shortage database that consistently defines, classifies and reports shortages, but also reports on more meaningful metrics, would improve drug shortage prevention and management. A mechanism that allows market authorization holders (MAHs) to report replenishment timelines as a metric would be a very useful marker for the community pharmacy channel to appropriately mitigate shortages. The development of local status supply reports for use by healthcare providers and community pharmacies could also better support prescribing decisions and medication access. Expanding the scope of the reporting framework to include non-prescription products or life-sustaining nutritional products (e.g., infant formula) would also be advantageous. Armed with more robust information, Health Canada and stakeholders can make data-driven decisions, identify vulnerable areas in the supply chain, and strategize resource allocation to ensure a steady supply of critical medications.

We recognize that some data is proprietary and note there are realities of anti-competition that must be navigated. However, from a community pharmacy perspective, a useful database and reporting framework is one that provides metrics that reflect patient access to medication within the supply chain.

- **Improve mechanisms for detecting early indicators of potential drug shortages.** All stakeholders should continue to work towards more robust methods of identifying and assessing early indicators of potential drug shortages within Canada. While we commend the Government's progress on establishing reporting and collaboration opportunities for MAHs, wholesalers and frontline providers to report drug shortage signals, there is more to be done. From the community pharmacy perspective, our members report receiving word of potential shortages 2-3 months before products run short. A system that provides earlier indicators can allow the market to prepare better and potentially mitigate impacts felt at pharmacy level.

- Expanding the sources of information considered for signalling drug shortages should also be explored. For example, the BC PharmaNet system, which tracks all prescriptions written in the province, was able to identify an anomalous and concerning increase in Ozempic™ prescribing, which allowed timely mitigation to prevent a potential shortage. Continuing to engage stakeholders throughout the supply chain to provide information and trends on product availability as well as factors impacting future supply (e.g., active pharmaceutical ingredient (API) shortages, manufacturing delays, workforce issues, regulatory delays, etc.) will better equip the Government to predict emerging shortages and take proactive measures.

A proactive approach that emphasizes collaboration, data-driven decision-making, and global supply chain insights will undoubtedly strengthen the resilience of Canada's pharmaceutical sector and safeguard the health and well-being of our citizens. These strategies have the potential to bolster the resilience of Canada's pharmaceutical supply chain and ensure that patients have access to the medications they need, when they need them.

2. Recommendations to Support an Enhanced Response to Drug Supply and Demand Challenges.

- **Create an at-risk medications list.** Creating a list of medications that are indispensable to the health and well-being of Canadians and are most at risk of shortages will help identify and prioritize critical medications that the Government must always keep in stock. At-risk medications should include both prescription drugs and over the counter products. All stakeholders in the medication supply chain should be engaged in developing the criteria for medications/medication classes on the 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. For example, the burden of disease on the healthcare system in the absence of medications to treat patients with complex, rare conditions, or those for widespread chronic diseases, cannot be overlooked. Another important factor to consider is the number of manufacturers producing the medication, as those with a limited number will be most vulnerable to shortages.

The list should be designed to be reviewed on a regular cadence, and flexible enough to respond to emerging challenges in the healthcare ecosystem. An at-risk medicines list should not be confused with the development of a minimum national formulary, one of the building blocks of implementing national pharmacare. The availability of an at-risk medications list can support focused Government efforts on ensuring a stable supply of critical drugs during times of heightened demand or supply chain disruptions.

- **Limit exportation of Canadian medications to the United States.** Canada's pharmaceutical supply system is designed and carefully managed to serve our population. Canada does not have the capacity to support the drug supply needs of the United States' population. To address concerns of medication shortages domestically, we encourage the Government to strengthen measures designed to prevent or restrict the bulk export to the United States of any prescription drugs intended for the Canadian market. Federal and Provincial/Territorial Governments should further explore interest in promoting a common cross-provincial approach to prevent shortages arising from exportation provisions. In parallel, the Government should continue to monitor and address approaches by the United

States seeking to capitalize on Canada's more affordable medications as a solution to their own drug shortage issues. By balancing trade dynamics with the need to meet domestic demand, the Government can ensure Canadians retain a reliable supply of domestically available medications, especially during emergencies or periods of scarcity.

- **Prioritize the collection of data on medication demand and inventory using existing pharmacy information management systems.** We applaud Health Canada's work to-date engaging the community pharmacy sector as a part of the ongoing stakeholder dialogue hosted by the Multi-Stakeholder Steering Committee on Drug Shortages. The pharmacy sector has been providing valuable timely reports of medication supply or drug shortage status at the community pharmacy level, and sharing useful feedback on public reaction to shortages, any signals pharmacies are receiving from their wholesalers, and innovative examples of management strategies being used. While we believe the current process is helpful to the Government in validating shortage status and impacts of mitigation activities, the current method of reporting places a burden on already stressed pharmacy teams.

We believe more can be done to facilitate an end-to-end picture of available stock throughout the supply chain. We strongly encourage the Government to work with pharmacy wholesalers, distributors and operators to consider the development of an integrated and efficient means of collecting, consolidating and analyzing real-time data on medication demand (i.e., prescription patterns and/or sales) and on-hand inventory at the community pharmacy level. Community pharmacies use many digital information systems and technology platforms to track and order inventory, process prescriptions, and make claims for drug coverage or services. These existing systems could be explored to find ways of triggering signals or notification of shortages based on pharmacy or distributor level data. However, it is essential that any systems do not add more data entry or reporting burden to pharmacy teams. We strongly encourage the government to place a priority on developing jurisdictional or pan-Canadian systems to collect and integrate real-time inventory information at the pharmacy level. By utilizing existing technology and available data, Canada can gain valuable insights into prescription and over-the-counter medication usage patterns, allowing for rapid response and resource allocation during potential shortages.

- **Apply a 'whole-of-Government' approach to healthcare policies impacting patient access to medications.** It is vital that the Government examine how other healthcare policies impact the domestic availability of medications. Policies intended to protect Canadians against prohibitive drug costs, or to curtail public drug spending by switching to lower cost alternatives can have negative downstream consequences on medication availability:
 - Policies relating to the pricing of both patented and generic pharmaceuticals may influence MAH's decisions to make certain drugs available in Canada.
 - As medication prices are compressed and margins decrease, wholesalers and distributors hold less stock on hand at any given time (e.g., a 2-week supply instead of a 6-week supply). While not true drug shortages, this limited available stock nevertheless can cause community pharmacies to run short of available medications at the store level, leading to delays in patients' access to medications and potentially causing public perception that a shortage exists.

- Biosimilar transition policies that have rolled out across the country can have considerable impact on medication supply and demand. A single biologic can have multiple biosimilars, meaning multiple manufacturers will be competing for similar APIs, potentially leading to additional shortages of these ingredients. The impact of a shortage or delay of complex biosimilar medications can have profound consequences on vulnerable patients.

A more resilient supply chain can recover more rapidly from disruption and unexpected changes in supply and demand. The development of an at-risk medications list, limitation on exports to the US, and an exploration of existing data system to provide timely data on medication availability at the community level can all support government and the community pharmacy sector to prepare for and react to changes in supply and demand. And, by proactively assessing potential interactions between policies, the Government can make informed decisions that prevent unintended consequences, such as shortages or disparities in access to medications.

3. Recommendations to Support More Agile Regulatory Toolbox

- **Accelerate entry of medications into the Canadian market.** Canada is a small market and has a very comprehensive drug approval system. Recognizing that there are already partnerships and memorandums of agreement in some aspects of the approval process, we would encourage the Government to further explore opportunities to streamline elements of the approval process with respect to comparable markets. We recommend that the Government consider reviewing existing powers or flexibility to add additional products to the list of drugs for exceptional importation and sale that are not approved in Canada but are manufactured with similar standards. An agile regulatory environment that supports more responsive channels or tools to accelerate approval and/or importation of critical or essential drugs into the Canadian market is an important facet of shortage prevention.
- **Develop and promote regulatory solutions to prevent dispensing of medications for non-Canadian residents.** As described earlier, the province of B.C. recently took action to prevent a looming drug shortage of Ozempic™, a drug indicated for weight management by patients with diabetes. Public demand for prescriptions of this medication (touted by media and influencers as a miracle weight loss drug) coupled with attractive comparative Canadian price points, resulted in thousands of prescriptions dispensed by pharmacies in B.C. and shipped to the United States. Alerted by the B.C. PharmaNet system (which demonstrated and the concerning prescribing trend) the provincial government was able to put a multipronged solution in place, including regulations that prevented the dispensing of medications to patients outside of the province. We encourage the Federal government regulators to learn from this success and collaborate with provincial and territorial counterparts to explore additional regulatory or legal solutions to protect the supply of medications and avoid the mass displacement of drugs outside of Canada.
- **Support appropriate scope expansion and remuneration for pharmacy teams to manage drug shortages.** We strongly encourage the Government to promote and support regulatory environments that enable all healthcare providers to work to the fullness of their scope to therapeutically substitute medications at the frontline. Empowering all pharmacists with the prescribing authority to therapeutically substitute medications will ensure continuity

of care for patients in the event of an unavoidable shortage or proactively manage medication inventory to prevent future shortages at the community level. Pharmacists have demonstrated that they can assess individual situations and determine the most appropriate alternative therapy specific to a patient's condition and current medication regimen. Pharmacy regulatory bodies in all provinces and territories, in partnership with governments, should authorize pharmacists to therapeutically substitute one medication for another with documentation and communication to the prescriber. Concurrently, pharmacies in all provinces and territories should be appropriately funded for therapeutic substitution services to ensure sustainable delivery.

Canada requires nimble regulatory frameworks and tools that can keep pace with changes that affect any part of the supply chain while still ensuring the safety and security of the medication supply. Our recommendations will support an agile regulatory environment to help to bring more medications to Canadian, keep more medications in Canada, and make medications more accessible to Canadians.

4. Recommendations Supporting Improved Communication and Transparency

We commend Health Canada and the Drug Shortages Task Force for their vigorous efforts to encourage a culture of open and transparent communication from all stakeholders in the medication supply chain to share important information that impacts drug shortage identification, prevention, monitoring and mitigation strategies. There have been several clear successes as a result of timely stakeholder collaboration and communication. The mitigation and public communication strategies carried out by stakeholders within the sector to respond to the Tier 3 Nitroglycerin shortage is an excellent example, drawing on the strengths of the individual MAHs to identify alternative products, the Government to execute appropriate approvals to extend the expiry dates of certain products, the clinical community to develop tools for practitioners to support appropriate therapeutic use of alternative products, and the pharmacy sector to ensure that pharmacy operators and individual practitioners were aware of the status, recommendations and tools.

- **Commit to continuous quality improvement (CQI) approach to drug shortage mitigation strategies.** A consistent lens of CQI on tactics activated in the event of a shortage would support an enhanced response. Accurately capturing key metrics and learnings regarding approaches and sharing with all stakeholders to understand how data was used, what tactics were applied, how the shortage was resolved and how effective was the solution would ensure that all stakeholders understand the value of their contribution to the process and the impact of their efforts. An ongoing feedback loop demonstrating the Government's commitment to CQI would continue to support all stakeholders' continued engagement in proactive solutions.
- **Build on communication successes.** We encourage Health Canada to continue its momentum to provide communication channels and opportunities to collect, analyze, disseminate, and act on the results of data and information. Enhanced data collection, analysis and dissemination tools will support increased stakeholder collaboration and more timely dissemination of information through the medication access pathway. We further encourage Health Canada to communicate its CQI efforts. Understanding how reporting enables drug shortage mitigation tactics and solutions will help stakeholders understand the

value of their efforts toward the shared goals of increasing medication access for Canadians and will ensure ongoing engagement

- **Develop appropriate public messaging:** The importance of clear and consistent messaging across all stakeholders in the supply chain and medication access pathway is well understood, and crucial to ensuring public confidence in Canada's drug supply system. However, as has been demonstrated recently, public behaviour and perceptions can be influenced by factors beyond the control of supply chain stakeholders. To minimize behaviours that might lead to unintended shortages, stakeholders must balance the needs of public information and safety with avoiding inaccurate perceptions of shortages in the minds of Canadians that could lead to increased demand for prescriptions or (in the case of OTC medications) excess purchasing and hoarding behaviours.
- **Raise awareness among the Canadian public regarding risks posed by non-legitimate online drug sellers.** As shortages continue, Canadians will increasingly look to purchase medications online. There is a need to steer Canadians away from rogue websites that may sell substandard or falsified medications not approved by Health Canada, or that may provide medications without requiring a legal prescription. We encourage the Government to work with stakeholders to develop communications tools to prevent Canadians from accessing medications outside of Canada's safe supply.

In Summary

We are pleased to provide considerations for possible solutions to support multi-stakeholder response to medication shortages under the four key areas identified for action. These recommendations are intended to better equip the frontline community pharmacy sector to fully play its part in collective solutions, and foster system-focused changes to better prevent, detect, and plan mitigation strategies for products that run short. Collectively, these diverse recommendations are intended to better identify issues and intervention opportunities at the supply and demand levels. We look forward to working with the Government, and all other stakeholders in the medication supply chain to continue to safeguard Canadians' access to medications.