

2025

# A Path Forward:

Collaborative Solutions  
to Strengthen Canada's  
Drug Supply

Canadian Generic  
Pharmaceutical Association (CGPA)  
Canadian Association for Pharmacy  
Distribution Management (CAPDM)

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**CGPA | ACMG**

 **CAPDM**

# EXECUTIVE SUMMARY

Medications are vital to patient health, quality of life, and the overall efficiency of the healthcare system. They are essential tools to the healthcare professionals who depend on them to provide safe, timely, and effective treatments to patients. A robust pharmaceutical supply chain is critical to meet these needs, and to ensure that medications remain accessible, reliable, and responsive to the evolving demands of patient care.

Drug shortages pose a growing challenge to Canada's already strained healthcare system, and to the reliable supply of essential medicines. Addressing this issue is complex, with no single solution or quick fix. The market is constantly evolving and innovating, making it critical for supply chain actors and influencers to collaborate strategically and embrace novel solutions that enhance supply stability.

Stakeholders across the healthcare ecosystem each have critical roles to play in ensuring Canadians have access to a reliable, sustainable supply of medications. Those in the pharmaceutical supply chain have begun to take steps to improve resilience, enabling them to better withstand, adapt to, and recover from challenges. Importantly, to ensure long-term stability, all stakeholders in the ecosystem must continually assess potential threats and refine their targeted, coordinated response.

Actions and measures must be aligned, with a deeper shared understanding of the underlying economic causes of supply vulnerabilities to develop effective, long-lasting solutions. Without a root-cause analysis and understanding of why shortages occur in the first place, misguided or uninformed policies could have unintended consequences—jeopardizing the long-term stability of Canada's medication supply, and

exacerbating already serious cases of drug shortages, or diminishing the competitiveness and appeal of the Canadian market.

Recognizing this, the Canadian Generic Pharmaceutical Association (CGPA) and the Canadian Association for Pharmacy Distribution Management (CAPDM) convened key pharmaceutical supply chain and healthcare system stakeholders to share perspectives and to develop priority actions to address drug shortages. Through consultations and summits with manufacturers, distributors, healthcare professional organizations, federal and provincial governments, hospital group purchasing organizations (GPOs), academia, and others, five key priority areas to prevent and mitigate shortages were identified:

- 1. Invest in supply chain diversification.**
- 2. Improve access to early and more consistent information to anticipate and mitigate potential shortages.**
- 3. Increase buffer stock to allow time for system-wide responses.**
- 4. Establish conditions to increase prices for medicines that are critical and vulnerable to shortages.**
- 5. Harmonize regulatory requirements to facilitate greater access to the global drug supply.**

Within each priority area are supportive actions with recommended owners and supporters required for their successful implementation.



This report is a directional resource for supply chain actors and influencers to help prioritize and target our collective, bilateral, and individual work to co-create meaningful and impactful solutions that ensure the sustainability of drug supply for Canadians.

# INTRODUCTION

Medications are essential to patient health and quality of life, and to the healthcare system, including the professionals who serve those patients. Recent data indicates that one in two adults and one in four children required a prescription within a single month.<sup>1,2</sup> Generic medications, the lowest-cost and highest-volume medications, represent more than 75% of all prescriptions filled in Canada.<sup>3</sup>

Drug shortages are an increasing global concern. In Canada, since 2017, 10-15% of drugs were in shortage at any given time and over half (55%) of marketed drugs have experienced at least one shortage.<sup>4</sup> In 2023-2024 alone, over 3,000 drug shortages were reported and the average duration of the shortage lasted 93.5 days.<sup>5</sup>

Shortages occur when demand exceeds supply, whether due to an unexpected increase in demand or a disruptive shortfall in supply. Shortages caused by supply constraints are often symptoms of deeper supply chain issues—highly complex and specific to the affected drug. Addressing these challenges is particularly difficult due to the multiplicity of underlying factors, only recently being acknowledged beyond the supply chain itself. Left unaddressed, these underlying factors will perpetuate persistent or worsening shortages.

As trade associations representing key players in the pharmaceutical supply chain, the Canadian Generic Pharmaceutical Association (CGPA) and the Canadian Association for Pharmacy Distribution Management (CAPDM) initiated broad consultations with supply chain stakeholders to determine interest in collaborative efforts and to explore potential solutions—including ways in which generic drug manufacturers and pharmaceutical distributors could enhance their roles. CGPA and CAPDM next facilitated a series of

meetings, first fostering open dialogue among manufacturers and distributors about their respective accountabilities, before expanding discussions to include representatives from federal and provincial governments, health-care professional associations, hospital group purchasing organizations (GPOs), and academia, among others. Participants shared insights into their responsibilities and accountabilities and identified needed independent and collaborative actions to strengthen Canada's drug supply. Many later commented that they gained a better understanding of the underlying factors and the diverse perspectives of supply chain stakeholders.

This report outlines the underlying causes of drug shortages from the Canadian supply chain perspective. It highlights the stakeholder-informed priorities and supporting actions within the context of generic prescription drug shortages. While discussions focused on generic medicines, the identified priorities and actions may be applicable to medicines in general. Additionally, while not exhaustive, this report provides related recommendations to inform and guide supply chain stakeholders in their individual and collective efforts to build a sustainable supply of medications.



1 Government of Canada, S. C. [The Daily — Prescription medication use among Canadian adults, 2016 to 2019](#) (2021).

2 Servais, J., Ramage-Morin, P. L., Gal, J. & Hales, C. M. Prescription medication use among Canadian children and youth, 2012 to 2017. *Health Rep.* 32, 3-16 (2021).

3 CGPA. Data derived from IQVIA Canada's PharmaFocus offering. 12-months "Compuscript" ending December 2023 (2024).

4 Canada Gazette, [Part I, Volume 158, Number 52](#) (2024).

5 Health Canada, [Drug Shortages in Canada: Fiscal Year 2023-2024 In Review](#) (2024).

# PHARMACEUTICAL SUPPLY CHAIN: ACTORS & INFLUENCERS

In Canada's pharmaceutical supply chain, there are actors and influencers.

Supply chain actors are those that physically touch the product to ensure it reaches the hands of patients. They include manufacturers and their suppliers; distributors; dispensers such as hospitals, pharmacies, and other points of dispensing; and the healthcare professionals and practitioners who physically dispense or administer the products to patients.

Supply chain influencers are those organizations that exert influence on supply chain actors.

These include federal, provincial, and territorial legislators, regulators, and policy makers; price setting agencies; insurers; and hospital group purchasing organizations.

The pharmaceutical supply chain is dynamic and interconnected—a change introduced in one part of the chain will inevitably impact another—requiring mutual understanding and coordinated, collaborative effort to inform and develop effective solutions.

## INFLUENCERS



Health Canada



PMPRB



Canada's Drug Agency



Federal, Provincial, Territorial Governments



pCPA



Group Purchasing Organizations



Insurers

## ACTORS



**Manufacturers**  
3PLs



**Distribution**  
Wholesale, Specialty, Self-Distributing



**Dispensing**  
Pharmacy, Hospital, Clinics



**Healthcare Professionals**



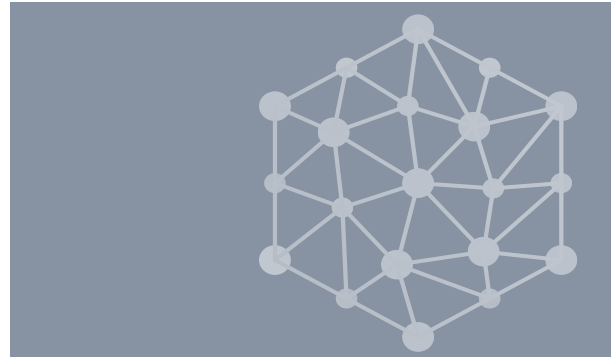
**Patients**

# PROBLEM IDENTIFICATION

Drug shortages have long been a concern, but are growing in frequency and difficulty. Critical shortages are taking longer to resolve and causing significant disruptions within an already strained supply chain and healthcare system. Given medications are used in varying ways and settings to cure and treat health conditions, shortages in medications are alarming to Canadians on a visceral level and create urgency to resolve and prevent them.

Health Canada’s Plan for Building Resilience in the Drug Supply (2024-2028) initiated a valuable dialogue with stakeholders, though its scope remains limited to actions within Health Canada’s direct control. Solutions to drug shortages are a responsibility and priority of various stakeholders, many with their own initiatives underway. However, when these initiatives are pursued in isolation, they may lack a comprehensive understanding of the problem or its impact on the supply chain, resulting in a patchwork approach that fails to achieve the intended benefit or desired outcomes.

Addressing drug shortages requires a courageous approach that addresses root causes while respecting public concern and the potential risks to patients when essential medications are unavailable. Ensuring a sustainable supply demands collaboration across the supply chain, with the health and well-being of Canadians as the top priority.



## **DRUG SHORTAGES: MULTIPLICITY OF FACTORS**

Drug shortages that arise from unexpected demand spikes in otherwise stable conditions can create temporary gaps in supply while inventory levels catch up, and are comparatively straightforward to address. However, shortages due to insufficient supply are far more challenging, given the multiple underlying factors—many of which have only recently been acknowledged beyond supply chain actors. If these factors are left unchecked, they may lead to persistent or increasingly severe shortages.

Drug shortages in Canada may stem from global supply issues, such as shortages of active pharmaceutical ingredients (APIs) needed to produce finished products or may be specific to Canada’s domestic market. The confluence of many factors—Canada’s relatively small size on the global market, its reliance on foreign supply, a fixed and low pricing framework, a lean modern supply chain, and at times conflicting regulations—may render the Canadian market disproportionately vulnerable to shortages.

## ECONOMIC FACTORS

Economic factors underlie and contribute in some capacity to all supply shortages. Canadians want and deserve affordable medicines, and federal, provincial, and territorial governments have sought to reduce prices to ensure affordability. However, affordability must be sought in concert with accessibility, and not at the expense of one concept over the other.

Prices for generic drugs from 2007 to 2018 have fallen by more than 60%, more so than in comparable countries,<sup>6</sup> without increases since. The pricing framework has eroded not only revenue that could be invested to strengthen the supply chain, but also has made Canada an unfeasible market: in some cases, a drug's price is lower than the cost of its production and/or importation. This downward pressure leads to the exit of products and manufacturers from the Canadian market, increasing vulnerability to shortages with limited or no alternative suppliers.

Similarly, the distribution of drugs across Canada's vast geography is a factor of listed drug prices, regardless of whether the product is delivered to an urban centre or to a rural community. Over the last two decades, this downward pressure has led to the exit of a major, international wholesale distributor – leaving just two national and five regional distributors, along with the closure of dozens of distribution centres. As a result, product must travel further to reach patients. By regulation, pharmaceutical products require temperature control monitoring and safeguards to protect product integrity and, ultimately, patient safety. Today, hundreds of generic medicines are distributed at break-even or financial losses, with distribution fees often less than the price of a postage stamp.

## RURAL SERVICE CHALLENGES

Distribution funding is not based on the cost of the service delivered, but on the price of the drug. Lower drug prices mean less is available for their distribution, and in many cases, less than the price of a postage stamp.

Product	Atorvastatin 10mg 100s
Dimensions	12.2 x 5.8 x 8.8 cm
Weight	0.15 g
Unit List Price (2017)	\$ 26.15
Distribution Fee (5%)	\$ 1.13
<b>Unit List Price (2024 reduced by \$8.72)</b>	<b>\$ 17.42</b>
<b>Distribution Fee (5%)</b>	<b>\$ 0.87</b>
<b>Canadian Postage Stamp</b>	<b>\$ 1.44</b>
Lowest Canada Post Parcel Rate from Toronto to Sault St. Marie (3 days)	\$ 19.01
Same with Liability Insurance (2 days)	\$ 42.36

Canada is among the world's least densely populated nations. While more than 66% live within one-hundred kilometres of the U.S. border, a full third of Canadians live in rural areas across more than nine million square kilometres. Only 40% of Canada's roads are paved, and some communities are accessible only by air or water. To date, pharmaceutical distributors were able to offset the costs of rural service delivery with volumes in urban centres. However, with falling prices, rural services now are at a vulnerable precipice.

<sup>6</sup> [PMPRB Press Release, August 14, 2019](#), accessed January 28, 2025.

### REGULATORY FACTORS

Regulatory misalignment and burden occur at the international, domestic, and provincial levels, limiting access to global supply and slowing an already strained supply chain.

Between nations, Canada is quite reasonably cautious in the interest of public health when governing the importation of pharmaceutical products. At times, the standards set by the Canadian government are more stringent or otherwise mismatched with those of other trading nations. Such misalignment can directly cause supply shortages and, during an active supply shortage, limit the ability to import alternative products to close the gap until the regular supply chain catches up.

Canada is struggling with growing regulatory overload, recognized to be a factor in decreased national productivity.<sup>7</sup> All drug manufacturers and distributors are subject to at least three federal acts and require up to seven licences to operate, depending on the product type and other variables. These supply chain stakeholders are under increasing administration pressure, with more frequent and numerous audits, and are facing a growing number of intended regulations, all of which draw heavily on already stretched resources.

Within government departments, there exists a clear lack of alignment and coordination across the varying groups responsible for enabling a drug to enter the market. Departments responsible for pre-market review, post-market enforcement, price setting, and supporting business growth risks, observably work in silos without consultation among them, and risk undermining the overall Government of Canada objectives for economic growth, safety and security.

### LEAN SUPPLY CHAIN LIMITATIONS

For decades, business management practices have emphasized the importance of establishing and maintaining lean supply chains. In pharmaceuticals, this approach prioritizes supplying medicines to the healthcare system and ultimately to patients in the most efficient, cost-effective manner while minimizing waste. To meet and compete with global expectations for lower prices, drug manufacturing has increasingly shifted outside of Canada, with production becoming more centralized in Asia. In many cases, products or their components, particularly active pharmaceutical ingredients (APIs), are sourced from a single supplier.

Domestically, manufacturers and distributors have optimized efficiency by consolidating operational locations, automating processes, and reducing on-hand inventory, which is costly to store, in alignment with just-in-time-delivery practices. Consequently, supply chains now operate with limited excess capacity and reduced manufacturing flexibility to adapt to sudden demand surges.

Increasing “buffer” stock is commonly asserted as a potential solution to prevent drug shortages. However, buffer stock alone does not resolve shortages—it merely extends the time available for the healthcare system to react and adjust to supply disruptions. Implementing buffer stock throughout the supply chain requires significant investment in storage capacity at multiple levels, additional new third-party providers, and increased supports to ensure it is properly managed to minimize waste. Such an undertaking would be expensive, and one that supply chain actors are ill-equipped to afford.

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<sup>7</sup> Green, Kenneth P., [Canada's Regulatory Overburden](#). The Fraser Institute. (2024).

# A PROPOSED PATH FORWARD

## GUIDING PRINCIPLES

In May 2024, CGPA and CAPDM held an Industry Summit to collaborate on plans to prevent and mitigate drug shortages. The discussion considered both global and domestic contexts, aligned on draft guiding principles, and examined the root causes of drug shortages to inform effective, long-term solutions. The Summit participants identified and tightly aligned to the following guiding principles (as adapted from the HDA Guiding Principles for Drug Shortages):<sup>8</sup>

- Avoid a top-down approach to policy. Policy should be co-created with industry, ensuring partnerships are adaptable and responsive to environmental changes.
- Recognize that different tools can help or hinder responses to drug shortages. Policies should enable and retain the tools used to mitigate and manage shortages, while applying flexible solutions tailored to different types of shortages.
- Multiple stakeholders share responsibility for managing drug shortages, and improved coordination and communication among them can enhance the overall response.

The following principles received wide alignment:

- Economic factors play a role in all supply vulnerabilities. For example, downward price pressure often forces stakeholders to lower drug prices in an unsustainable way. Economic policies must be prioritized and reflect the complexities of the operating environment.
- Each drug shortage has a unique root cause and driver. Policies to address them should manage this nuance, as “one-size-fits-all” policies will fall short.
- Drug shortages related to geographic market concentration can be a matter of national security. A lack of geographic diversity in medicine production presents a strategic risk to national security.

<sup>8</sup> [Healthcare Distribution Alliance. HDA Guiding Principles for Drug Shortages. p1 \(2024\).](#)



# STAKEHOLDER PRIORITIES & ACTIONS

Building on the May Industry Summit, CGPA and CAPDM engaged with stakeholders across the supply chain throughout June and July 2024 to gather feedback on how generic manufacturers and distributors could improve collaboration to prevent and mitigate shortages. Key stakeholders included federal and provincial governments, hospital GPOs, healthcare professional and practitioner associations, academia, and other supply chain influencers. The engagement identified five priority areas for solution development:

1. Invest in supply chain diversification (identified by all stakeholders interviewed, including manufacturers and distributors).
2. Improve access to early and more consistent information to anticipate and mitigate potential shortages (identified by supply chain influencers).
3. Increase buffer stock to allow time for system-wide responses (identified by supply chain influencers).
4. Establish conditions to increase prices for medicines that are critical and vulnerable to shortages (identified by manufacturers and distributors).
5. Harmonize regulatory requirements to facilitate greater access to the global drug supply (identified by manufacturers and distributors).

In September 2024, CGPA and CAPDM next convened a Multi-Stakeholder Summit, bringing together generic drug manufacturers, distributors, and key stakeholders from the pharmaceutical supply chain and the healthcare system. Participants engaged in facilitated discussions on each priority area, identifying potential actions. Building on this work, CGPA and CAPDM hosted a workshop in January 2025, where participants refined and prioritized actions, assigning ownership and identifying supporters key to successful implementation. Stakeholders were subsequently polled to assess their collective degree of alignment. While all priority areas achieved alignment (defined as an average participant score of 6 on a 10-point scale), some areas had stronger consensus than others.



### Priority 1: Invest In Supply Chain Diversification

All stakeholders widely recognize the need for incentives to support supplier diversification and expand local manufacturing, helping to overcome the pressure of an increasingly globalized supply chain. Diversification can be achieved in many ways. Increasing the availability of API suppliers, adopting new and advanced manufacturing technologies, expanding domestic production of finished products, and increasing the number of Health Canada-authorized products present significant opportunities to introduce more redundancy in the drug supply chain. However, policies to improve market stability for critical products must be balanced against the realities of a globalized supply chain that remains highly reliant on foreign imports.

Stakeholders identified and ranked the following actions to support investment in supply chain diversification, along with proposed owners and supporters key to successful implementation.

**Average participant alignment score: 7.8/10.0.**

	Priorities / Actions	Owners / Supporters
<b>1</b>	Create market incentives to encourage greater investment in Canadian manufacturing to increase resilience against shortages. Suggested solutions include: financial and tax incentives, trade agreements, and fee remissions.	<b>OWNERS:</b> Federal Government, pCPA <b>SUPPORTERS:</b> Manufacturers
<b>2</b>	Increase visibility to key starting materials (i.e., API, packaging) and points of geographic concentration, while creating incentives to strengthen supply chain redundancy and diversification. Suggested solutions include: fee remissions and regulatory flexibility.	<b>OWNERS:</b> Manufacturers <b>SUPPORTERS:</b> Health Canada
<b>3</b>	Introduce incentives for manufacturers to invest in and adopt technologies that support supply chain diversification.	<b>OWNERS:</b> Manufacturers <b>SUPPORTERS:</b> Academia, Global Regulators

## Priority 2: Improve Access To Early And More Consistent Information Sharing To Mitigate Potential Shortages

Improved and earlier information sharing is essential to strengthening collaboration in preventing and mitigating shortages, particularly for critical products that if unavailable present marked risk to patients. Supply chain actors have a responsibility to provide early warning signals about potential shortages, allowing partners, including the healthcare system and healthcare professionals, time to coordinate a response and minimize disruption to patients. To be effective, shared information must be clear, accurate, and provided in a consistent format, helping stakeholders estimate demand and resupply timelines while reducing the risk of panic buying. Wherever possible, information systems should be integrated and automated to minimize duplication, ensuring data is centrally streamlined while maintaining confidentiality. Additionally, protocols for identifying therapeutic alternatives should be aligned and revised in a coordinated manner, with clear communication back to manufacturers. This will help manufacturers anticipate market shifts and adjust supply accordingly.

Stakeholders identified and ranked the following actions to support early and more consistent information sharing needed to respond to and mitigate potential shortages, along with proposed owners and supporters key to successful implementation.

**Average participant alignment score: 8.3/10.0.**

	Priorities / Actions	Owners / Supporters
<b>1</b>	Stakeholders align with protocols and processes to identify therapeutic substitutions, enabling manufacturers to adjust production and importation for critical drugs.	<b>OWNERS:</b> Health Canada, Provincial and Territorial Drug Shortages Task Team <b>SUPPORTERS:</b> Health Professional Organizations, GPOs
<b>2</b>	Develop a centralized portal for stakeholders to input defined, confidential information (e.g., demand, actual utilization, inventory levels, shortage reports, and resupply dates) for critical drugs, improving the ability to assess and understand supply risks.	<b>OWNERS:</b> Health Canada
<b>3</b>	Implement and adapt strategies to avoid the unintended consequences of signaling shortage risks too early (e.g., panic buying).	<b>OWNERS:</b> Manufacturers, Distributors, Provincial and Territorial Governments, Health Canada, Patient Advocacy Groups

### Priority 3: Increase Buffer Stock To Allow Time For System-Wide Responses

Buffer stock provides stakeholders with additional time to analyze, coordinate, and act to prevent and mitigate shortages before they impact the healthcare system. Manufacturers already efficiently and effectively manage a feasible amount of buffer stock to maintain high service delivery to customers, ensuring timely distribution to patients while minimizing waste. Demands to maintain additional buffer stock should be targeted specifically to critical drugs and supported by financial incentives to carry more inventory. The costs associated with increasing buffer stock, such as additional warehouse space, should be fairly distributed to share risk, and alternative solutions should be explored with a clear understanding of Canada's supply chain capacity. However, implementing buffer stock strategies presents challenges, including the financial burden of establishing and managing excess inventory, as well as the complexities of rotating inventory before it expires based on demand.

Stakeholders identified and ranked the following actions to support increased buffer stock, along with proposed owners and supporters key to successful implementation. Notably, among all priority areas, increasing buffer stock received the least amount of support, and the ranked actions had the lowest alignment scores. Several stakeholders asserted that additional buffer stock—beyond the existing 30-day supply typically maintained by manufacturers and distributors—is unnecessary and could lead to increased waste. Additionally, some stakeholders do not support compensating manufacturers for carrying more inventory. Despite these concerns, most stakeholders agreed on the importance of this priority area and its ranked actions.

**Average participant alignment score: 7.1/10.0.**

	Priorities / Actions	Owners / Supporters
<b>1</b>	Establish a clear, limited list of critical drugs that would correspond to expectations for increased stock and shortage management plans.	<b>OWNERS:</b> Health Canada, Manufacturers <b>SUPPORTERS:</b> Clinical Experts (Healthcare Practitioners and Industry), Academia
<b>2</b>	Develop a business model and/or financial incentives to help manufacturers offset the cost of maintaining additional inventory.	<b>OWNERS:</b> Federal and Provincial Governments, Public Health Agency of Canada <b>SUPPORTERS:</b> Manufacturers, GPOs
<b>3</b>	Explore and review buffer stock best practices in other jurisdictions and assess their feasibility for adoption by the Canadian supply chain.	<b>OWNERS:</b> CGPA, Health Canada
<b>4</b>	Extend expiry dates to allow buffer stock to remain viable for a longer period.	<b>OWNERS:</b> Manufacturers <b>SUPPORTERS:</b> Health Canada
<b>5</b>	Establish API reserves for products manufactured in Canada, given APIs have longer expiry dates/shelf life.	<b>OWNERS:</b> Manufacturers

### Priority 4: Establish Conditions To Increase Prices For Critical And Vulnerable Medicines

A priority for manufacturers and distributors is to explore economic policies and incentives that address the underlying causes of supply vulnerabilities to prevent drug shortages. Critical drugs should be priced in accordance with their value to the healthcare system to ensure a stable and continuous supply. To sustain investment and increase the availability of essential drugs, manufacturers require a viable market that accounts for the additional costs associated with mitigating drug shortages. Stakeholders must collaborate to design and implement targeted, workable solutions.

Stakeholders identified and ranked the following actions to support conditions to increase prices for medicines that are critical and vulnerable to shortages, along with proposed owners and supporters key to successful implementation.

**Average participant alignment score: 7.3/10.0.**

	Priorities / Actions	Owners / Supporters
<b>1</b>	Establish incentives for marketing critical drugs. Solutions include: establishing floor prices.	<b>OWNERS:</b> pCPA and participating jurisdictions, GPOs <b>SUPPORTERS:</b> Manufacturers, Health Canada
<b>2</b>	Enable price increases in line with inflation (CPI).	<b>OWNERS:</b> pCPA and participating jurisdictions, GPOs <b>SUPPORTERS:</b> Manufacturers
<b>3</b>	Introduce a mechanism to adjust prices to respond in emergency situations (i.e., pandemic) to maintain a sustainable supply.	<b>OWNERS:</b> pCPA and participating jurisdictions, GPOs <b>SUPPORTERS:</b> Manufacturers, Health Canada
<b>4</b>	Link critical drug pricing to API commodity prices.	<b>OWNERS:</b> pCPA and participating jurisdictions, GPOs <b>SUPPORTERS:</b> Manufacturers

## Priority 5: Harmonize Regulatory Requirements To Enable Greater Access To The Global Drug Supply

Greater flexibility and agility within Canada’s federal regulatory system are needed to help Canadian companies better access globally produced products. Addressing Canadian-specific regulatory and guidance requirements will improve international harmonization, reduce costs, and minimize disruptions. Health Canada has an opportunity to strengthen its reliance on trusted global counterparts, such as the United States and Europe, to streamline facility and product assessments. Furthermore, inconsistencies among provincial and territorial processes for listing generics should be addressed to accelerate patient access to new products and cost savings.

Stakeholders identified and ranked the following actions to support harmonized regulatory requirements for expanded global drug access, along with proposed owners and supporters key to successful implementation.

**Average participant alignment score: 7.9/10.0**

	Priorities / Actions	Owners / Supporters
<b>1</b>	Establish a Mutual Recognition Agreement with the U.S. FDA while increasing reliance and regulatory flexibility to streamline inspections and accelerate product access.	<b>OWNERS:</b> Health Canada, U.S. FDA <b>SUPPORTERS:</b> Manufacturers
<b>2</b>	Identify and resolve regulatory misalignments between Health Canada and other trusted global regulators, as well as between provinces and territories, that limit access to the global supply chain.	<b>OWNERS:</b> Health Canada, Provinces and Territories <b>SUPPORTERS:</b> Manufacturers, Academia
<b>3</b>	Expedite timelines to update and/or add new sites to Drug Establishment Licenses to incentivize supply chain redundancy to prevent shortages.	<b>OWNERS:</b> Health Canada <b>SUPPORTERS:</b> Manufacturers
<b>4</b>	Increase the use of foreign reference products supported by rigorous studies accepted by trusted global regulators to streamline bioequivalence assessment in Canada.	<b>OWNERS:</b> Health Canada <b>SUPPORTERS:</b> Manufacturers
<b>5</b>	Improve and expand the process for expediting approvals for drugs to address shortages, including greater reliance on foreign approved dossiers of critical and vulnerable drugs.	<b>OWNERS:</b> Health Canada <b>SUPPORTERS:</b> Manufacturers
<b>6</b>	Modernize and eliminate outdated country-specific guidelines that perpetuate misalignment.	<b>OWNERS:</b> Health Canada <b>SUPPORTERS:</b> Manufacturers, Academia

# RECOMMENDATIONS

This report reflects months of consultation with key supply chain stakeholders, both actors and influencers, and captures critical discussions and insights. It serves as a strategic directional resource for supply chain actors and influencers to prioritize and target collective, bilateral, and individual work to co-create meaningful and impactful solutions that ensure a stable drug supply for Canadians.

Arising from this work, listed in order of alignment, the collective recommendations are:

1. Enhance collaboration through early, proactive, and more consistent sharing of information to respond to and mitigate potential shortages.
2. Harmonize regulatory requirements to enable greater access to the global drug supply.
3. Invest in supply chain diversification.
4. Establish conditions to increase prices for medicines that are critical and vulnerable to drug shortages.
5. Increase buffer stock to allow time for system-wide responses.

This report further suggests actions to achieve these recommendations, serving as a starting point for coordinated approaches and solutions.

The issue of drug shortages is complex and ever-changing, influenced by factors beyond the control of any single stakeholder in the supply chain. Ultimately, resilience against drug shortages rests on the strength of partnerships. This is why CGPA and CAPDM embarked upon a process to bring stakeholders together to answer Health Canada's call for collaboration to build resilience against health product shortages.

The identified priorities and supporting actions in this report serve as a compass and as a foundation for ongoing dialogue. Continued coordination is needed to create the right conditions for drug supply chain sustainability, to increase accountability for each actor and influencer's roles, and to co-create solutions to reinforce the continued viability of the pharmaceutical supply chain and the critical market it serves: Canada's healthcare system, professionals, and patients.



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Collaborative Solutions to  
Strengthen Canada's Drug Supply**

# ORGANIZATIONS CONSULTED BY CGPA & CAPDM

Accuristix
Albright Stonebridge Group
Apotex Inc.
Alliance for Safe Online Pharmacies
Association des bannières et chaînes de pharmacies du Québec
Association Québécoise des pharmaciens propriétaires
Aurobindo
British Columbia Ministry of Health
Canada's Drug Agency
Canadian Pharmacists Association
Cencora
Distribution Pharmaplus
Fresenius Kabi
Health Canada
Health Partners International of Canada
HealthPRO
Imperial Distributors Canada Inc.
Innovation, Science and Economic Development Canada
Juno Pharmaceuticals
Kohl & Frisch
Mantra Pharma
Marcan Pharmaceuticals
McKesson Canada
Metro
Mint Pharmaceuticals
Mohawk Medbuy
Natco Pharma
Neighbourhood Pharmacy Association of Canada
Ontario Ministry of Health
pan-Canadian Pharmaceutical Alliance
Pharmascience
Sandoz Canada
Shoppers Drug Mart
SteriMax
Taro Canada
uniPHARM Wholesale Drugs
United States Pharmacopeia
University of Toronto, Leslie Dan Faculty of Pharmacy
Viatrix Canada

## ABOUT CGPA

The Canadian Generic Pharmaceutical Association (CGPA) represents Canada's generic pharmaceutical industry. The industry plays an important role in controlling health-care costs in Canada. Generic drugs are dispensed to fill 77.4 percent of all prescriptions, but account for only 22.4 percent of the \$46.3 billion Canadians spend annually on prescription medicines.

## ABOUT CAPDM

The Canadian Association for Pharmacy Distribution Management (CAPDM) is the leading trade association representing Canada's healthcare supply chain, offering comprehensive end-to-end visibility of the pharmaceutical distribution network across the country. CAPDM members streamline the ordering and delivery processes for over 15,000 product SKUs from hundreds of manufacturers to more than 12,000 dispensing locations across Canada. This highly efficient system saves the country over \$1 billion each year while maintaining an accuracy rate of over 99.9%.

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