Drug Shortages – The Ongoing Saga

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Outline

1. Scope of medication shortages in Canada
2. Causes of medication shortages
3. Impact of medication shortages
4. Canadian endeavours to address the situation
5. Available resources to deal with medication shortages
Scope of Medication Shortages
CPhA Survey

(http://www.pharmacists.ca/content/About_CPHA/Whats_Happening/CPhA_in_the_News/CPhADrugShortagesReport_Dec2010.pdf)

- Conducted in October 2010
- Responses: 427 members
- Results released in December 2010
- Difficulty locating a medication during their last shift: 81% of respondents
  (median number of prescriptions = 3)
- Difficulty locating a medication during last week: 94% of respondents
  (median number of prescriptions = 10)
CMA Survey

(http://www.cma.ca/shortages-generic-drugs)

- Conducted in January 2011
- Responses: 743 members
- Shortage encountered in the past year: 74% of respondents

- Descriptive retrospective study
  - Drug shortages in relation to all hospital medication supply contracts
  - Administrative regions of Montréal, Laval, and the Eastern Townships in the province of Québec

- Results (over 56 months):
  - Separate instances of inventory shortages = 2400
  - Mean duration = 108 days, range = 5 to 1623 days
  - Manufacturers implicated = 70
    - 4 manufacturers responsible for 50%
Causes of Medication Shortages
Multifactorial and Global

- Globalization of manufacturing
- Mergers and consolidations of manufacturers
- Monopolization of supply (single source)
- Growing international demand
- Manufacturing issues in specific plants
- Lack of active pharmaceutical ingredients
- Regulatory barriers
  (approval of new drugs and notifiable changes)
- Increased number of recalls
- Provincial generic price-capping legislation
- Group purchasing
- “Just-in-time” inventory management
Impact of Medication Shortages

- CPhA Survey:
  - Average amount of time per shift spent dealing with shortages: median of 30 minutes
  - Patients’ health outcomes adversely affected: 70% of respondents
  - Inconvenience to patients: 91% of respondents

- CMA Survey:
  - Implications for their patients and practice: 2/3 of respondents
Impact of Medication Shortages
Medications most commonly affected

- **CPhA Survey:**
  - Antidepressants/neuroleptics (25%)
  - Antibiotics (22%)

- **CMA Survey:**
  - Antibiotics (47%)
  - Antidepressants (24%)
  - Antihypertensives (15%)
  - Cardiovascular medications (10%)

- *Can J Hosp Pharm* 2011;64(6):426-435
  - CNS medications (24%)
  - Anti-infectives (13%)
  - Cardiovascular medications (12%)
Canadian Endeavours to Address the Situation
Barriers

- No system-wide accountability mechanism for the drug supply chain
- Lack of reporting system for supply constraints
- Proprietary information
- No time lines for limited supply

Need to establish Canadian drug supply monitoring system
American Society of Health-System Pharmacists (ASHP) consulted

Highly HR intensive
- University of Utah Drug Information Service
  - Validation of shortages and suggestion of alternatives
  - 2-3 FTEs
- ASHP
  - 1 FTE + IT

Pilot inquiry conducted by ASHP and CSHP to test feasibility of incorporating Canadian data in the center → Failure
- Potential regulatory and legal barriers preventing monitoring to work across the border
- Canadian parties’ and stakeholders’ acquiescence to releasing information on drug shortages in Canada to an American inquirer
Federal Minister of Health’s Action

- Letter to BIOTECanada, Canadian Generic Pharmaceutical Association and Canada’s Research-Based Pharmaceutical Companies in March 2011:
  - Consequently, I would appreciate it if your members would voluntarily provide information on drug shortages.
  - Information would be disclosed upon a set of criteria to be established by key stakeholders, including your organizations and members.
  - In the event this option is not viable, we will consider regulatory alternatives.

- Copy to CPhA, CSHP and provincial/territorial ministers of health
Drug Shortage Working Group

Membership:
- BIOTECanada
- Canada’s Research-Based Pharmaceutical Companies (Rx&D)
- Canadian Association for Pharmacy Distribution Management (CAPDM)
- Canadian Association of Chain Drug Stores (CACDS)
- Canadian Generic Pharmaceutical Association (CGPA)
- Canadian Medical Association (CMA)
- Canadian Pharmacists Association (CPhA)
- Canadian Society of Hospital Pharmacists (CSHP)

Purpose:
- Define shortage
- Possible collaborative actions

First face-to-face meeting on April 18, 2011
CSHP/CPhA Survey on Drug Shortage Monitoring System

- Conducted in June 2011
- Similar survey by CMA
- Responses: 837 members
  - 40% hospital pharmacists
- Important information (> 50% of respondents rating as “very important” or “important”):
  - Products affected including generic & brand name, manufacturer, formulation, strength, package size
  - Expected duration of the shortage
  - Suggested therapeutic alternatives
  - Dates information updated
  - Notification that the shortage is resolved
CSHP/CPhA Survey on Drug Shortage Monitoring System

- Notification of shortages:
  - Never: 16% of respondents
  - Infrequently: 36% of respondents
  - Sometimes: 32% of respondents

- Notification of shortages by:
  - Wholesaler: 46% of respondents
  - Manufacturer: 30% of respondents

- Bearing on ability to deliver care to patients from greater knowledge about the availability of a particular drug:
  - 91% of respondents
CSHP/CPhA Survey on Drug Shortage Monitoring System

- Frequency of consultation of drug supply monitoring system, if available:
  - Each shift: 22% of respondents
  - 3-5 times/week: 35% of respondents

- Identification of therapeutic alternatives:
  - Personal investigation: 84% of respondents
  - Consultation of colleagues: 54% of respondents
Follow-up letter from Minister Aglukkaq to BIOTECanada, CGPA, Rx&D, CMA, CPhA and CSHP in August 2011

- “... an effective plan must include an agreed to standard for notifications of drug shortages to health professionals that is timely, accurate and comprehensive.
- Should the proposed plan fall short on any of these elements, Health Canada is prepared to proceed with a regulatory proposal for the mandatory disclosure of shortage information.
- ... I would also encourage you to consider measures to help reduce drug shortages.
- ... ask that you contact Mr. Paul Glover, ADM of Health, so he may participate in and monitor the progress of the dialogue...”
Drug Shortage Monitoring System
Short-term solution

- CGPA and Rx&D:
  ◦ Collect information from their member companies about actual and impending drug shortages
- Saskatchewan Drug Information Services and Pharmacy Practice Research Unit at the Centre hospitalier universitaire Sainte-Justine on behalf of SigmaSanté (the health care group purchasing organization for the Montréal and Laval regions in Québec):
  ◦ Post the details on their public drug shortage websites
- Launched in December 2011
Drug Shortage Monitoring System
Long-term solution

- Single, more robust national system, with a greater scope of attributes:
  - Functionality for individual reporting of suspected shortages
  - Minimum information for each drug listed:
    - generic & brand names
    - manufacturer
    - dosage form
    - strength
    - package size
    - classification as a single or multi-source product
    - reason for shortage
    - expected resupply date
    - date of shortage resolution
    - therapeutic alternatives
    - revision date of record
  - Electronic notifications of new shortages or revisions
- Bilingual
- Publicly available
- Free of charge to users
- Information available for analysis or research purposes
- Shortages to be validated by the manufacturer if reported by anyone else
- To be launched by end of 2012
February 15, 2012: Notice from Sandoz Canada about temporary suspending the production of injectable products

- Hospital pharmacists on high alert
- Provincial Ministries of Health coordinating the management of the situation
- Commitment from Health Canada to expedite approvals for products from alternate suppliers
- Numerous media interviews
Recent Developments

- March 2, 2012: Launch of CSHP Drug Shortage eForum
- March 7, 2012: Letter to Federal Minister of Health to request a meeting
- March 12, 2012: Commitment of $100,000 from each of Rx&D and CGPA toward drug shortage monitoring system
- March 27-April 3, 2012: Hearings by House of Commons Standing Committee on Health
Available Resources

- American Society of Health-System Pharmacists: [http://www.ashp.org/shortages](http://www.ashp.org/shortages)
- Canada’s Research-Based Pharmaceutical Companies: [http://www.canadapharma.org/shortage/overview.asp](http://www.canadapharma.org/shortage/overview.asp)
Available Resources

- Canadian Society of Hospital Pharmacists: [http://www.cshp.ca/advocacy/CSHPspeaks/drugShortages_e.asp](http://www.cshp.ca/advocacy/CSHPspeaks/drugShortages_e.asp)
- Pharmacy Practice Research Unit at the Centre hospitalier universitaire Sainte-Justine, SigmaSanté:
  - [www.fridaypm.ca](http://www.fridaypm.ca)
  - [www.vendredipm.ca](http://www.vendredipm.ca)
- Saskatchewan Drug Information Services: [www.druginfo.usask.ca/healthcare_professional/canadian_drug_shortages.php](http://www.druginfo.usask.ca/healthcare_professional/canadian_drug_shortages.php)