Canada’s Multi-Stakeholder Approach to Drug Shortages

Health Canada Presentation to the Canadian Agency For Drugs And Technologies In Health
April X, 2017
Overview

• Context

• A Collaborative Multi-Stakeholder Approach

• Role of Health Canada

• Mandatory Reporting

• Moving Forward
Drug shortages are a complex, national and global problem that have become a serious, ongoing issue for Canada’s health care system.

Drug shortages have most commonly been linked to manufacturing related problems, such as production or Good Management Practices (GMP) issues, unexpected surges in demand or difficulties obtaining raw materials.

Some shortages can pose risks to the health and safety of Canadians, including compromised or delayed medical procedures, medication errors and substitutions with alternative treatments that are not as safe or effective.
A Collaborative Multi-Stakeholder Approach

- Addressing drug shortages requires collaborative action from all stakeholders in the health care system, including provinces and territories, manufacturers, distributors, practitioners, healthcare institutions, patients and the federal government.

- Launched in 2012, the Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) plays a lead role in advancing policy and tools in support of these efforts.

- Co-chaired by Health Canada and alternating provincial Ministries of Health (currently Manitoba), the MSSC brings together key stakeholders from across the drug supply chain (see Annex A for a full list of members). Its activities are focused along three integrated pillars:
A Collaborative Multi-Stakeholder Approach: MSSC (Cont.)

- Significant progress has been made through the MSSC on drug shortage communication, mitigation and coordinated crisis management.
  - Developed guidance and tools to support stakeholder efforts across the drug supply chain, such as the *Multi-Stakeholder Toolkit* and *Guidance Document to Mitigate Drug Shortages through Contracting and Procurement*.
  - Enhanced coordination and collaboration between stakeholders to address critical national shortages.

- Recent MSSC activities focussed on addressing causes and prevention of drug shortages.
  - Established a dedicated working group to examine the underlying causes of drug shortages and advance best practices and preventative measures.
  - Published *Preventing Drug Shortages: Identifying Risks and Strategies to Address Manufacturing-Related Drug Shortages in Canada* (Prevention Report).
In 2013, the MSSC developed the Protocol for the Notification and Communication of Drug Shortages (Protocol), which sets out a tiered process for notifying and communicating drug shortages. It is premised on the early notification of drug shortages or discontinuations by manufacturers/importers and was updated in 2017 in response to the introduction of the regulations on mandatory drug shortage and discontinuation reporting by the Government of Canada.
The Role of Health Canada

• During an actual shortage, Health Canada collaborates with key stakeholders to determine the details and status of the shortage, coordinate information sharing and identify mitigation. Health Canada assumes a lead role in coordinating communications for these activities in Tier 3 shortages.

• As the federal regulator, Health Canada works closely with industry to ensure that all new supplies of needed drugs are safe, effective and high quality. It has a number of tools and strategies to assist companies in minimizing the impact of supply disruptions.
  – When applicable, employs regulatory tools to address critical shortages, including expedited review processes, Special Access Programme.
  – Works with manufacturers to identify alternate suppliers, changes in manufacturing processes or changes in manufacturing locations, if required.
  – Engages international counterparts to identify additional sources of supply and share needed safety and quality information.

• As part of its regulatory responsibilities, Health Canada is responsible for compliance and enforcement activities in order to verify that the mandatory reporting requirements are being applied appropriately.
Mandatory Reporting

• Early notification of potential disruption in product supply is an important tool to effectively mitigate drug shortages.

• Although reporting alone cannot deal with root causes, such as manufacturing issues or business decisions, timely and reliable information allows the healthcare system to respond more quickly and minimize the impact of potential drug supply disruptions.

• Making public reporting of drug shortages and discontinuances mandatory builds on collaborative steps Health Canada has taken in recent years to help mitigate and prevent shortages and manage discontinuations.
### Mandatory Reporting (Cont.)

<table>
<thead>
<tr>
<th>Date</th>
<th>Events</th>
</tr>
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<tbody>
<tr>
<td>Since 2012</td>
<td>• Drug shortages have been voluntarily reported to an industry-administered site (<a href="http://www.drugshortages.ca">www.drugshortages.ca</a>)</td>
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<tr>
<td>June 2012</td>
<td>• Standing Committee on Health Canada to work with stakeholders to better anticipate, mitigate, and manage drug shortages</td>
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<td>May 2014</td>
<td>• Extensive consultations with stakeholders on the voluntary notification system</td>
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<td>June 2015</td>
<td>• Minister announced the regulatory proposal for mandatory drug shortage reporting</td>
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<td>June 2016</td>
<td>• Final regulations were posted in Canada Gazette, Part II</td>
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<td>March 2017</td>
<td>• Regulations came into force and launch of a new third-party reporting website and mobile application, DrugShortagesCanada.ca</td>
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Mandatory Reporting (Cont.)

- Drug manufacturers are now required to report on DrugShortagesCanada.ca:
  - an anticipated drug shortage six months in advance;
  - a planned discontinuation of a drug six months in advance; and
  - any unanticipated shortage or discontinuation within five days of learning about it, if less than 6 months in advance.

- To date, over 1,271 shortage/discontinuance reports have been published (1140 shortage and 131 discontinuation) by 45 market authorization holders (MAHs).

- Moreover, approximately 180 accounts were created for MAHs and 146 accounts were created for public users.

- Approximately 50 inquiries were received (e.g., clarification on regulatory scope, assistance with user account creation and 7 inquiries related to potential non-compliance (e.g., unreported shortage)
Drug Shortages Website

• DrugShortagesCanada.ca includes a number of system enhancements, including:
  o mandatory fields for industry reporting;
  o advanced search features;
  o a free mobile application that is compatible with iOS (Apple) and Android phones;
  o the option to receive customisable notifications by email and the mobile app. Users can choose to receive notifications for all new or updated records, and/or for a specific product, company or ingredient; and
  o the ability for users to download data subsets using third-party software.

• DrugShortagesCanada.ca continues to grow and evolve. Improvements and enhancements will be considered and prioritized based on feedback from all stakeholders.
Homepage

- Website is available in both official languages
- Most recently updated shortage reports and discontinuation reports appear on the homepage
Search Page

- Search by keyword and/or by selecting pre-defined filters

- Viewing results:
  1. Brief line listing
  2. By brand name, company, or active ingredient
  3. Report details
  4. Save results in Excel
Notifications

- Customized user notifications
- Daily notifications

"Public User1" - User

Saved searches

- Stop receiving notifications for all drugs
- Notifications Editing tools

Followed notifications

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Last notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-FLUOXETINE</td>
<td>Drug</td>
<td>- - -</td>
</tr>
<tr>
<td>AMLODIPINE (AMLODIPINE BESY...</td>
<td>Active Ingredient</td>
<td>- - -</td>
</tr>
<tr>
<td>SANDOZ CANADA INCORPORATED</td>
<td>Company Name</td>
<td>- - -</td>
</tr>
</tbody>
</table>
Mobile phone application

- Data feeds are the same as website
- Follow and receive notifications
Moving Forward

- Continue engagement of stakeholders and MSSC members for feedback on possible improvements to the website.

- Planning of future releases will begin post-launch, this includes: addressing any new bugs/fixes, enhancements or improvements, and/or new features within limits of the existing contract with the developer.

- The MSSC is currently updating tools to better incorporate the perspective of patient group stakeholders.

- At their Fall meeting, the MSSC will hold a way forward discussion to identify future initiatives.

- Health Canada will continue to evaluate our collaborative approach and work with stakeholders to identify opportunities to make it work even better.
Annex A: MSSC Membership

- Health Canada
- Provinces and Territories, via Manitoba Health, Seniors and Active Living Canadian Pharmacists Association (CPhA)
- Canadian Society of Hospital Pharmacists (CSHP)
- Canadian Medical Association (CMA)
- Canada's Research-Based Pharmaceutical Companies (Rx&D)
- Canadian Generic Pharmaceutical Association (CGPA)
- BIOTECanada
- Canadian Association for Pharmacy Distribution (CAPDM)
- Neighbourhood Pharmacy Association of Canada
- HealthPRO
- MEDBUY
- Canadian Agency For Drugs And Technologies In Health (CADTH)
- HealthCareCAN
- Best Medicines Coalition (BMC)
Annex B: Useful References

- MSSC Documentation:
  - Protocol for the Notification and Communication of Drug Shortages
  - Guidance Document to Mitigate Drug Shortages through Contracting and Procurement
  - MSSC Multi-Stakeholder Toolkit
  - Preventing Drug Shortages: Identifying Risks and Strategies to Address Manufacturing-Related Drug Shortages in Canada

- Canadian Drug Storage Database: www.drugshortagescanada.ca

- Health Canada Guide to reporting drug shortages and discontinuations