



# WHAT WE HEARD:

IMPROVING ACCESS TO DRUGS AND  
OTHER HEALTH PRODUCTS IN CANADA

---

DECEMBER 2023



Health  
Canada

Santé  
Canada

Canada

**Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.** Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Également disponible en français sous le titre :  
Améliorer l'accès aux médicaments et à d'autres produits de santé au Canada

To obtain additional information, please contact:

Health Canada  
Address Locator 0900C2  
Ottawa, ON K1A 0K9  
Tel.: 613-957-2991  
Toll free: 1-866-225-0709  
Fax: 613-941-5366  
TTY: 1-800-465-7735  
E-mail: [publications-publications@hc-sc.gc.ca](mailto:publications-publications@hc-sc.gc.ca)

© His Majesty the King in Right of Canada, as represented by the Minister of Health, 2023

Publication date: December 2023

This publication may be reproduced for personal or internal use only without permission provided the source is fully acknowledged.

Cat.: H14-467/2023E-PDF  
ISBN: 978-0-660-69072-8  
Pub.: 230625

## Table of Contents

Executive summary .....	2
Improved communication and transparency .....	2
Agile regulatory toolbox .....	2
Greater supply chain visibility .....	2
Enhanced response to supply and demand .....	3
Introduction .....	4
Consulting people in Canada .....	4
Who participated and responded .....	5
Improved communication and transparency .....	7
Proposed improvements and strategies .....	8
Agile regulatory toolbox .....	10
Create a list of critical and vulnerable drugs and other products .....	10
Safety stocks .....	10
Requirements to report shortages .....	11
Plan to prevent and manage shortages .....	12
Streamline regulatory requirements and processes .....	12
Include more products .....	13
Greater supply chain visibility .....	14
Data collection .....	14
Cooperation and sharing information .....	14
Enhanced response to supply and demand .....	16
Strengthen domestic manufacturing .....	16
Procurement practices and pricing .....	16
Allocation and distribution practices .....	17
Collaboration and partnerships .....	17
Next steps .....	19
Annex A: Advisory Committee .....	20

## Executive summary

Shortages of drugs and other health products are a growing issue around the world and can affect a person's ability to access the products they need and their health. Canada represents a small part of the global market and relies on imported products. This makes us more vulnerable to shortages.

The Government of Canada plays a leadership role in managing health product shortages and has taken steps to improve access to drugs and other health products. The COVID-19 pandemic highlighted weaknesses in the health product supply chain, and some of the challenges seen during this time continue.

Health Canada created a Drug Shortages Task Force to look at how to better address health product shortages. The task force launched an online consultation focused on identifying the challenges and possible solutions for building a resilient supply of drugs and other health products. These are the highlights of what we heard.

### Improved communication and transparency

Stakeholders want to receive more information about shortages more quickly. They want to know where and when products are available, how products will be allocated and alternative products. We heard that patient advocacy, community groups and healthcare providers play an important role in communicating shortages to patients. Industry stressed the importance of information

sharing and protecting proprietary information.

Respondents also suggested making improvements to the drug shortages website, including a more user-friendly design with detailed and up-to-date information. Communications should also be tailored to specific audiences, including the public, patients and caregivers, industry and healthcare providers.

### Agile regulatory toolbox

Stakeholders indicated the need to create a list of drugs that are critical to patients and the healthcare system and are vulnerable to shortages. To better prevent shortages, additional requirements could be put in place for products on the list such as safety stocks.

Stakeholders also suggested making improvements to existing shortage reporting requirements and planning to prevent shortages. We were cautioned not to impose undue burden on industry. Stakeholders also stressed that streamlining regulations and making them more in line with the international community would encourage a more competitive and diversified Canadian market.

### Greater supply chain visibility

Stakeholders wanted improved inventory level data at different points of the supply chain to better anticipate shortages. Respondents indicated that expanding data collection to areas such as historical epidemiological data and prescription patterns and improving analytics would enable

better forecasting. We heard that better drug sales data could be available through improved provincial and territorial data infrastructure and sharing.

Stakeholders suggested leveraging new technologies to track goods in real-time and detect early signs of shortage.

### Enhanced response to supply and demand

Stakeholders stressed that domestic manufacturing should be strengthened. We also heard that procurement and contracting practices could support health product supply resilience by prioritizing security over price and by contracting with multiple

suppliers. Stakeholders suggested distribution based on needs, including in times of emergency.

We also heard that improving collaboration and partnership among all stakeholders in areas such as drug pricing, formulary listing and pharmacist scope of practice can help prevent and mitigate shortages.

The Government of Canada thanks everyone who participated in the online consultation and meetings held over the last several months. Your insight was invaluable. Our next phase will focus on developing a plan to improve the resilience of Canada's health product supply chain based on this input.

## Introduction

Shortages of drugs and other health products are a growing issue around the world. Shortages are more severe, taking place more often and are lasting longer.

Canada represents a small part of the global market and relies on imported products. This makes us more vulnerable to shortages.

Shortages happen when a manufacturer is unable to meet demand. Disruptions can happen at any point in the supply chain and it is not always possible to anticipate or prevent a disruption.

Factors that regularly contribute to supply disruptions include manufacturing and quality issues. The lack of access to raw materials, distribution challenges and unexpected increases in demand can also play a role. The COVID-19 pandemic highlighted weaknesses in the health product supply chain, and some of the challenges seen during this time continue.

Health product shortages can affect a person's ability to access the products they need. This can have an impact on their health. Shortages can also mean that healthcare providers have to spend time looking for alternatives.

Over the past decade, Health Canada has played a leadership role in bringing key stakeholders together. We have taken important steps to improve access to drugs and other health products for people in Canada. We also monitor and help mitigate the impacts of shortages and work with partners and stakeholders to find solutions to resolve them when they do happen.

However, more can be done to build a more resilient health product supply chain for drugs, medical devices and life-sustaining foods in Canada.

### Consulting people in Canada

In November 2022, Health Canada created the Drug Shortages Task Force. The task force looked at additional ways to:

- address health product shortages
- make drugs and other health products more available and accessible for everyone

Although the Government of Canada plays a key leadership role in managing health product shortages, it takes many stakeholders to help prevent and mitigate shortages. Healthcare providers, provinces and territories, industry, the academic community, the media and the public all have an important role to play.

Before beginning an online consultation on June 5, 2023, the task force first reached out to hear from many stakeholders for their ideas on preventing shortages. We also set up an external advisory committee made up of representatives from drug and other health product industry sectors, healthcare

providers and academia. Committee members shared their expertise and provided advice on ways to prevent and manage shortages (Annex A).

Engaging with these stakeholders early on provided a foundation for the online consultation. Through this online consultation, we asked the public and all health product partners and stakeholders to share their views. We wanted to hear their thoughts on the challenges and possible solutions for building a resilient drug and other health product supply in Canada.

We produced a consultation guide to seek people's views on 4 key areas:

- **Improved communication and transparency:** How to help people in Canada make informed health decisions and identify solutions to prevent and mitigate impacts.
- **Agile regulatory toolbox:** How to ensure our regulatory tools keep pace with changes that affect the supply chain and stay effective.
- **Greater supply chain visibility:** How to better share information between those involved in the supply chain to prevent and mitigate shortages.
- **Enhanced response to supply and demand:** What actions are needed to strengthen and make the health products ecosystem more resilient.

## Who participated and responded

Health Canada distributed the consultation guide to individuals and organizations across Canada.

For the online consultation, we received 160 written submissions. Most were from industry (45%), including major industry associations representing the views of multiple stakeholders. Industry groups included manufacturers, group purchasing organizations, distributors and retailers of a wide range of health products, such as:

- foods
- biologics
- medical devices
- consumer products
- natural health products
- human and veterinary drugs

Additionally, we received written submissions from:

- the public (22%)
- healthcare providers (15%), such as:
  - optometrists
  - veterinarians
  - medical doctors
  - hospital and community pharmacists
- patient advocacy groups (8%), such as:
  - groups representing patients with cancer, chronic diseases and genetic diseases
- not-for-profit organizations (6%)
  - focused on areas such as identifying safe, effective, cost-effective medicines and other products
- the academic community (3%)
- provinces and territories (1%)
- Indigenous groups (1%)

During the consultation period, the task force also reached out to existing committees, such as:

- the Multi-Stakeholder Steering Committee on Drug Shortages
- the Medical Device Shortages Multistakeholder Committee
- federal-provincial-territorial drug shortages tables

As well, we set up an interdepartmental committee with representatives from 12 federal departments and agencies.

In addition to the online consultation, we met directly with key stakeholder groups. These included:

- retailers
- distributors
- manufacturers
- healthcare providers
- Indigenous communities
- patient advocacy groups
- groups representing vulnerable patients such as children

We also met with international regulators who are working to better prevent drug and other health product shortages.



## Improved communication and transparency

Many stakeholders are responsible for responding to a shortage, whether anticipated or actual. By sharing accurate information quickly, governments, healthcare providers, patients, manufacturers, distributors and international partners can help to better prevent and manage shortages.

Stakeholders said they want to receive the following information:

- the reason for a shortage
- estimated start and end dates
- the scope (local, national, global)
- available alternative products and therapies
- who is working to resolve the shortage and the actions being taken
- measures that should be put in place to conserve remaining stocks

Stakeholders want to receive information about a product's available and anticipated supply in Canada and how it is allocated and distributed. This information includes:

- current inventory levels
- plans to allocate the products
- when the product will be resupplied
- health products under review for approval by Health Canada
- manufacturing locations for products on the Canadian market

Stakeholders also want to receive more information about:

- medical device shortages
- physician standard of care protocols
- changes to a drug's vulnerability profile

We heard about the significant role that patient advocacy, community groups and healthcare providers play in letting patients know about a shortage. Patient advocacy groups and clinicians can educate patients about keeping an adequate supply on hand and about alternative medicines and therapies.

Healthcare providers told us that distributors do not always share their inventory levels. Providers only learn of a shortage when they're not able to order a product.

Pharmacists said it's difficult to hold extra stock because they don't know how long a shortage will last. They are hesitant to hold unnecessary extra stock due to cost and space constraints. One suggestion was to have a system that centralizes supply chain information and that everyone could access.

Industry stakeholders pointed out the challenge of broadly sharing proprietary information, such as on:

- pricing
- trading terms
- monthly demand
- current inventories
- marketing strategies
- the root cause of a shortage
- resupply quantities (and timelines)

## Proposed improvements and strategies

Respondents also gave feedback on the Drug Shortages Canada website. Real-time updates and increased flexibility would help everyone involved in the supply chain and those who could be affected prepare for shortages.

The Drug Shortages Canada website should:

- be redesigned and more user-friendly
  - engage healthcare providers and industry in the redesign
- contain detailed information on a drug shortage, such as:
  - location and level of stocks across the supply chain
  - estimated duration of the shortage
  - available alternatives for products in shortage
  - indication of changes in demand
- be expanded to include information on medical devices shortages

The form used to report information and how information is displayed on the website should be improved as follows:

- eliminate repeat entries about a shortage
- make it possible to edit existing entries
- differentiate between a shortage, discontinuation and disruption
- add resources such as webinars and FAQs
- set up a central repository of real-time information on the website where stakeholders can enter information and information can be filtered
  - industry could indicate real-time demand and supply issues
  - governments and group purchasing organizations could input hospital demand data

We also received suggestions directed to specific stakeholders:

- let healthcare providers and professional organizations know about anticipated and actual shortages
  - use texts or emails
- communicate inventory information from distributors directly to healthcare providers
- tailor communications to specific audiences to promote confidence
  - audiences include the public, patients and caregivers, industry, healthcare providers
- create a secure communication channel with businesses to encourage the exchange of proprietary information and support more transparency
- form a roundtable of stakeholders involved in emergency response to maintain the flow of materials and medications during an emergency
- develop standard practices for communicating drug recalls
- have patient groups represented on all shortage roundtables, advisory bodies and working groups to ensure that solutions meet patient care needs
- engage with Indigenous communities during each shortage
- establish common terminology and definitions

While most stakeholders want more transparent communication and more information shared, some said that increased transparency could lead to panic buying, reduce confidence in Canada's supply, and increase burden on industry.

## Agile regulatory toolbox

Stakeholders offered several ideas for improving regulatory tools.

### Create a list of critical and vulnerable drugs and other products

Create an evergreen list of drugs and other products that are critical to patients and the healthcare system and are vulnerable to shortages, such as those used:

- in oncology
- to treat chronic pain
- to treat opiate addiction
- for gender-affirming care
- to support infant development

The list should also include:

- infant formulas
- non-prescription drugs
- critical and vulnerable medical devices

Criteria should be developed to help determine which drugs and other health products should be listed. Suggestions for criteria included:

- life-sustaining
- 1 or 2 suppliers
- low market share
- history of shortages
- risk to health if in shortage
- little or no therapeutic alternative

Safety, efficacy, cost and impact on animal health and food safety were also mentioned.

We also heard that Health Canada should develop the list in consultation with health professionals, patient advocacy groups, industry and small communities that are most vulnerable to shortages. Products on the list should have additional requirements aimed at better preventing shortages and incentives such as expedited regulatory authorizations.

### Safety stocks

We heard that there should be safety stocks of critical or vulnerable products. Some safety stocks do exist in Canada within the supply chain to meet contractual obligations. But this measure is not universal or designed to respond to a significant change in demand or to mitigate shortages.

Views were split on who should be responsible for holding these stocks. Some said manufacturers are responsible. Others said distributors, wholesalers and retail/hospital pharmacies also share the responsibility. Others used the COVID-19 Critical Drug Reserve as an example to say that this responsibility lies with the federal, provincial and territorial governments.

Criteria that could be used to help determine the quantity of products that should be stocked include:

- historical demand
- current contract requirements
- extra supply (20%) for drugs that typically go into shortage

Other considerations include:

- shelf-life
- expiry dates
- stock rotation
- storage requirements
- variation in demand and supply

Some stakeholders indicated that a reserve of raw materials would offer more flexibility. Others believed that requirements should be tailored for each product.

Some stakeholders were concerned about imposing requirements for safety stocks. They said this could:

- increase costs
- create wastage
- reduce storage capacity, particularly for narcotics
- lead to a lack of products internationally to meet Canadian safety stock requirements

They also noted the lack of existing storage capacity, particularly for narcotics that have specific storage requirements.

Both healthcare and industry stakeholders suggested financial incentives to expand safety stocks.

## Requirements to report shortages

Stakeholders had different views on what should be reported and by whom. Suggestions for the information that could be reported overlap with the suggestions for improving transparency and communication.

Other suggestions included:

- clarify what information is needed in existing reporting forms
- require information on therapeutic alternatives and demand
- reimburse administrative costs associated with mandatory reporting
- limit reporting requirements to critical products that impact patients
- require information on shortages of non-prescription drugs and infant formula
- require distributors, hospitals and pharmacies to report on potential shortages
- limit reporting to essential information and protect confidential business information

Respondents stressed the importance of reporting shortages quickly and accurately.

They said that:

- compliance monitoring and enforcement of reporting requirements should be increased
- penalties, such as fines for poor performance, or a system to publicly acknowledge positive performance should be put in place

## Plan to prevent and manage shortages

As stated earlier, some respondents said more can be done to identify earlier when products are at risk of going into shortage. They said:

- market authorization holders are best placed to identify risks and early signs of shortages
- risk assessment should consider the availability of different dosage forms and alternative therapies

However, industry said that added risk assessment requirements could increase regulatory burden and hinder flexibility when it comes to responding to a shortage.

## Streamline regulatory requirements and processes

Respondents said market entry requirements should be more in line with those in other countries. Minimizing the regulatory burden for industry would lower the cost to enter the Canadian market and lead to a more resilient health products supply.

Respondents also said that Canadian-specific market requirements can make it difficult to tap into the global supply. New regulatory requirements related to shortages should reflect international best practices.

Suggestions from stakeholders were to:

- increase regulatory flexibility to modify an existing market authorization
  - such as a change to active pharmaceutical ingredients
- expand the accelerated review criteria for products and establishments to reduce timelines for approving products
- expand the use of foreign market approval to speed up market authorization and establishment licence approvals
- decrease regulatory requirements for high-priority drugs
- tailor the regulatory framework for self-care products
- create regulatory guidelines that can be automatically applied when a product is in shortage, such as:
  - extending expiry dates
  - giving permission to pharmacists to compound
  - allowing pharmacists to prescribe alternative treatments
- make permanent the regulatory flexibilities applied during the COVID-19 pandemic
- establish pre-approval processes for manufacturing sites and foreign products that can be triggered in times of shortages
- implement a mandatory duty-to-supply requirement for manufacturers
- adapt and streamline the Special Access Program for use in times of shortages

## Include more products

Stakeholders suggested that we include the following products in the shortages requirements:

- veterinary drugs
- drugs for rare diseases
- self-care products, such as:
  - natural health products
  - over-the-counter products
- medical foods, supplements and infant formulas
- medical devices and medications used in harm reduction of substance use

## Greater supply chain visibility

Stakeholders said the supply chain is not as transparent as it should be. A lack of visibility limits the ability to quickly predict and monitor changes in demand and supply to predict shortages. It also presents a challenge for community pharmacies.

### Data collection

Proposals for collecting additional information match up with the recommendations for improving communication and transparency. The feedback we received stressed the need to:

- know inventory levels at different points in the supply chain
- have information on alternative therapies for products in shortage
- have better data on the demand and supply, including for active pharmaceutical ingredients

Respondents also said that better demand forecasting would give manufacturers more lead time to increase production when necessary. Along with historical epidemiological data, real-time information on the following would improve forecasting:

- hospitalization rates
- prescription patterns and trends
- consumption rates for health products

Respondents said:

- we must be careful not to collect unnecessary data
- confidential business information must be protected
- demand-and-supply data can become outdated before it can be analyzed

Systems and standard protocols to collect supply chain data must be in place. Respondents mentioned that artificial intelligence, as well as Global Trade Item Numbers (GTIN) and Global Location Numbers (GLN), could be used to track goods in real-time and detect signs of early shortages.

### Cooperation and sharing information

Stakeholders said that provinces and territories should cooperate and invest in better data systems to help forecast demand. For example, they said there was no inter-provincial and territorial data system for tracking sales of drugs and other health products.

Retailers asked for support to establish information-sharing processes that would help them anticipate and react to supply disruptions.



Respondents said a strong and dedicated analytics system could help to:

- identify trends
- forecast future shortages
- quantify the size of a shortage
- connect demand-and-supply data
- establish short- and long-term priorities

Input received pointed to the cost associated with systems for collecting and sharing information. Stakeholders suggested financial support to help make this happen.

## Enhanced response to supply and demand

Respondents identified challenges and several strategies to improve Canada's supply chain resilience and minimize the impact of disruptions. Many of these strategies are outside the scope of the mandate of the Government of Canada and would require leadership from other supply partners. These partners include:

- provinces and territories
- group purchasing organizations
- healthcare professional regulatory bodies
- manufacturing and distribution industry sectors

### Strengthen domestic manufacturing

Just-in-time manufacturing was cited as a barrier to making the supply chain resilient. Respondents said the:

- lead time to increase production can take several months
- lack of surplus drugs when there's a shortage has a direct impact on a patient's ability to access these drugs

They also expressed concern about procuring drugs from 1 supplier.

Respondents indicated that a strong, diversified market is key to counteracting sudden changes in demand and supply. This is especially true when there's a global shortage and many jurisdictions are trying to access the same drugs or health products at the same time. A strong, diversified market is related to the ability of manufacturers to enter the market easily.

Suggestions included the following:

- Health Canada review and align Canadian market entry requirements with those of other jurisdictions
- the federal government support domestic manufacturing in Canada through financial, taxation and regulatory incentives
- the federal government create a corporation that could assume responsibility for manufacturing drugs that have limited profit-margin in Canada

### Procurement practices and pricing

Stakeholders said procurement and contracting practices could be improved to support a more resilient drug supply in Canada. They recommended that:

- group purchasing organizations prioritize supply security over price
- strategies be put in place to help multiple companies achieve sustainable sales volumes
- manufacturers have at least 2 suppliers of active pharmaceutical ingredients

To help prevent shortages, stakeholders suggested:

- revising the pricing structure of drugs and other health products
- allowing prices to increase over time to counteract higher production costs and encourage profit margins in a competitive market
- adjusting the price for drugs and other health products in shortage

## Allocation and distribution practices

Respondents noted that locations with higher historical purchasing volumes seem to get more inventory.

When there's a shortage, respondents said a needs assessment based on epidemiological data and patient vulnerability should be used to determine distribution. They also said it's important to maintain the flow of drugs and other health products during emergencies, such as wildfires and flooding.

Better collaboration between governments, distributors and manufacturers and the automation of inventory management could improve transparency around how inventory is allocated. These measures could also reduce waste and stabilize the supply of drugs faster.

## Collaboration and partnerships

Collaboration between federal, provincial and territorial governments is essential to mitigating shortages. Respondents said the federal government should play a lead role in coordinating actions among stakeholders to better prevent and mitigate shortages.

Respondents suggested that the federal, provincial and territorial governments work together to:

- coordinate public messaging
- review the drug pricing framework
- develop online pharmacy regulations
- initiate domestic manufacturing incentives
- distribute and allocate health products equitably
- review formularies to include alternatives to critical and vulnerable drugs

They also recommended that the provincial and territorial governments work together to define a common scope of practice for pharmacists during a shortage. Pharmacists should be able to independently prescribe therapeutic alternatives, including controlled substances, during a shortage. Also, stakeholders suggested financial reimbursement for healthcare providers for the time they spend managing shortages (for example, researching alternatives, responding to patient questions and locating stock).

Respondents stressed the importance of a whole-of-government approach to ensure that policies advanced outside Health Canada do not negatively impact health product manufacturing. They gave, as an example, the changes in single-use plastics regulations, which reduces the available supply of materials.

Some stakeholders said the national pharmacare plan will improve access to health products across the country. Some said the plan should cover all life-sustaining medicines. Others added it should pay the cost to switch to alternative or compounded products during a shortage.

Finally, stakeholders stressed that healthcare professional regulatory bodies, provinces and territories, and manufacturers should collaborate on the following:

- formulary delisting
- automatic substitutions
- overprescribing practices
- changes to prescribing guidelines

These factors all contribute to drug shortages.

Prescribing appropriately and notifying manufacturers about changes to prescribing guidelines affecting their products could help improve access to drugs and other health products.

## Next steps

The Government of Canada thanks everyone who participated in the online consultation and the various meetings that have been held on health product shortages over the last number of months. Your input has given us valuable insights and practical suggestions to address shortages and improve access to drugs and other health products.

You told us that more actions can be taken by Health Canada, the federal government as a whole and other key partners to prevent or mitigate the impact of shortages on people in Canada.

For the next phase of our work, we will focus on developing a plan that will consider this input. To improve the resilience of Canada's health product supply chain, we will consider:

- the roles and responsibilities of all the partners who have a role to play
- initiatives already underway across the federal government

## **Annex A: Advisory Committee**

Health Canada thanks the members of the Health Product Supply Chain Advisory Committee, from the following organizations:

- Apotex Inc.
- Association québécoise des distributeurs en pharmacie
- Canadian Association for Pharmacy Distribution Management
- Canadian Generic Pharmaceutical Association
- Canadian Hospital Specialties Ltd.
- Canadian Pharmacists Association
- Canadian Society of Hospital Pharmacists
- Familiprix
- Food, Health & Consumer Products of Canada
- HealthPRO Canada
- Innovative Medicines Canada
- Johnson & Johnson Inc.
- McKesson Canada
- Medtech Canada
- Neighbourhood Pharmacy Association of Canada
- Pfizer Canada
- Faculty member, University of Windsor
- Faculty member, University of Toronto
- Shoppers Drug Mart
- Supply Chain Advancement Network in Health