

Drug Shortages in Canada Overview, Causes & Approaches

AFDO – International & Government Relations Committee
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Drug Shortages in Canada: A Brief Chronology



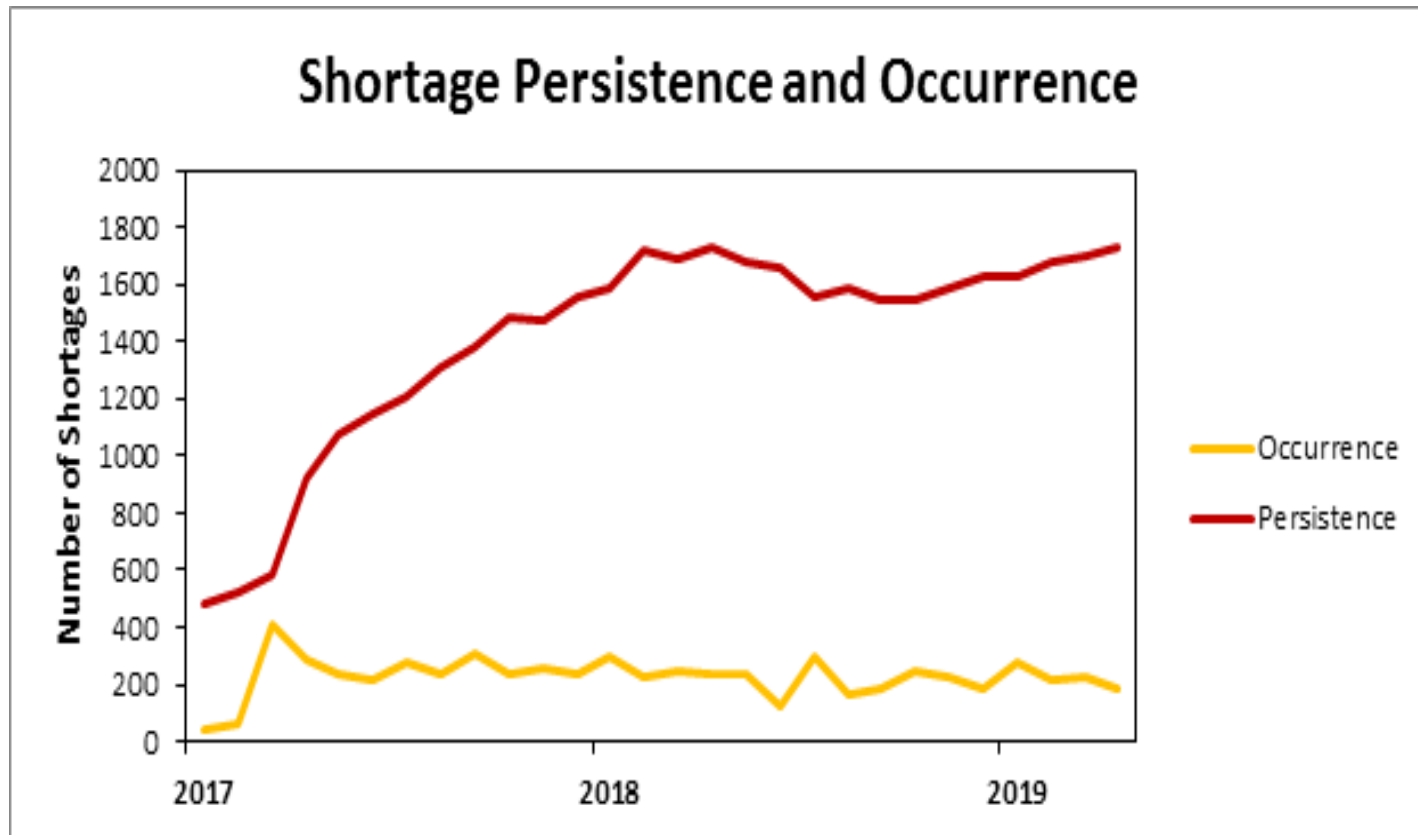
Mandatory Reporting of Drug Shortages

- On March 14, 2017 amendments to the *Food and Drug Regulations* came into force that make it mandatory for drug authorization holders to publicly report drug shortages and discontinuations to a third-party website.
- Public notifications are available on drugshortagescanada.ca as well as through the mobile application. This early notification of actual and anticipated disruption in supply is an important mitigation tool that enables the drug supply chain and the healthcare system to respond appropriately to minimize impact.
- A drug shortage means a situation in which **an authorization holder for a drug is unable to meet demand for the drug**. A shortage is reported on the website when there is reason to believe that a shortage is likely to occur or one is occurring. Discontinuations must also be reported on the website.
 - Drug shortage(determining and meeting demand): You should interpret demand for your drug based on orders you receive from your Canadian clients. According to these guidelines, a shortage occurs when you cannot fill orders from your Canadian clients in their entirety and / or on time.
 - Drug discontinuation: If you are a drug authorization holder, you are discontinuing the sale of your drug if you permanently stop selling it.
- Since the launch, Health Canada has been actively working to improve upon the website. Ongoing updates to the website include improvements, such as new options and features. Some features include: **Company Dashboard, Summary Report, Application Programming Interface, Data Export, Proactive Notifications, & Report History**

Drug shortages are a complex public health and social issue...

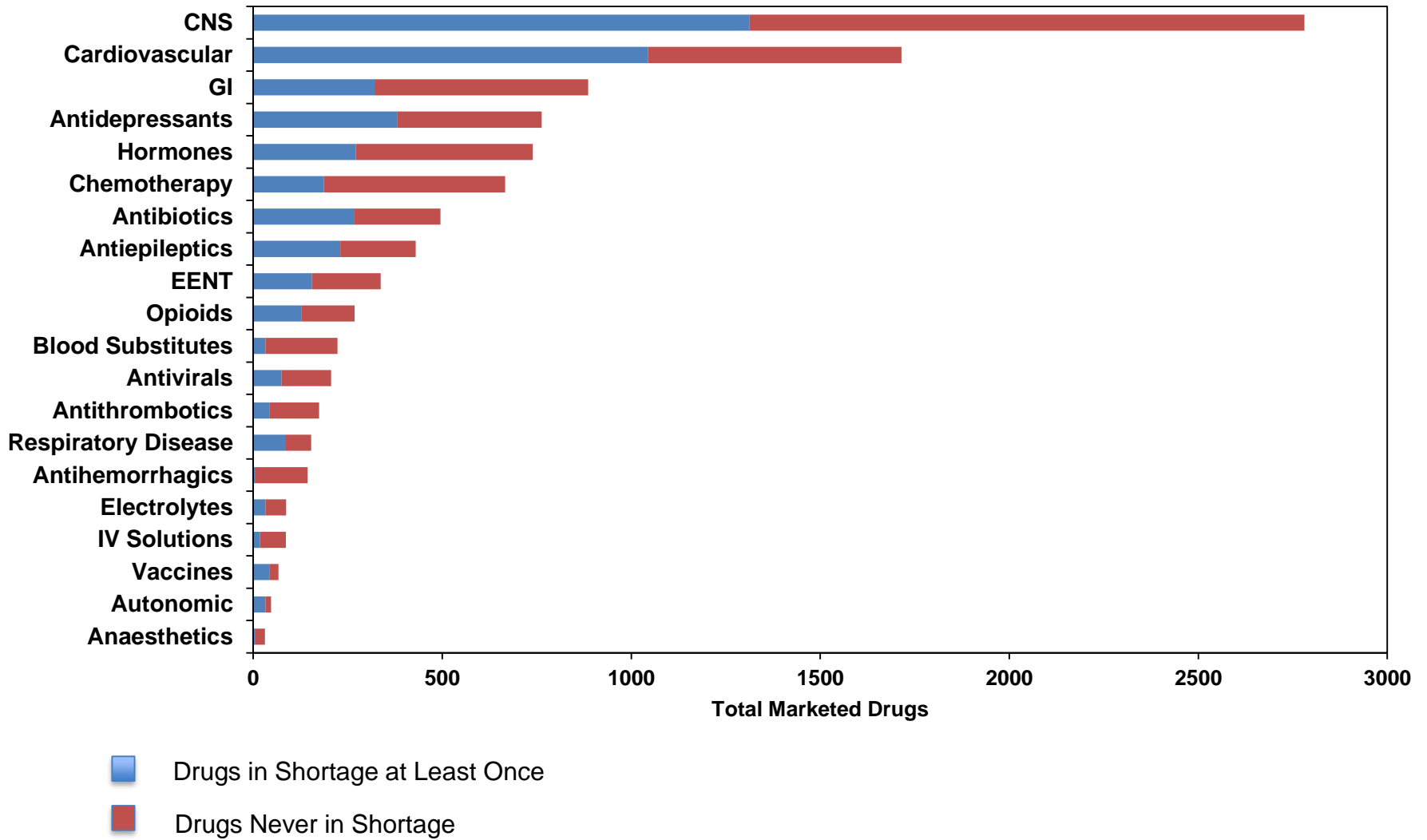
- Canada is the tenth largest market for drugs with total consumption representing 2-3% of the global market (ISED).
- Many drugs in Canada are medically necessary. They are used to diagnose, prevent or treat a serious, life-threatening or severely debilitating disease or medical condition.
- The number of drug shortages in Canada remains high.
 - Since the enactment of the legislation, 4,838 drugs have gone into shortage at least once (44% of marketed drugs).
 - As of May 31, 2019, Canada was reporting 1,538 drugs in shortage (14% of marketed drugs) and 3,300 resolved shortages.
 - 38% of all companies have reported a shortage since March 2017.
- The problem of drug shortages has become more persistent - meaning the number of unresolved shortages is increasing steadily in Canada.
- The complexity, intensity, and duration of each shortage varies. Mitigation efforts are often complex, labour intensive, and involve many players.
- Drug shortages create barriers to optimal care.
- Drug shortages impact the health status, quality of life, and mortality of Canadians.

What the data is showing us...



Total = 4838 Shortages
83% lasted less than a year
17% lasted more than a year

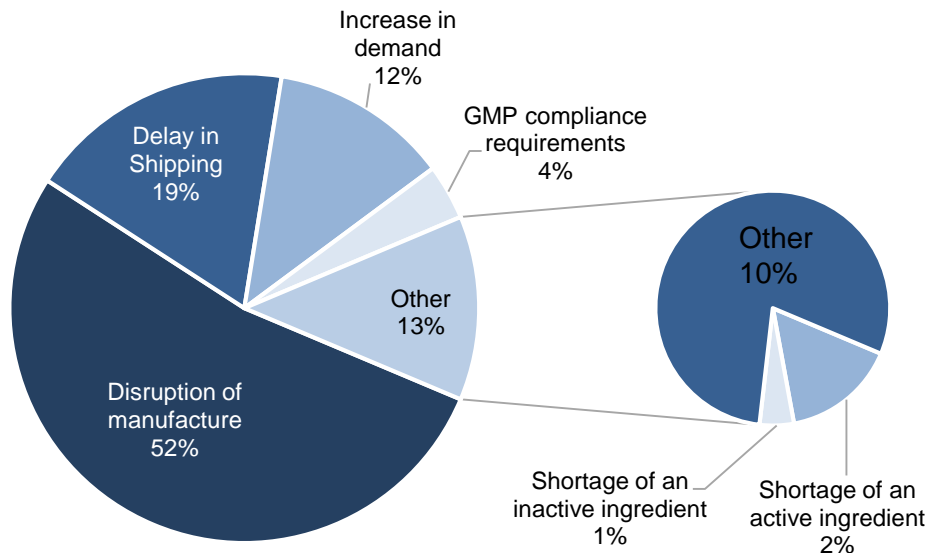
Proportion of drugs in shortage, by class...



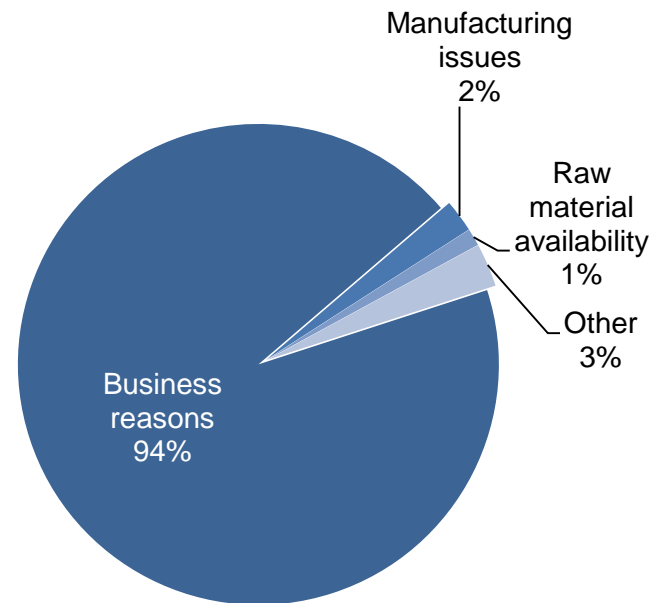
Reasons for Shortages and Discontinuations

*As of May 1, 2019

Reasons for Shortages



Reasons for Discontinuations



It is Health Canada's expectation that regulated parties, as per the mandatory reporting requirements, are accurately reporting the reasons for shortages and discontinuations. To date, companies have responded favourably to Health Canada's requests and continue to demonstrate a willingness to comply.

Understanding root causes is key...

Raw Material Availability

Quality Issues

Regulatory Changes & Issues

Recalls

Business & Economic Issues

Industry Consolidations

Clinical Practices

Capacity, resiliency, redundancy

Unexpected and/or increased demand

Changing demand

Speculative stockpiling

Lack of proactive risk identification

Natural disasters



Health Canada's Roles and Responsibilities: Managing Drug Shortages

Health Canada has made progress in ...

- Establishing and cultivating the multi-stakeholder approach, key to addressing drug shortages in Canada.
- Creating a case management framework for managing drug shortages.
- Increasing industry accountability.
- Placing more information in the hands of those who need it most.

Multi-Stakeholder Steering Committee on Drug Shortages ...

- Health Canada, together with the Province of Alberta, launched a **Multi-Stakeholder Steering Committee on Drug Shortages (MSSC)** made up of government, industry and health care representatives, to work towards a more rigorous and coordinate approach to drug shortages.
- The MSSC is supported by the work of several groups
 - **Health Canada's Drug Shortages Unit** is responsible for: drug shortage case management; compliance verification and promotion in relation to mandatory reporting; and stakeholder engagement.
 - **The Provincial and Territorial Task Team on Drug Shortages** coordinates with the health system to confirm and assess shortages, notifies Health Canada when facilitation is needed and confirms and assesses shortage specifics with stakeholders.
 - **Federal/Provincial/Territorial Working Group** clarifies roles & responsibilities and develops process and tools.

Health Canada's Roles and Responsibilities Cont'd

The MSSC has developed a number of key tools for stakeholders.

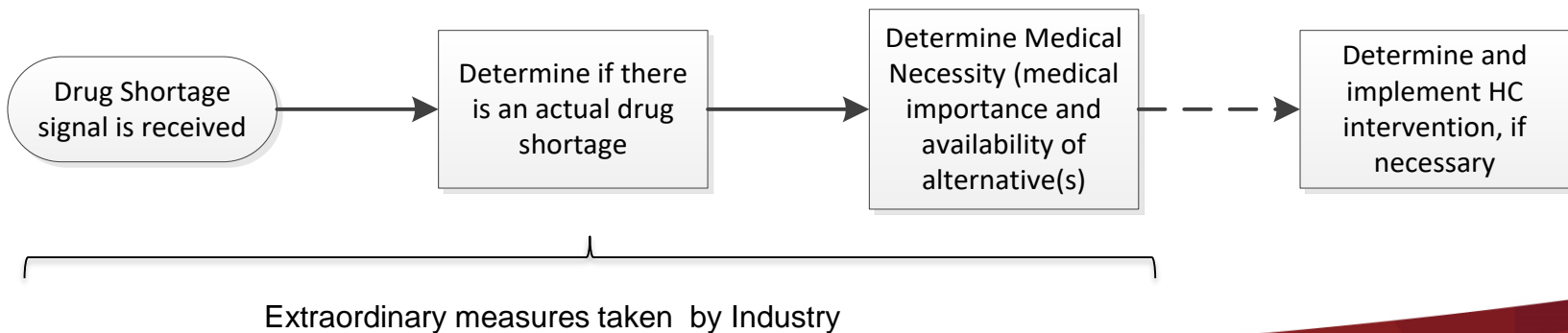
- **Protocol for the Notification and Communication of Drug Shortages:** Sets clear expectations in anticipation of, or in response to drug shortages.
- **Multi-Stakeholder Toolkit:** Describes the Canadian drug supply chain, clarifies roles and responsibilities of key players, and identifies the tools and strategies to address drug shortages.
- **Guidance Document to Mitigate Drug Shortages through Contracting and Procurement:** Outlines best practice contracting guidelines, procurement strategies and tools to address drug supply chain shortage vulnerabilities.
- **Preventing Drug Shortages: Identifying Risks and Strategies to Address Manufacturing-Related Drug Shortages in Canada:** Proposes strategies to reduce and prevent the manufacturing-related causes of drug shortages in Canada.

All documents are available at drugshortagescanada.ca

See - About & Resources

Case Management

- Health Canada undertakes several key activities central to drug shortage case management including:
 - Ensure manufacturers post timely and accurate information on drugshortagescanada.ca in accordance to the mandatory reporting regulations
 - Gather critical information, conduct supply and demand analysis and assess the scope of shortages
 - Determine medical necessity and identify the availability of therapeutic alternatives for products in shortage
 - Collaborate with the supply chain to address root causes and identify plans for mitigating impacts of shortages
 - Consult with other key stakeholders to develop strategies for the avoidance and mitigation of shortages
 - Coordinate communication and information sharing with relevant stakeholders
 - Working with international counterparts to identify additional sources of supply and share needed safety and quality information
 - Exercise appropriate administrative and regulatory tools to mitigate drug shortages



Key Drug Shortages

Sodium Bicarbonate (various uses: surgical, antidote for poison, organ failure) –2017

Global shortage due to a third party manufacturing delay and a recall was exacerbated by company being Canada's sole supplier. A strict allocation protocol was implemented: life-saving procedures and critical emergency use only. Lack of availability was considered a crisis by hospitals and first responders. Alternative products, compounding, alternative international suppliers all considered. Shortage was mitigated through allocation and resolved when another product came to market.

Epipen (anaphylaxis) - 2018

Serious shortage of epinephrine auto injectors created significant concern for thousands of Canadians at risk or with a history of serious life-threatening allergic reactions. Caused by manufacturing disruptions beginning in 2017 but were supplying EpiPens through measured national allocation. Situation reached a critical point with limited or no release of new product, and 'stock out' situations severely impacting access for Canadians. An Interim Order facilitated the import and sale of a U.S. product, Auvi-Q.

5-fluorouacil (oncology drug) – 2017

Canadian shortage stemming from a GMP issue which resulted in cracked vials and a potential sterility issue. There were 3 marketed DINs, but competitors were unable to meet the unforeseen and increased demand. Patient treatments were skipped/delayed due to shortage. To mitigate the shortage, Health Canada did not object to the release of quarantined product. The risk/benefit of not objecting to potentially cracked vials was difficult to assess. Upon receipt, HCPs who administered product were asked to visually inspect vials before use. The manufacturer ultimately secured a new vial supplier and product returned to market.

Pilot Project: Tier Assignment Committee

- Tier 3 captures those shortages with the greatest potential impact on the Canadian drug supply and health care systems by virtue of availability of alternative supplies, ingredients or therapies.
- In March 2019, a six-month Pilot Project of the Tier Assignment Committee (TAC) and associated Tier 3 shortage response functions was launched to address gaps in identifying, assessing, and communicating on Tier 3 shortages.
- Health Canada's Drug Shortages Unit and the Provincial and Territorial Drug Shortages Task Team will identify actual and anticipated shortages that meet the criteria for a Tier 3 shortage, and will engage the TAC to make a consensus determination on the shortage tier, and to advise on potential mitigation strategies.
- The objectives of the Committee are to:
 - Increase consistency and transparency in Tier 3 assignment
 - Increase collaboration between stakeholders affected by drug shortages
 - Contribute to effective case management of drug shortages

Early observations from recent cases:

- Increased stakeholder communication led to productive and well-informed discussions on decision-making.
- Increased transparency on impact of the shortage and mitigation strategies under consideration.
- Increased information sharing amongst stakeholders and the market authorization holder as a result of multi-stakeholder meetings scheduled at the recommendation of the TAC.

Tracking the problem globally...

Systems and reporting adopted in some countries, but variable

- The definition of drug shortages and the scope of reporting systems varies globally.
- Reporting systems established in industrialised countries but not all are government-mandated: Belgium, the Netherlands, Italy, UK, Australia, US, Germany, Spain, England, France.
- A small number of countries have made reporting mandatory: Canada, Australia, USA.
- In 2016, the World Health Assembly published resolutions for “Addressing the global shortage of medicines and vaccines ”

Countries are investing in studying the causes and impacts of drug shortages:

- **France**
 - Senate Task Force examined the issue and recommended boosting manufacturing, public programs to guarantee availability of certain medicines, penalizing companies for not meeting supply obligations, allowing pharmacists to offer alternatives, and more international cooperation
- **Europe**
 - Although most shortages are handled by national authorities, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) have created a Task Force to advise on tackling disruptions that affect multiple member states.
 - The Task Force has held several multi-stakeholder workshops and has published a ‘work programme’ outlining actions for regulators and industry to ensure availability of medicines.

A global notification system for shortages does not exist.

Next Steps

- Analysis
- Compliance Promotion
- Enhanced Risk Mitigation
- Collaboration
- Prevention

Drug shortages are a complex global problem. As we continue to fine tune our risk mitigation tools, we must also assess the underlying factors that affect the likelihood, severity, and duration of shortages in Canada and globally. Understanding the root causes and drivers will enable all stakeholders to work strategically to prevent drug shortages.

Thank you

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