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# Health Product Shortages: Overview & Path Forward

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# Purpose



# Shortages impact Canadians and the healthcare system

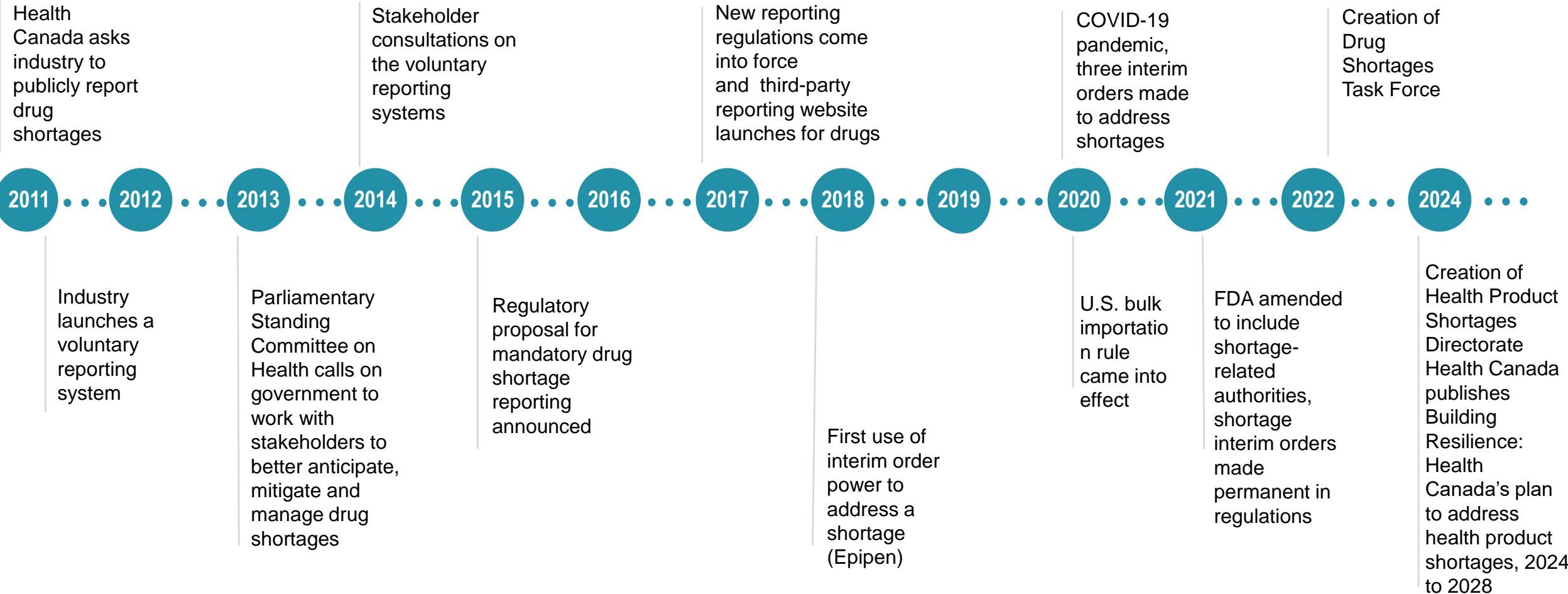
Canada is a small market with a heavy reliance on imported health products

- 68% of Canadian drugs are imported and 83% of the regulated activities for drugs occur outside of Canada
- The vast majority of Canada's medical devices are imported
- Canada holds 2% of global market share for drugs and 1.8% for medical devices

12% of all marketed prescription drugs are currently in shortage

61 medical devices are currently reported in shortage

# Evolution of Health Canada's Shortage Program



# The health product supply chain is complex

Health product accessibility is shaped by many factors:



**Economic**

(e.g., rising costs: labour, material, transportation)



**Regulatory**

(e.g., regulatory burden)



**Geopolitical**

(e.g., conflicts, economic sanctions)



**Trade**

(e.g., competitiveness, profitability)



**Environmental**

(e.g., natural disasters)

Disruptions to access can be initiated at any point of the supply chain



**Raw materials**

- Shortages of raw materials
- Foreign procurement measures to reserve supplies, such as the U.S. *Defence Production Act*



**Manufacturing**

- Quality problems and product recalls
- Equipment failure or maintenance
- Labour disruptions



**Distribution**

- Shipping disruptions
- Foreign export bans
- Diversion of supply to foreign markets



**Retailer or healthcare**

- Poor demand forecasting as part of procurement
- Foreign personal exportation
- Changes in prescribing practices (e.g., off label use)
- Contracting practices (e.g., lack of diversity in suppliers)



**Consumer**

- Changing health profile of the population
- Sudden increased demand due to public health emergencies
- Hoarding

Growing consolidation of global supply chains reduces redundancy and increases the likelihood of shortages emerging

# Existing legislative and regulatory tools support the shortage response

Authorities in the *Food and Drugs Act*, *Food and Drug Regulations* and *Medical Devices Regulations* provide Health Canada the ability to take regulatory measures to prevent and alleviate shortages of therapeutic products.

## Shortage Reporting

Mandatory reporting of drugs and select medical device shortages in certain circumstances

Improves ability to identify and track shortages

## Exceptional Importation

Authority to import drugs and medical devices not authorized in Canada, but manufactured to comparable standards

Used to source alternate supply of drugs and medical devices during a shortage

## Request for Information

Authority to request information about a shortage, or risk of a shortage, to help evaluate the shortage and its potential risk to health

Permits the collection of additional information to identify and combat shortages

## Prohibition

It is prohibited to distribute certain drugs outside of Canada that are intended for the Canadian market if it could cause or worsen a shortage

Responds to the threat posed by foreign bulk importation programs, such as the one in the U.S.

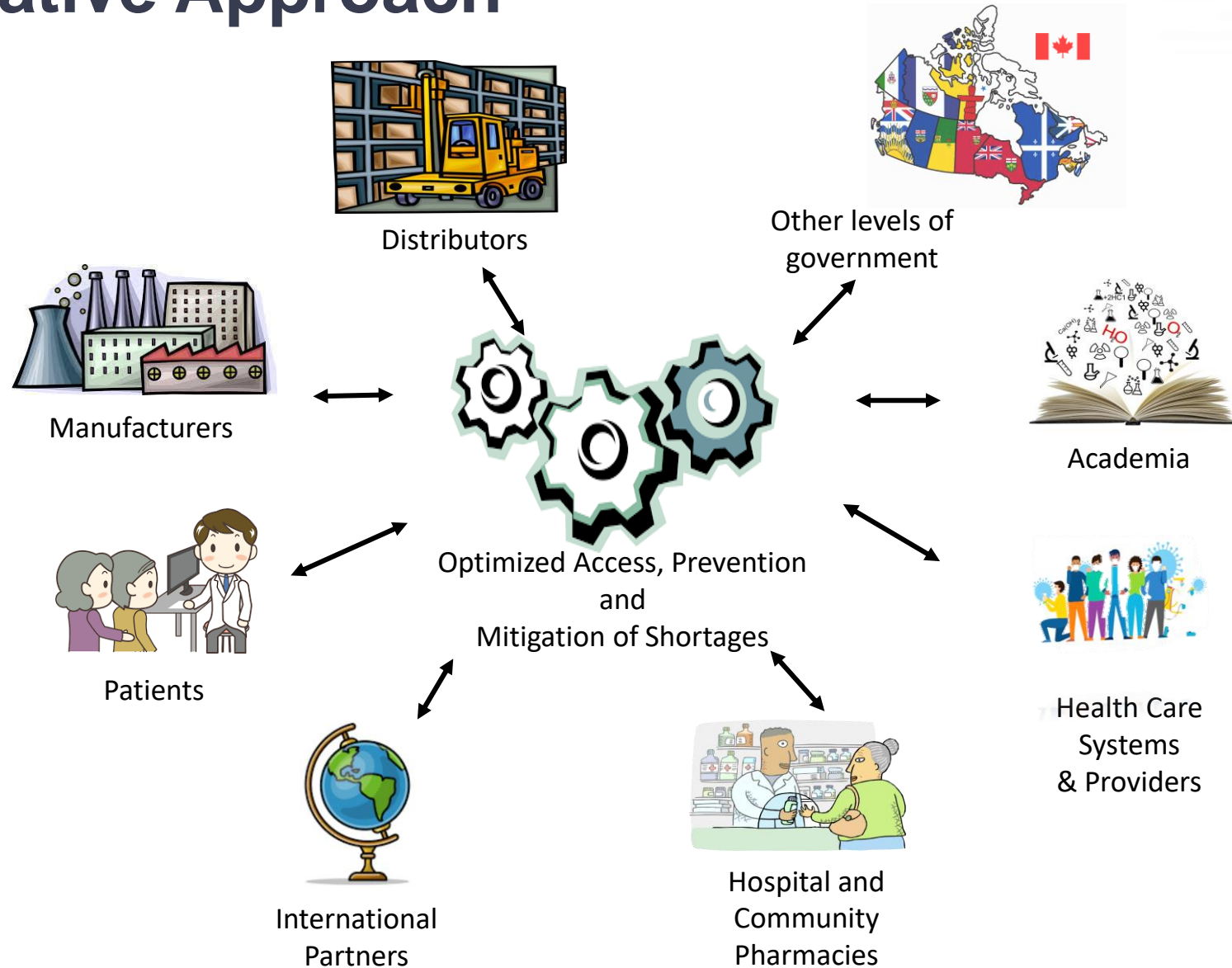
# Drug Shortage and Discontinuation Reporting

Since 2017, MAHs are required to post a report when the manufacturer is unable to meet demand for the health product in Canada.

## Shortages (actual/anticipated)

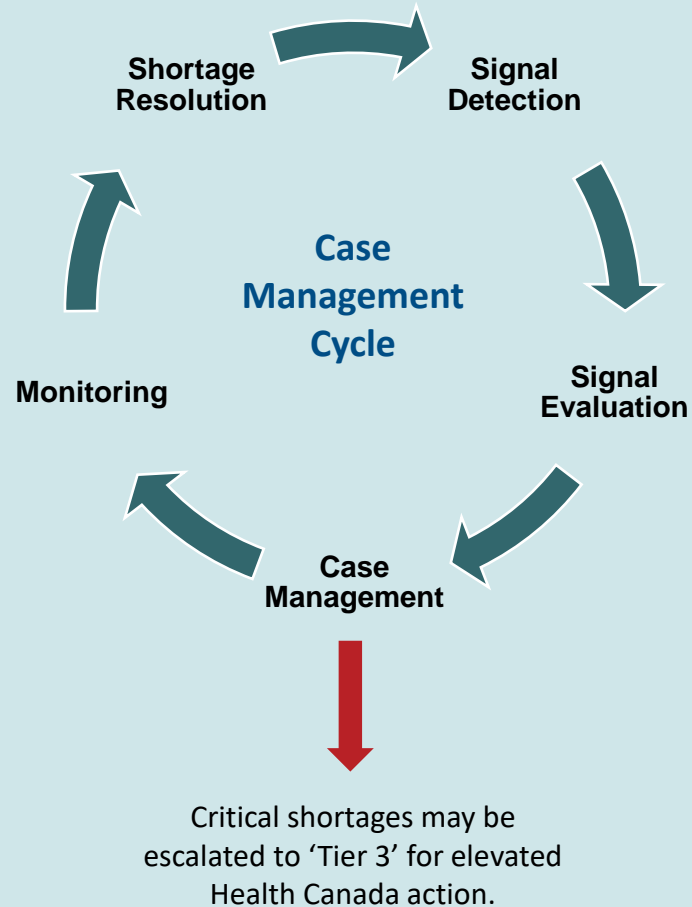
- if they anticipate that a shortage will begin in more than six months, at least six months before the day on which they anticipate it to begin;
- if they anticipate that a shortage will begin in six months or less, within five days after the day on which they anticipate it; or
- if they did not anticipate the shortage, within five days after the day on which they become aware of it.

# A Collaborative Approach





# Case Management Approach



**Signal detection:** Signals are received from many different sources including from the healthcare system, from patients, community and hospitals pharmacies, supply chain actors, from various monitoring activities, regulatory partners and provinces and territories.

**Signal evaluation:** Assessed based on the medical importance of the drug and the severity of the shortage impact to determine if case management is required.

**Case management:** Entails efforts to increase supply and/or strategically reduce demand to minimize the impact of the shortage.

**Monitoring:** Sustained for cases that are on track to be resolved or have been resolved and there are potential ongoing vulnerabilities.

**Shortage resolution:** Resolution occurs when a case is closed with appropriate justification.

# Mitigation Strategies

**Communication and stakeholder engagement are key components of all case management strategies**

- Multi-stakeholder meetings
- PT DSTT engagement
- Supply Notices
- TAC engagement
- Health care professional messaging
- Manufacturer communications

## Reduce Demand

P/T sharing

Allocations & Filters

Conservation measures

HCP guidance

## Increase supply

Expedited review

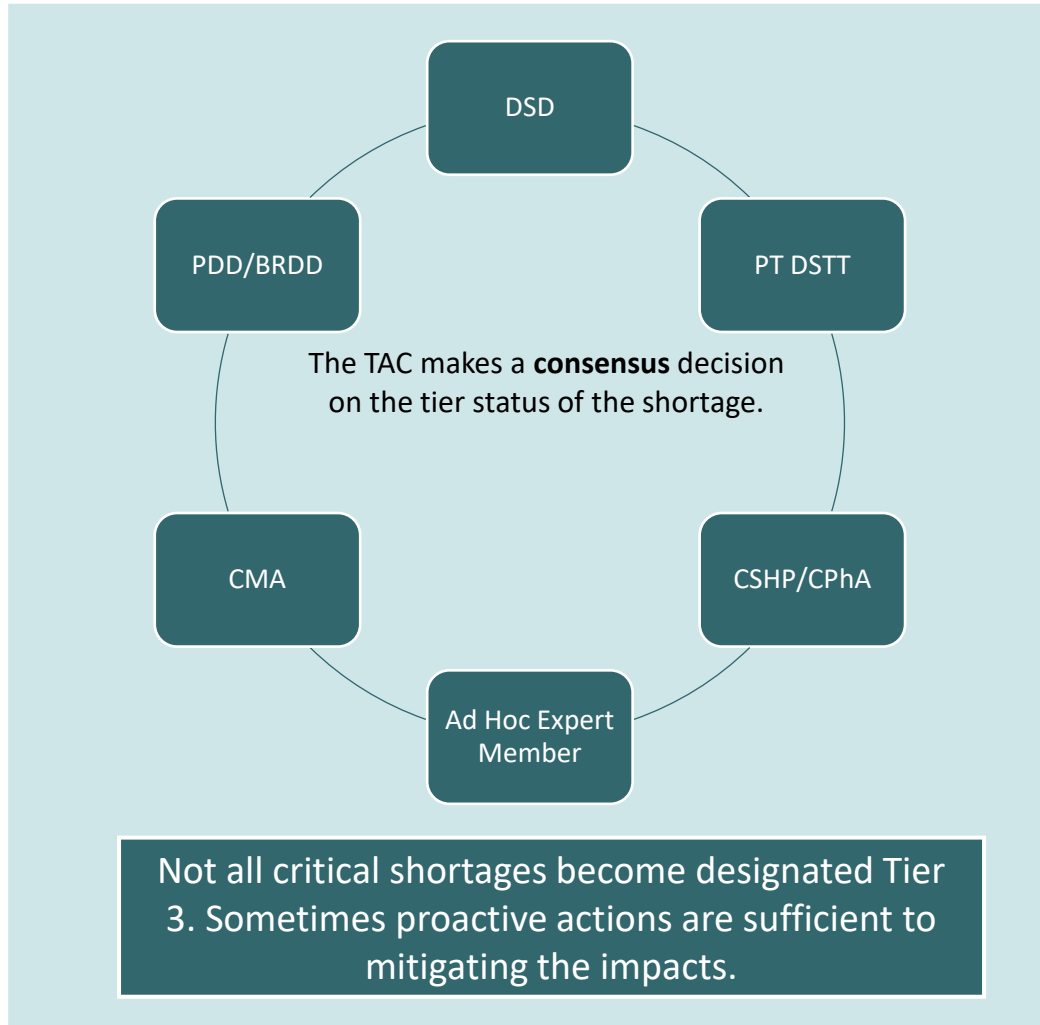
Existing MAHs increase production

Foreign authorized product

Other Flexibilities

Usage Date Extension

# Case Management Approach



Tier 3 shortages are those that have the greatest potential impact on Canada's drug supply and health care system.

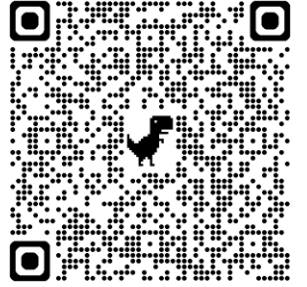
Tier 3 shortages are determined by the Tier Assignment Committee (TAC). The TAC makes recommendations on the tier assignment of actual and anticipated drug shortages based on:

- a review of the information gathered on the drug shortage
- a thorough discussion of the potential impact of the shortage
- a discussion of next steps to be taken to mitigate the impact of the shortage

Tier 3 designations are posted publicly to facilitate transparency and to help support mitigation efforts.

# Communication

Health Canada uses supply notices to communicate information about a drug shortage or supply concern.



## List of drug supply notices

- [Notice: Pantoprazole for injection in short supply](#) [2024-07-29]
- [Shortage of Loxapac \(loxapine\) intramuscular 50 mg/mL injection in Canada: Notice](#) [2024-07-04]
- [Pfizer facility tornado damage: Notice](#) [2024-05-28]
- [Carbamazepine controlled release tablets in short supply: Notice](#) [2024-05-24]
- [Aminophylline in short supply: Notice](#) [2024-04-19]
- [The measles vaccine supply in Canada: Notice](#) [2024-03-28]
- [Cholestyramine in short supply: Notice](#) [2024-02-21]
- [Supply of acetaminophen, ibuprofen and cough and cold medicines: Notice](#) [2023-09-06]
- [Supply of antibiotic oral suspension products: Notice](#) [2023-09-06]
- [Update on the supply of Ozempic and other GLP-1 receptor agonists: Notice](#) [2023-04-06]

# Overview of Proposed Regulatory Amendments

# Health Product Shortages Plan

In May 2024, Health Canada published a four-year plan entitled *Building Resilience: Health Canada's Plan to Address Health Product Shortages 2024-2028*. The plan commits to 8 actions:

Action 1: Publish a list of drugs that are critical and vulnerable to shortages

Action 2: Require shortage management plans and safety stocks for drugs that are critical and vulnerable to shortages\*

Action 3: Enhance regulatory responses and reporting requirements\*

Action 4: Improve reporting systems\*

Action 5: Strengthen data analytics and shortage management capacity

Action 6: Improve information sharing

Action 7: Enhance transparency and clear communication

Action 8: Modernize regulatory frameworks\*



# Annex

# Health Canada's interventions have evolved

