

The Management of Drug Shortages



YOUR HEALTH AND SAFETY... OUR PRIORITY.

Objectives

To highlight the how critical drug shortages are managed in Canada by

- providing an overview of roles and responsibilities; and,
- providing details related to the role of Health Canada in case management.

Background

In 2012, several drivers caused Health Canada to look at its role in the management of drug shortages...

- Drug shortages had become a complex, national and global problem and a serious, ongoing issue for Canada's health care system.
- In early 2012, a business decision by one of Canada's generic drug manufacturers instigated some of the largest drug shortages known in Canada's history sparking significant concern, and resulting in an Emergency Debate in the House of Commons and a Standing Committee on Health (HESA) report.

As a result, the Department worked with other key players to clearly define roles and responsibilities.

The Governance

- Health Canada, together with the Province of Alberta, launched a Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) made up of industry and health care representatives, to work towards a more rigorous and coordinated approach to drug shortages.
- The MSSC is supported by the work of several groups
 - The Multi-stakeholder Working Group examines key questions on which input from all parties is required and convenes meetings to discuss specific shortages for purposes of sharing information and developing mitigation strategies.
 - The P/T Drug Shortage Task Team coordinates with the health system to confirm and assess shortage situations, notifies HC when facilitation is needed and confirms and assesses shortage specifics with relevant stakeholders.

The *Protocol for the Notification and Communication of Drug Shortages*

The MSSC developed the *Protocol for the Notification and Communication of Drug Shortages* which, among other things

- Explains the categorization of drug shortages into 3 tiers
 - Tier 1. Anticipated shortages
 - Tier 2. Actual shortages, and
 - Tier 3. Shortages with the greatest potential impact.
- Clarified Health Canada's responsibility of playing a supporting role to provinces /territories in management of Tier 1 and Tier 2 shortages, and a lead role in coordinating a response in Tier 3 situations.

Principles

The Protocol outlines a number of principles which guides the work of all stakeholders in managing drug shortages

- ***The health and safety of patients*** is the top priority in all drug shortage communication and responses.
- Manufacturers will post all drug shortages, anticipated or actual as well as discontinuations, on www.drugshortagescanada.ca, no less than six months in advance or if known less than six months in advance, it should be reported within five days from when they become aware of it, to allow maximum opportunity for the healthcare system to react to the shortage.
- Drug shortages are a multi-stakeholder responsibility, requiring the ***coordinated involvement of all players*** across the drug supply chain.
- Drug shortage responses are based on a ***flexible***, case-by-case approach.
- Communication of drug shortages is ***transparent, reliable, timely, consistent and comprehensive***.
- All drug shortage assessments, notifications, and updates are ***based on sound evidence*** confirmed by relevant stakeholders.
- Sharing of information is ***compliant with applicable laws*** (such as privacy, access to information, laws relating to confidential business information and competition).

Outcomes

These principles are designed to lead to a set of outcomes shared by all stakeholders:

- Early warning is provided before most drug shortages occur
- Information requirements are clear and appropriate
- Notification and communication are enhanced amongst all drug supply chain stakeholders
- Information is disseminated as early as possible, in a consistent, ongoing and coordinated fashion
- Time needed to respond to drug shortages is minimized
- Coordinated responses to drug shortages are enhanced
- Contacts/leads for key stakeholders in the drug supply chain are identified
- Impact of drug shortages on the health care system, care givers and patients, is mitigated

Responsibilities – Tier 1

- Manufacturers post comprehensive information on www.drugshortagescanada.ca:
 - 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.
- Manufacturers collaborate with all key stakeholders to provide and validate reliable, timely and comprehensive information.
- P/T Health Ministries, Regional/Local Health Authorities, hospitals, federal drug plans, wholesalers, distributors and other stakeholders, as applicable, share information to ascertain, assess and confirm the nature and circumstances of anticipated shortage.

Responsibilities – Tier 2

Tier 2 sets the notification and communication requirements for all actual drug shortages. It is expected that the vast majority of Tier 2 shortages will have first been posted as anticipated Tier 1 shortages.

- Manufacturers must update the information on www.drugshortagescanada.ca within two days after the day on which they make or become aware of change or post information within five days after the day on which they become aware of the change.
- Manufacturers collaborate with stakeholders to provide and validate reliable, timely and comprehensive information.
- The P/T Drug Shortages Task Team coordinates communication requirements, to confirm and assess status and details of shortage.
- Federal, provincial and territorial health ministries, RHAs, hospitals, federal drug plans, and other key stakeholders work together to ascertain details of shortage, coordinate information sharing and mitigation/management strategies.

Responsibilities – Tier 3

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. The response time required for action at Tier 3 is immediate.

- Manufacturers update the information on www.drugshortagescanada.ca within two days after the day on which they make or become aware of change or post information within five days after the day on which they confirmed or identified the shortage.
- Manufacturers collaborate with stakeholders to provide and validate reliable, timely and comprehensive information.
- The Federal Health Portfolio, primarily Health Canada, coordinates communication requirements with the P/T Drug Shortage Task Team, manufacturer(s) and all other key stakeholders.
- Provincial and territorial health ministries, RHAs, hospitals, federal drug plans, and other key stakeholders work together to coordinate information sharing and mitigation/management strategies.

Tier 3 Case Management

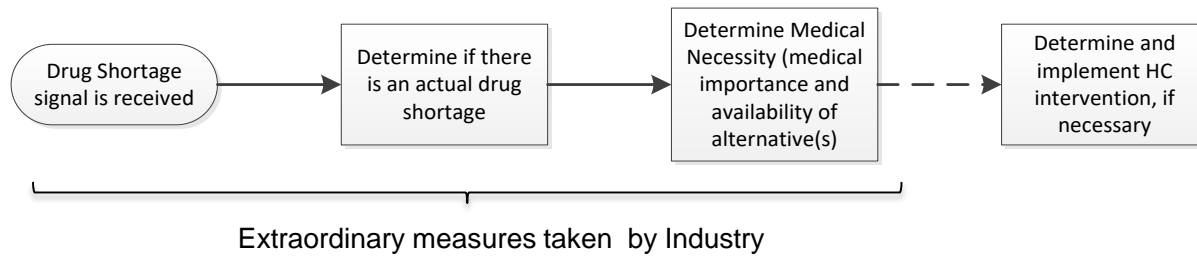
It is during a Tier 3 shortage that Health Canada's role is most significant:

- Works with manufacturers to address issues and identify alternate supplies
- In consultation with partners, develops strategies for shortage prevention and mitigation
- Coordinates communication with P/Ts and external stakeholders
- Conducts medical necessity assessments
- Communicates advice and support during high-profile shortages
- Works with international counterparts to identify additional sources of supply and share needed safety and quality information
- Responsible for the implementation, compliance and enforcement of the mandatory reporting regulations, which came into force in March 2017

Case Management

Health Canada has developed and implemented a robust case management process...

- All shortage signals (ex. from patient, media, P/Ts etc.) are directed to the Shortage Central Point of Contact (CPC).
- Upon receipt of a shortage signal the CPC, in consultation with other Directorates, gathers information to determine if there is an actual shortage.
- If an actual shortage exists it is further determined if the shortage meets the criteria for medical necessity (definition: the drug is medically necessary and there are no alternatives available).
- If the product is deemed medically necessary, the CPC, in collaboration with other Directorates, works with stakeholders across the drug supply chain to coordinate information sharing and identify collaborative mitigation strategies (ex. seeking additional sources of supply, use of enforcement discretion, Special Access Program, expedited review etc.)



Other Health Canada Roles

Other Key responsibilities include

- Mandatory Reporting: 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. Priorities include:
 - Compliance Verification: Verifying compliance with regulations in response to signals and continued compliance promotion through one-on-one guidance and webinars.
 - Website Enhancements: Identification, development and release of enhancements to drugshortagescanada.ca and the introduction of such enhancements to regulated parties through webinars, notifications and one-on-one engagement.
 - Data Visualization and Monitoring: Increase internal transparency and monitoring through regular reporting of drug shortage and discontinuation stats (e.g. website stats, compliance verification) via a monthly dashboard.
- MSSC: Providing support and leading strategic projects including the recently launched review of roles, responsibilities and processes as they relate to drug shortages and discontinuations
- International Collaboration: Working with international regulators on case management and improving foresight through data sharing and trending.

Questions