Drug Shortages – The Ongoing Saga

Myrella Roy, BScPhm, PharmD, FCCP
Executive Director
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)
Average amount of time per shift spent dealing with shortages: median of 30 minutes
CPhA Survey

- Notification of shortages:
  - Never or infrequently: 63% of respondents

- Notification of shortages by:
  - Wholesaler: 29% of respondents
  - Manufacturer: 16% of respondents

- Patients’ health outcomes adversely affected:
  - 70% of respondents
  - Anguish to patients
  - Disruption in continuity of care
  - Alternatives: none available, less effective, more toxic
  - Reduced adherence

- Inconvenience to patients: 91% of respondents
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
- Implications for their patients and practice: 2/3 of respondents
Triggered by CPhA survey report in December 2010

- Globe and Mail
- CBC (CSHP – [http://www.cshp.ca/advocacy/CSHPnews/index_e.asp](http://www.cshp.ca/advocacy/CSHPnews/index_e.asp))
- National Post
- Radio Canada
- CTV
- Over 30 other media outlets
Political Attention

- Meeting between federal Minister of Health and CPhA in January 2011
- Question on shortages from Jack Layton to the Minister in the House of Commons in February 2011
- CADTH charged with conducting environmental scan on drug supply disruptions (causes and impact)
Causes
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
Additional Barriers

- No system-wide accountability mechanism for the drug supply chain
- Lack of reporting structure for supply constraints
- Proprietary information
- No timelines for limited supply
Healthcare Associations’ Endeavours

- CSHP contacted by Canadian Anesthesiologists' Society (CAS) as early as October 2010 to consider partnership
- Coalition of stakeholder organizations formed in February 2011:
  - Led by CPhA
  - Best Medicines Coalition
  - CAS
  - CACDS
  - CMA
  - CSHP
  - Sask College of Pharmacists
- Purpose:
  1. Share information and initiatives unique to each organization
  2. Gauge level of interest in working more collaboratively
  3. Discuss joint tactics/strategies/initiatives
- Coalition agreed to establishment of drug supply monitoring system
ASHP Drug Product Shortages Management Resource Center

- ASHP consulted +++
- Highly HR intensive
  - University of Utah Drug Information Service
    - Validation of shortages and suggestion of alternatives
    - Small grant from Novation (GPO)
    - 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, CGPA and Rx&D 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

- Hearings on drug shortages by Standing Committee on Health scheduled for March 31, 2011
  - Cancelled as a result of federal election
Drug Shortages Working Group

- **Membership:**
  - Led by CGPA
  - BIOTECanada
  - CACDS
  - CAPDM
  - CMA
  - CPhA
  - Rx&D

- **Purpose:**
  - Define shortages
  - Possible collaborative actions

- First face-to-face meeting on April 18, 2011
Second Wave of Media Attention

- CSHP interviewed by:
  - Vancouver Sun about drug shortages in Canada on May 4, 2011
  - CBC TV about shortages of antineoplastic agents on May 6, 2011
  - CMAJ about shortages of antineoplastic agents on May 17, 2011

- [http://www.cshp.ca/advocacy/CSHPnews/index_e.asp](http://www.cshp.ca/advocacy/CSHPnews/index_e.asp)
CSHP/CPhA Survey on Drug Supply 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 Supply 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 Supply 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
Second face-to-face meeting on June 29, 2011

Agenda:
◦ Results of CSHP/CPhA survey and CMA survey
◦ Definition of “shortage”: report from sub-group
◦ Hosting options for drug supply monitoring system
  ➢ Preference for existing system
Third Wave of Media Attention

- Health Canada MedEffect e-Notice to Hospitals,
  - Potential supply shortage of certain injectable and inhalational sterile drugs imported from the contract manufacturer Ben Venue Laboratories Inc. located in Bedford, Ohio, US
- CSHP interviewed by:
  - Globe and Mail
  - CBC
  - Radio-Canada
- [http://www.cshp.ca/advocacy/CSHPnews/index_e.asp](http://www.cshp.ca/advocacy/CSHPnews/index_e.asp)
Latest Political Developments

- Shortages raised by Minister Aglukkaq in her address at CMA’s Annual Meeting in August 2011
- 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.”
- Standing Committee on Health requested to reschedule hearings on drug shortages
Drug Shortages Working Group

- Third face-to-face meeting on September 14, 2011
- Agenda:
  - Evaluation of existing drug supply monitoring system
  - Key elements of national drug supply monitoring system
  - Response to Minister of Health
Next Steps

- Sept. 29, 2011:
  - Next face-to-face meeting of the Working Group
  - Paul Glover, Health Canada ADM invited
- Response to Minister being drafted
- Drug supply monitoring system:
  - Short-term solution: partnership with existing system
  - Mid-term solution
In August, Premiere Healthcare Alliance in the US released a report into the “grey market” for pharmaceuticals. The report revealed significant price gouging for drugs in short supply – average was 650% higher, some reports of prices 1000% and 2000% higher. Two American Senators reported that the US Senate has created a bipartisan committee to look into drug shortages / grey market. No similar reports in Canada as of yet – something to remain aware of.