THE MULTI-STAKEHOLDER STEERING COMMITTEE ON DRUG SHORTAGES IN CANADA

Protocol for the Notification and Communication of Drug Shortages

2013

Protocol for the Notification and Communication of Drug Shortages

FOREWORD

The Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) was assembled in 2012. The MSSC includes representatives of industry associations, federal, provincial and territorial governments, and health professional associations, coming together to address drug shortages in a collaborative and coordinated manner. The MSSC recognizes that drug shortages are a complex, global problem involving all stakeholders across the drug supply chain.

The early notification and communication of drug shortage information are critical to helping all aspects of the drug supply and health care systems respond appropriately to drug shortages, informing the timely coordination of mitigation measures, and enabling health care practitioners and their patients to make timely and well-informed decisions.

The *MSSC Protocol for the Notification and Communication of Drug Shortages* (Protocol) sets out clear expectations for the notification and communication of information in anticipation of or response to a drug shortage. It is premised on the earliest possible notification by manufacturers/importers of drug shortages on **www.drugshortages.ca**.

The Protocol has been developed in conjunction with the *MSSC Multi-Stakeholder Toolkit* (Toolkit), which describes the Canadian drug supply chain (including chemical pharmaceuticals, biologic drugs and vaccines), clarifies roles and responsibilities of key players, and identifies the tools and strategies available to address drug shortages at specific stages of the supply chain.

By clarifying the roles, responsibilities, strategies and expectations of key stakeholders across the complete Canadian drug supply chain, together the Toolkit and Protocol establish the understanding and expectations for coordinated multi-stakeholder notification, information-sharing and action to prevent, mitigate and manage drug shortages in Canada.

These documents were prepared by members of the Multi-Stakeholder Steering Committee, with input from the Provincial/Territorial (P/T) Drug Shortage Task Team, the Multi-Stakeholder Working Group comprised of industry and health care associations and responsible for managing **www.drugshortages.ca**, as well as a number of regional health authorities, health regions, and other healthcare centers.

The list of Multi-Stakeholder Committee members is included in Appendix A. Guidance on key information to inform stakeholder responses to an anticipated or actual shortage is provided in Appendix B.

The Protocol will guide all parties' notification and communication of drug shortage information for as long as necessary, and will be reviewed and updated as required.

Quebec has collaborated in the multilateral efforts to strengthen notification and communication methods and to identify the best strategies for managing and preventing drug shortages, but it intends to retain control over the implementation of measures it deems appropriate with respect to drug shortages.

TABLE OF CONTENTS

1. PURPOSE 3
2. SCOPE 4
3. PRINCIPLES 4
4. OUTCOMES 5
5. STAKEHOLDERS 5
6. TIERED NOTIFICATION AND COMMUNICATION 6
APPENDIX A – MSSC MEMBERSHIP LIST 10
APPENDIX B – GUIDANCE DOCUMENT: INFORMATION GUIDE FOR DRUG SHORTAGE NOTIFICATION AND COMMUNICATION 11

PROTOCOL FOR THE NOTIFICATION AND COMMUNICATION OF DRUG SHORTAGES

1. PURPOSE

The Protocol for the Notification and Communication of Drug Shortages (Protocol) sets out a tiered process for the notification and communication of information in response to a drug shortage.

Notification involves the posting of drug shortage information on **www.drugshortages.ca** by manufacturers and importers. It is the foundation upon which collaborative, informed drug shortage response is built. Manufacturers/importers must post all shortages on **www.drugshortages.ca** as soon as they are anticipated or known to occur. **Communication** is the sharing of critical information amongst stakeholders to facilitate early warning and action of anticipated and/or actual drug shortages. All parties should adopt a proactive and precautionary approach to information sharing.

Together, the early and ongoing notification and communication of reliable and comprehensive drug shortage information are critical to helping all aspects of the drug supply and health care systems respond appropriately to supply-based shortages, informing the timely coordination of mitigation measures, and enabling health care practitioners and their patients to make timely and well-informed decisions.

Building on the Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) *Multi-Stakeholder Toolkit,*[1] the Protocol outlines:

- drug shortage tiers based on pre-determined criteria
- process and minimum content requirements for the notification and communication of drug shortage information
- coordinating leads for all actual shortages
- key stakeholder contacts

This Protocol establishes notification and communication requirements for all drug shortages, understood as a situation when ***a manufacturer/importer anticipates that they cannot supply a drug to meet projected demand.***[2,3] For these shortages, due to the circumstances and potential impact of the shortage, the engagement of inter-provincial/territorial or federal actors may be required. The Protocol outlines tiered requirements for the notification and the communication of information beneficial for all stakeholders engaged in anticipating and managing these shortages.

The Protocol does not speak to nor establish expectations relating to distribution channel disruptions most likely to occur at the local, regional or individual provincial or territorial level for which existing networks, prevention strategies, and stakeholder tools might be used. Distribution

[1] The MSSC Multi-Stakeholder Toolkit outlines the Canadian drug supply chain and the responsibilities, tools and strategies available to individual stakeholders in response to a specific shortage.
[2] For added clarity, all anticipated shortages must be posted regardless of the percentage of the total Canadian market represented by the specific drug in shortage.
[3] It is understood that manufacturers will operationalize these requirements based on the anticipated scope and severity of the shortage, inventory practices and drug specifics, so as to minimise impact on patient care.

channel disruptions might arise from a variety of causes within a given region or jurisdiction that are unrelated to manufacturing issues. In these cases, while all stakeholders, including manufacturers might have important obligations to provide comprehensive information and assistance resolving the disruption, it is not expected that the disruption would be posted on **www.drugshortages.ca** nor addressed through this Protocol.

The Protocol's tiered notification and communication system provides certainty as to the notification of all anticipated and actual shortages on **www.drugshortages.ca** and the coordination of information sharing and response, while still allowing for a flexible approach based on the scope and severity of the circumstances.

2. Scope

The Protocol addresses anticipated or actual shortages of human pharmaceutical and biological drugs authorized for sale and marketed in Canada, including public and private market vaccines. The scope is consistent with the definition of drug shortages provided above, and committed to by industry associations, for the purpose of posting on **www.drugshortages.ca.**

The tiered requirements set out here apply equally to **drug discontinuances**, providing stakeholders with the earliest possible information on all manufacturing disruptions that might lead to shortages or otherwise affect the availability of drugs and negatively impact patient care. It is expected that manufacturers will provide six months advance notification of discontinuances on **www.drugshortages.ca**.

The Protocol sets out agreed principles and approaches to the notification and communication of information amongst key stakeholders across the drug supply chain. The measures each stakeholder can apply in preventing, mitigating or managing drug shortages, consistent with their respective responsibilities, are set out in the *MSSC Toolkit.*

While establishing essential notification and communication requirements, the Protocol does not otherwise alter, replace or affect the responsibilities of identified stakeholders to address specific drug shortages, nor the development of similar response protocols (e.g., local or regional response protocols, front line processes, publicly managed vaccine procurement, etc.).

Key players spanning the drug supply chain support the Protocol: manufacturers, wholesalers, distributors, contractors, regional/local health authorities, provinces/territories, hospitals, pharmacies, health care professionals,and the federal government.

3. Principles

- ***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, on **www.drugshortages.ca,** at the earliest possible date, 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)

4. Outcomes

The goal of the Protocol is to enhance notification and communication amongst key stakeholders and jurisdictions to prevent or minimize the negative impacts of drug shortages on patients.

Specifically:

- 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

5. Stakeholders

The Protocol establishes requirements for the notification and communication of drug shortage information amongst the following stakeholders:[4]

- Manufacturers
- Group Purchasing Organisation (GPOs)
- Wholesalers and Distributors
- Community Pharmacists and other Healthcare Professionals
- Regional/Local Health Authorities (RHAs) and Hospitals
- Provincial/Territorial Health Ministries
- Provincial/Territorial Drug Shortages Task Team
- Federal Drug Plans[5]
- Federal Health Portfolio (Health Canada and the Public Health Agency of Canada)

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[4] See Appendix A.
See *MSSC Multi-Stakeholder Toolkit* for detailed information on stakeholder responsibilities and tools.
[5] The Government of Canada, through various programs, provides drug coverage for over one million Canadians who are members of eligible groups, including: First Nations and Inuit; members of the military; veterans; members of the RCMP; eligible refugees; and inmates in federal penitentiaries.

6. Tiered Notification and Communication

The *Tiered Notification and Communication Framework* (figure 1) provides a flexible structure for the notification and communication of drug shortage information, depending on the characteristics of a drug shortage. Further details on the use of relevant tools and strategies to prevent, mitigate or manage a shortage are set out in the accompanying *MSSC Toolkit*.

Each Tier clearly identifies the stakeholders responsible and/or involved in coordinating the notification and communication of anticipated or actual drug shortages. Guidance on communicating key drug shortage related information is provided in Appendix B.

The timely, reliable and comprehensive notification of all anticipated and actual shortages by manufacturers on **www.drugshortages.ca** is essential in ensuring coordinated, timely and appropriate responses to drug shortages; it is the necessary foundation upon which all three notification and communication tiers are built.

In the event that any party becomes aware of information or events that might forecast or lead to a potential shortage, they are encouraged to proactively communicate with other relevant stakeholders for the purpose of preventing and mitigating any potential shortage and associated impacts.

Tier 1 sets the notification and communication requirements for all **anticipated drug shortages**. Anticipated shortages are those of which a manufacturer or importer expects that future supply may not meet projected demand. Tier 1 emphasizes the earliest notification and communication of anticipated drug shortages that might impact the drug supply chain, and ultimately, patient care. It is expected that manufacturers will favour advance notification and communication of information in those circumstances in which a degree of uncertainty remains as to the potential for, or possible duration of a shortage.

- Manufacturers post comprehensive information on **www.drugshortages.ca** as soon as an anticipated shortage is identified.

- 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.

In the case of publicly funded vaccines, manufacturers will work with the Vaccine Supply Working Group (VSWG), supported administratively by the Public Health Agency of Canada and inclusive of all jurisdictions, to determine when an anticipated shortage would merit posting on **www.drugshortages.ca**.

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 update or post comprehensive information on **www.drugshortages.ca** as soon as a shortage is confirmed or identified.

- 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.

Confirmed shortages of publicly funded vaccines will be posted on **www.drugshortages.ca**.

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. It is expected that the vast majority of Tier 3 shortages will have first been posted as anticipated Tier 1 shortages.

- Manufacturers update or post comprehensive information on **www.drugshortages.ca** as soon as shortage is confirmed or identified.

- 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.

Confirmed shortages of publicly funded vaccines will be posted on **www.drugshortages.ca**.

Regardless of tier, for all drug shortages, anticipated and actual, it is expected that all shortages will be posted on **www.drugshortages.ca**, and that all stakeholders will communicate in a transparent, timely, and comprehensive manner to ensure the best results for the Canadian drug supply and health care systems, and affected patients.

Figure 1 – Tiered Notification and Communication Framework

It essential that all drug shortages are posted on **www.drugshortages.ca** as soon as they are first anticipated or known to occur, and that information is shared amongst stakeholders in as open, timely and comprehensive manner as possible. The *Tiered Notification and Communication Framework* (figure 1) provides a flexible structure for the notification and communication of information, to be tailored to the specific characteristics of each drug shortage.

Tier 1: ANTICIPATED Drug Shortages

Manufacturer(s) will:

- Post up-to-date, comprehensive drug shortage details to www.drugshortages.ca
- In addition:
  - Collaborate with stakeholders across supply chain and validate comprehensive drug shortage details
  - Provide early notice to stakeholders to emerging shortages of concern

P/T Health Ministries, Regional Health Authorities, Hospitals, and Federal Drug Plans:

- Confirm/assess shortage specifics in consultation with relevant stakeholders including hospitals pharmacies, manufacturers, GPOs, distributors and wholesalers
- Provide regular and ongoing communication of shortage details to local healthcare delivery stakeholders

GPOs, Distributors, Wholesalers, Community Pharmacies and Healthcare Professionals:

- Collaborate with stakeholders across supply chain to share and confirm comprehensive drug shortage details by monitoring stock levels and providing regular and ongoing communication of the shortage details at the local, regional, provincial or territorial level

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Tier 2: ACTUAL Drug Shortages

Manufacturer(s) will:

- Post up-to-date, comprehensive drug shortage details to www.drugshortages.ca
- In addition:
  - Collaborate with stakeholders across supply chain and validate comprehensive drug shortage details, including detailed information on mitigation measures, and drug supply, allocation, distribution and return to market dates
  - Provide early notice to stakeholders of emerging shortages of concern
  - Notify P/T Drug Shortage Task Team of all actual drug shortages

P/T Drug Shortage Task Team:

- Coordinate communications with F/P/T Health Ministries, Regional Health Authorities, Federal Drug Plans, and Manufacturers to confirm/assess status and details of shortage (including tier 2 and 3 criteria)
- Notify Health Canada in the event shortage is deemed to meet Tier 3 criteria

Federal Health Portfolio (Health Canada):

- Participate in communications between manufacturers and P/T Drug Shortage Task Team to assess details and status of drug shortage
- Liaise with P/T Drug Shortage Task Team Chair

P/T Health Ministries, Regional Health Authorities, Hospitals, and Federal Drug Plans:

- Confirm/assess shortage specifics in consultation with relevant stakeholders including hospital pharmacies, manufacturers, GPOs, distributors and wholesalers
- Provide regular and ongoing communication of shortage details to local healthcare delivery stakeholders

GPOs, Distributors, Wholesalers, Community Pharmacies and Healthcare Professionals:

- Collaborate with stakeholders across supply chain to share and confirm drug shortage details
- Communicate allocation and distribution information, as needed

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Tier 3: ACTUAL Drug Shortages
With NO AVAILABLE THERAPEUTIC ALTERNATIVES[6] Marketed in Canada

Manufacturer(s) will:

- Post up-to-date, comprehensive drug shortage details to www.drugshortages.ca
- In addition:
  - Collaborate with stakeholders across supply chain and validate comprehensive drug shortage details, including detailed information on mitigation measures, and drug supply, allocation, distribution and return to market dates
  - Provide early notice to stakeholders of emerging shortages of concern
  - Notify P/T Drug Shortage Task Team of all actual drug shortages with no available therapeutic alternative marketed in Canada

P/T Drug Shortage Task Team:

- Coordinate communications with P/T Health Ministries, Regional Health Authorities, Federal Drug Plans, and Manufacturers to confirm/assess status and details of shortage (including tier 2 and 3 criteria)

Federal Health Portfolio (Health Canada and Public Health Agency of Canada):

- Coordinate communications between manufacturers and P/T Drug Shortage Task Team to confirm/assess details and status of drug shortage, and identification of collaborative mitigation strategies
- Provide regular and ongoing updates to P/T Drug Shortage Task Team Chair

P/T Health Ministries, Regional Health Authorities, Hospitals, and Federal Drug Plans:

- Confirm/assess shortage specifics in consultation with relevant stakeholders including hospital pharmacies, manufacturers, GPOs, distributors and wholesalers
- Provide regular and ongoing communication of shortage details to local healthcare delivery stakeholders

GPOs, Distributors, Wholesalers, Community Pharmacies and Healthcare Professionals:

- Collaborate with stakeholders across supply chain to share and confirm drug shortage details
- Communicate allocation and distribution information, as needed

[6] **Therapeutic Alternatives:** Medicinal products containing the same active ingredients or different active ingredients but which are of the same pharmacological class, and which have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses. Information on available therapeutic alternatives will be made available through www.drugshortages.ca.

Appendix A –MSSC Membership List (as of September 2013)

Organization	Representative
Industry Associations	
Canada's Research-Based Pharmaceutical Companies	Jared Rhines, Vice President, Scientific and Strategic Affairs
Canadian Generic Pharmaceutical Association	Jim Keon, President
Health*PRO*	Kathy Boyle, Vice-President, Pharmacy Services
MEDBUY	Ann Kelterborn, Director, Strategic Sourcing & Member Services – Pharmacy
BIOTECanada	Jon Flemming , Vice President, Industry Affairs
Canadian Association of Chain Drug Stores	Justin Bates, Vice President, Pharmacy Affairs
Canadian Association for Pharmacy Distribution Management	Terri Power, Vice President of Industry and Member Relations
Health Care Professional Associations	
Canadian Pharmacists Association	Jeff Morrison, Director, Government Relations and Public Affairs
Canadian Society of Hospital Pharmacists	Myrella Roy, Executive Director
Canadian Medical Association	Lucie Boileau, Senior Advisor, Communications and Public Outreach
Provinces/Territories	
Alberta Health	John Cabral, A/ Assistant Deputy Minister, Alberta Health, Health Benefits and Compliance **(co-chair)**
Federal Health Portfolio	
Health Canada	Kathryn McDade, Assistant Deputy Minister, Health Products and Food Branch **(co-chair)**
Other	
Canada's Agency for Drug and Technologies in Health	Chander Sehgal, Director, Common Drug Review and Optimal Use of Drugs

Appendix B – Guidance Document:
Information Guide for Drug Shortage Notification and Communication

Purpose: *In addition to notification on* **www.drugshortages.ca**, *key information/considerations to notify and inform stakeholders of an anticipated or actual shortage, and to facilitate appropriate multi-stakeholder response.*

1. Drug Product Information

- Drug Identification Number (DIN)
- Trade name
- Established, proper, or generic name
- Name and address of manufacturer
- Product indications
- Drug strength/concentrations
- Dosage form
- Package size

2. Cause of Shortage

Examples:

- problem with manufacture or sourcing of Active Pharmaceutical Ingredients (API)
- manufacturing problem or issue (whether here or abroad)
- unexpected increase in demand for a specific drug
- constraints associated with inventory management strategies
- drug discontinuances
- regulatory delays in manufacturing site and/or health product approvals

3. Supply Gap

- Quantitative impact on the supply to the Canadian market (e.g., 25% of total supply to the Canadian market)
- Known therapeutic alternatives, availability, suppliers, etc.
- Related shortages (ex. other manufacturers on back order or other medications within same therapeutic class in shortage)
- Allocation measures, if known

4. Duration of shortage

- Start date of shortage, anticipated or actual
- Projected duration of supply shortfall (estimated resupply dates)
  - *Note: does not include consideration of inventory supply in the drug supply chain;*

5. Geographic Scope of Shortage

- List the regions, provinces, territories, and countries affected by shortage

6. Impact (Medical Necessity)

- Information on how/if the drug in question is used to prevent, treat or diagnose a serious or life-threatening disease or medical condition[7]
- Potential implications of shortage on patient care and safety
  - *Note: Best determined by a qualified health care professional*

7. Supply

- Name and contact information of supplier
- Is the drug (or API) sole supplied?
  - *Note: supply is considered to be sole source if it constitutes more than 50% of the Canadian market (based on available market data)*

8. Alternatives

- Indicate alternative therapeutic products marketed in Canada
- Indicate alternative therapeutic products marketed in other countries
- Indicate alternative management strategies
  - *Note: Best determined by a qualified health care professional*
- Therapeutic alternative information source

[7] A "serious" disease or medical condition may be determined by factors such as survival, day-to-day functioning or the likelihood that the disease/condition, if left untreated, will progress from a less severe condition to a more serious one should all taken into account. 'Serious' conditions are generally associated with morbidity with a substantial impact on day-to-day functioning. Reversible persistent or recurrent morbidity outcomes may also be sufficient to qualify for consideration. Alternatively, examples of insufficient morbidity would normally include short-lived and self-limiting morbidity. Examples of serious conditions include, but are not limited to: HIV/AIDS, Alzheimer's Dementia, Amyotrophic Lateral Sclerosis (ALS), Angina Pectoris, Heart Failure, Cancer, and other diseases that are clearly serious in their full manifestations.