



Building resilience:

Health Canada's plan to address
health product shortages, **2024 to 2028**



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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.

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Message from the Minister of Health



The Honourable Mark Holland
Minister of Health

Ensuring people in Canada can get the health products they need, when they need them, is a top priority for our government.

Health products like drugs and medical devices are essential to maintaining and improving our health. Shortages of these products can affect patients and their loved ones. They also put stress on our health care system.

I am concerned about health product shortages and the impact that shortages can have on Canada’s public health care, including for children and families.

I share the concerns of patients, parents, caregivers and health care providers who see their access to health products jeopardized by shortages.

I am also concerned by the:

- additional pressure that shortages place on our health care system and
- burdens that shortages place on health care providers who are working hard to find solutions for their patients

Together with many key partners, we have been working to minimize the impact of shortages and to prevent them whenever possible. In recent years, the Government of Canada has introduced new measures to strengthen the supply of health products in Canada. This includes the:

- Pediatric Drug Action Plan
- Biomanufacturing and Life Sciences Strategy
- National Strategy for Drugs for Rare Diseases
- new regulatory tools to address shortages and safeguard the drug supply against foreign bulk importation programs

Health Canada will continue to play a leadership role in responding to health product shortages. At the same time, it’s the responsibility of many parties to help prevent and reduce shortages, including:

- federal, provincial and territorial governments
- manufacturers, importers and distributors
- the health care system and providers
- consumers

The ability to prevent and reduce shortages depends on all of us to do our part. This is why I am introducing *Building Resilience: Health Canada’s Plan to Address Health Product Shortages*. This plan outlines actions that Health Canada will take over the next 4 years.

As we move forward on implementing this plan, it’s critical that we work together to support a strong health care system in Canada.

Health product shortages in Canada

Shortages of health products like drugs and medical devices are a growing global problem. Shortages happen when a manufacturer is unable to meet demand for its products.

Shortages are caused by reductions in supply, increases in demand or shifts in both supply and demand.

Reductions in supply | are caused by issues like manufacturing or distribution problems, recalls, transportation issues, major geo-political developments or environmental events. Supply problems have become more frequent in recent years, in part because manufacturers have consolidated operations. Consolidation has reduced industry's ability to withstand manufacturing and supply chain disruptions.

Increases in demand | are caused by changes in disease trends or product usage, which can cause a spike in the need for select products.

Shifts in both supply and demand | can cause severe shortages. The COVID-19 pandemic is a good example of a situation where both supply and demand challenges caused serious shortages. Supply was disrupted by problems in manufacturing, shipping and logistics. Some countries also limited exports, which affected the supply for key goods. The pandemic also increased demand for key products like personal protective equipment and certain key medicines and medical devices used to treat COVID-19 symptoms. This extra demand put added pressure on the health care system.



One of the reasons Canada is vulnerable to shortages is that it's a small market, representing only about 2% of global drug and medical device sales. Most of the drugs and medical devices used in Canada are imported. It is often the case that these products are sourced from a single supplier.

Disruptions at any point in health product supply chains can make them vulnerable to shortages. This is because disruptions at one point in the chain can greatly affect other points in the supply chain. Further complexity is introduced in the medical device supply chain because of the large number of parts and components that are needed for manufacturing.

Most shortages are mitigated or resolved before they cause harm to patients. When this is not the case, the most severe shortages can impact our health care system and pose risks to the health of people in Canada. At this time, the number of critical drug shortages is the same as at the height of the pandemic, though the challenges are no longer related to shortages of drugs used to treat patients with COVID-19. We expect that many of the supply chain challenges that Canada experienced during the pandemic will continue.

Canada also faces challenges from foreign programs designed to allow bulk imports of drugs intended for the Canadian market. Canada has taken strong action to address this challenge and safeguard our drug supply.

Finally, changes in technology that shorten the life cycle for certain medical devices used to diagnose and treat disease, are making shortages of these products more likely and severe.

What Health Canada is doing

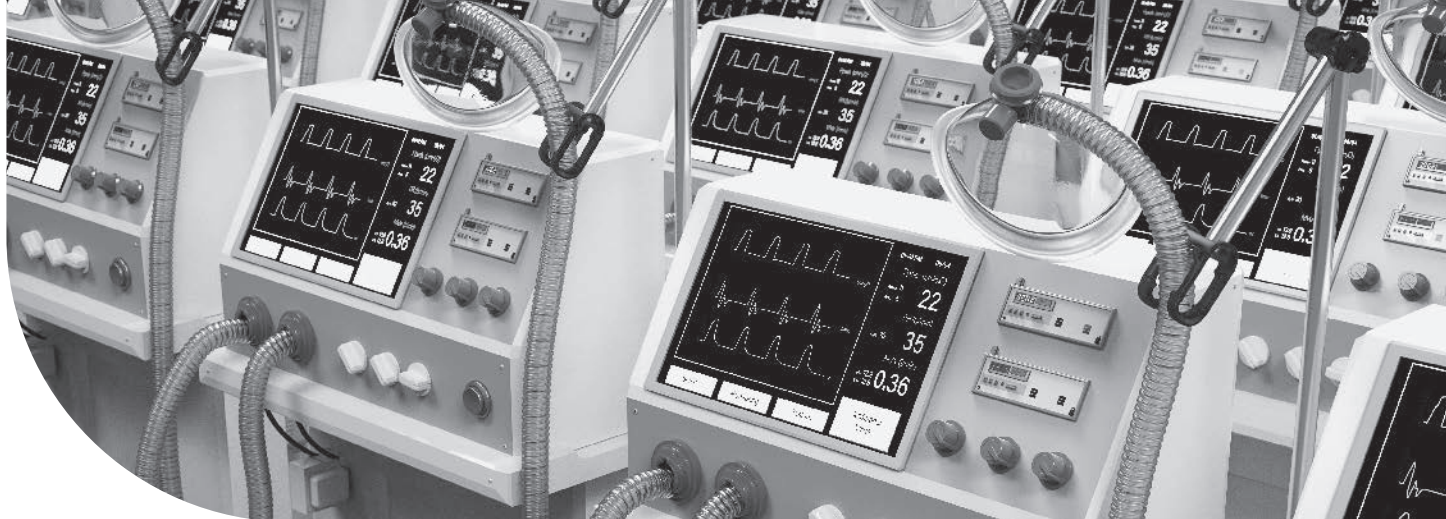
Together with many key partners, we have been working to minimize the impact of shortages and to prevent them when possible.

We use a range of tools to monitor and mitigate the impacts of shortages when they occur. For example, we:

- require manufacturers of prescription drugs and certain medical devices to report shortages
- prohibit the distribution outside of Canada of drugs that are made for the Canadian market when it could cause or worsen a shortage
- work with supply chain actors to identify alternative supply and explore opportunities they may have to increase production or fast-track re-supplies
- authorize the importation of foreign-authorized products that are not authorized for sale in Canada but are manufactured to similar standards
- work with supply chain actors and health care systems and providers to conserve available supply

These tools are effective when a shortage is anticipated or the supply already shows signs of constraint. But we’re also seeing significant shortages in product lines we have not seen in the past, like non-prescription drugs and infant formula.

It’s important that there are strong tools and approaches to better prevent shortages.



To help us in this work, we:

- conducted a broad national public consultation with people in Canada over the spring and summer of 2023
- held a wide-ranging series of stakeholder engagements
- set up an external advisory committee made up of representatives from health product industry sectors, health care providers and academia

In these engagements, we received extensive feedback from governments, industry, patient communities, health care providers and representatives of Indigenous groups. We published a report of what we heard from stakeholders in December 2023.

[What we heard: Improving access to drugs and other health products in Canada](#)

Our consultation was focused on human drugs and medical devices. But we also heard from interested parties about veterinary drugs and foods for a special dietary purpose. We took stock of this feedback and, though these products are not the focus of this plan, we will continue to consider solutions to shortages of these products.

Resilience and health product shortages

Everyone has a stake in improving Canada’s resilience against shortages to reduce the harm they pose to people in Canada. Resilience means being able to withstand, adapt to and recover from challenges.

We can strengthen Canada’s resilience by building better collective capacity in 3 areas:

Planning

- + designing systems and standard operating procedures that promote readiness and rapid response to shortages

Prevention

- + detecting shortage risks and intervening to avoid shortages before they happen

Response

- + detecting shortage signals early, minimizing the impacts of shortages when they occur and restoring access to needed products quickly



Building resilience through actions

This plan outlines actions to help build resilience against health product shortages and protect people in Canada from the worst effects of shortages. Taken together, these actions will help us make shortages less likely, less severe and less disruptive to patients and the health care system.

01. Identifying and addressing shortage risks

The health product industry is too large and diverse for governments, industry and the health care community to apply a single approach to building resilience against all shortages. In Canada, the market for health products includes over:

- 9,300 prescription drugs
- 2,000 non-prescription drugs
- 30,000 licensed medical devices, components and parts

With our partners, we will increase our focus on the health products that present the greatest risks to patients and the health care system when these products are in shortage. This will allow us to use resources efficiently and effectively.



ACTION 01:

Publish a list of drugs that are critical and vulnerable to shortages

We plan to develop and publish a list of drugs that are critical to Canada's health care system and are most vulnerable to shortage.

The list would be used to focus our work on reducing harm caused by the most serious shortages. Other parties like manufacturers, distributors and pharmacies will be able to use the list to help build their resilience and focus on areas where shortages carry the greatest risk to people in Canada.

We would develop the list in collaboration with health care providers, supply chain experts and academia. A draft list would be published for consultation, where we could obtain broader feedback from people in Canada, including patient groups and Indigenous groups.

We would also publish the method used to create the list. It would be updated to reflect changes in drug usage and advances in our understanding of medical supply chains.

Building resilience: Health Canada's plan to address health product shortages, 2024 to 2028

Current regulations are focused mostly on addressing shortages after a supply chain issue has been identified. In Canada, shortages are caused mainly by:

- manufacturing disruptions
- quality control failures
- shipping delays
- shortages of active ingredients of drugs or accessories and parts of medical devices

We need companies to take actions that would decrease the likelihood of a shortage that would cause harm to people in Canada from occurring. These actions can include practices such as:

- **shortage management plans** to anticipate, identify, mitigate and manage the risks of shortages in critical supplies, materials or resources
- **safety stocks** (extra supplies of health products that a company would be required to ensure is maintained) to prevent or mitigate a shortage during a period of low supply or high demand

Health Canada is aware that these practices are already in use in certain areas across the health products supply chain. For example, some group purchasing organizations have made a practice of requiring suppliers to maintain safety stocks. However, inconsistent use of these practices presents a continuing threat to the health of people in Canada.

Proposed regulations would address this threat by requiring manufacturers to adopt practices to reduce the likelihood of a shortage occurring and to mitigate the impacts of shortages when they happen.



ACTION 02:

Require shortage management plans and safety stocks for drugs that are critical and vulnerable to shortages

We propose to advance regulations that would require manufacturers to:

- establish and maintain shortage management plans and procedures for critical and vulnerable drugs
- ensure that safety stocks for drugs that are critical and vulnerable to shortages are maintained in Canada

These actions are in line with actions taken by other international regulators to prevent the worst effects of shortages being felt by patients and the health care system.

While advancing these regulations, we would account for product-specific criteria, like shelf life, and current industry practices in maintaining safety stocks. This would help ensure that new measures are applied in ways that support access and manage burden on industry.

02. Enhancing and sharing supply chain information

Many players are involved in the health product supply chain, including manufacturers, distributors, importers, health care organizations, community and hospital pharmacies, and retailers. Each has a role to play and has deep knowledge about their part of the supply chain, but knowledge and understanding of other parts of the supply can be limited.

Improving everyone’s knowledge about the supply chain and sharing this knowledge among everyone will help build resilience against shortages.

We introduced regulations in 2017 requiring drug manufacturers to report when their products were going into shortage or being discontinued. We introduced similar requirements in 2020 for manufacturers and importers of select medical devices.

Shortage reporting requirements have shown their value over time. Shortage reporting has helped governments and industry develop plans to reduce the impact of shortages and discontinuations. The practice has also helped health care providers and patients identify shortages and discontinuations that may affect them.

Recent shortages of non-prescription drugs have highlighted risks for other products in the supply chain. Regulatory tools used to respond to health product shortages, such as the exceptional importation of foreign authorized products and reporting requirements, do not currently apply to these products. There are opportunities to improve the system to cover more products and alert us when products are in shortage or being discontinued.

ACTION 03:

Enhance regulatory responses and reporting requirements

We propose to advance regulations to better respond to and report shortages of drugs and medical devices. These changes would bring a range of benefits, allowing us to:

- use the full range of regulatory options (for example, exceptional importation) to address shortages of non-prescription drugs
- mandate that drugs outside the normal scope of shortage reporting be reported when a risk of shortage has been identified
- refine and improve the requirements for reporting drug and medical device shortages and discontinuations

These changes would help give everyone more advance notice about shortages and discontinuations, and more time to identify alternatives if needed.

Shortage reports are published online and can be accessed and used by anyone. But the shortage reporting model was originally designed to be used by governments, supply chain actors, businesses, and health care organizations and providers. Improving the information provided online and the platforms used to report shortages will help us meet the needs of more stakeholders, including health care providers, patients, caregivers and researchers.

ACTION 04: Improve reporting systems

We intend to make the platforms used to report shortages of health products less technical and easier to use.

We also intend to align the systems for reporting drug and medical device shortages. This will simplify the reporting process and improve the experience of reporting shortages and learning about them.

Shortage reporting is critical to information sharing, but it’s important to acknowledge the limits of shortage reporting. Shortage reports contain information about shortages that have already happened or may happen soon. Only a small number (3% of drug shortages and 2% of medical device shortages) describe situations where a shortage was prevented or avoided. Everyone involved in the supply chain will need to draw on a wider variety of data sources to build resilience against shortages.

The federal government holds certain kinds of data that could be useful in this work. For example, the Public Health Agency of Canada conducts epidemiological studies based on ongoing disease surveillance. Data from these studies could be used to help anticipate changes in demand for some health products.

Linking existing datasets in this way could help give insight into the entire supply chain. This knowledge could be shared to improve resilience against shortages of key products.

ACTION 05:

Strengthen data analytics and shortage management capacity

We will improve our ability to detect and anticipate shortages by updating our information management systems. This will involve gathering new data from new sources, connecting existing data from different databases and developing new capacity to analyze the supply chain.

These updates will make our programs more efficient, more effective and more proactive. They will also improve knowledge of the supply chain, allowing us to collaborate more effectively with partners.

Other players hold important sources of information about the health products supply chain. These include provincial and territorial governments, manufacturers, importers, distributors, pharmacies and those involved in the health care system.

We lead or co-lead a number of forums with stakeholders, where we share information and coordinate our actions. We regularly engage with:

- provincial and territorial governments
- manufacturers, importers and distributors
- health product procurement organizations (group purchasing organizations)
- health care organizations
- health professional associations and representatives
- patient representatives
- international regulators

We also communicate directly with health care providers about important shortages when they occur. This often involves sharing information about what we are doing to mitigate shortages. It can also involve working to ensure clinicians and patients are aware of certain key risks related to shortages.

Still, the exchange of information about product demand and inventories continues to be a challenge. Current data-sharing practices make it very difficult to know where the pressures are in the supply chain. This is particularly challenging because many companies consider this information to be confidential.

ACTION 06:

Improve information sharing

We will strengthen our partnerships with stakeholders to improve the sharing of information among everyone, including information on demand and inventories for certain health products.

We will also develop a secure, confidential communication platform so stakeholders can share sensitive information on issues about health products with us.

This combined approach will give a better picture of where pressures are in the supply chain. It will also help us make the best and most efficient use of our partnerships without compromising confidentiality.

To further develop Canada’s resilience against shortages, it’s important for health care providers, patients and caregivers to have access to good information about shortages that might affect them. This means making sure that patients have the information they need to make informed decisions about their health. It also means making sure health care providers and caregivers are able to give the best advice about alternative solutions.

To address this challenge, we work with clinical experts, including health care professionals, patient advocacy groups and provincial and territorial governments, to share information on specific shortages.

ACTION 07:

Enhance transparency and clear communication

We will continue to improve our web presence and online communications to enhance transparency on critical, national shortages and the measures taken to resolve them.

We will invest in communications tactics across various platforms, including social media, so that targeted audiences can receive the information they need where they seek it.

We will work in partnership with health care providers and patient advocacy groups to give patients, families and caregivers the information they need to navigate critical shortages.

03. Improving access to health products

We play a key role in improving access to safe, effective and high-quality health products in Canada. A strong and diversified market is important to promote resilience against shortages. For example, we lead or partner on a range of initiatives aimed at developing Canada’s market for health products and strengthen access. Examples include:

- implementing a [Pediatric Drug Action Plan](#)
- investing in the [national pharmacare program](#)
- investing through the [National Strategy for Drugs for Rare Diseases](#)
- strategic investments to grow manufacturing capacity for innovative health products through the [Biomanufacturing and Life Sciences Strategy](#)

We have been looking at options to remove barriers to market entry without compromising the safety of people in Canada. For example, we launched a multi-year regulatory modernization initiative in 2019.

This initiative is aimed at ensuring our regulatory system is more modern, agile and aligned with international regulatory partners. The changes it includes will help us regulate the risks, benefits and uncertainties of more diverse and complex products. It will also help us to be more responsive to the innovation environment, including changes in the biomanufacturing and life sciences sector.

ACTION 08: Modernize regulatory frameworks

We will continue to modernize our regulatory frameworks in ways that improve access to safe, effective and high-quality health products. For example, we will:

- update establishment licensing for [drugs](#) and [medical devices](#)
- advance [agile regulations for drugs and medical devices](#)
- amend [regulations governing clinical trials in Canada](#)
- review the regulations governing foods for special dietary use and foods for infants in Canada

We will also continue to improve our drug and medical device shortage programs. We will focus on improving program efficiency, consistency, responsiveness and stakeholder engagement on health product shortages. This could involve improving regulations that govern shortages as conditions change over time.

Conclusion

This plan highlights our commitment to build resilience against health product shortages to reduce the harm they pose to people in Canada.

In developing this plan, we benefited from extensive feedback from a wide range of stakeholders, including:

- provincial and territorial governments
- representatives of Indigenous groups
- representatives from the health products industry
- patient and consumer advocacy groups
- health care providers and professionals

Our plan also reflects our best efforts to align with international regulatory partners, promote consistent practices, and reduce administrative and regulatory burdens. We are committed to continuing conversations with all these groups as we move to implement the plan.

The health product supply chain is a complex network. Everyone involved in the supply chain plays an important role in addressing shortages. Canada’s resilience against health product shortages rests on the strength of our partnerships.

We invite our provincial and territorial partners, industry, health care providers and the public to work with us in building Canada’s resiliency against health product shortages. By working together to put in place new strategies to mitigate and prevent health shortages, we will help ensure that people in Canada get the health products they need, when they need them.