

PUBLIC CONSULTATION ON DRUG SHORTAGES

Many people's first introduction to drug shortages is hearing their pharmacist say "your medication isn't available". This shocking news comes out of the blue with little time to seek solutions. Suddenly switching treatments is not advisable for people with epilepsy. Drug changes should be made gradually and preferably not at all if a medication is working well to control seizures. Drug shortages have put people in the untenable situation where they have had no choice but to suddenly switch to a different drug.

Health Canada is holding a [public consultation on the current approach to drug shortages](#) from May 22 to July 5, 2014. The Canadian Epilepsy Alliance encourages everyone concerned about drug shortages to participate.

Over the past five years there have been an increased number of drug shortages in Canada, including multiple shortages of epilepsy medications. There is no indication that the situation is improving. If nothing is done to identify and address the causes of drug shortages we expect to see a greater frequency of supply disruptions in the coming years.

The Canadian response to the growing number of drug shortages has primarily focused on the development of an industry-run, voluntary notification website launched in March 2012. The current approach in Canada is that ***early notification is requested to allow opportunity for the healthcare system to react to the shortage.***

Even though a website has been established where pharmaceutical companies can voluntarily report shortages, the reality more than two years after the launch of drugshortages.ca is that most people still learn about a drug shortage when they need their prescription refilled and the drug is not available. Often patients are still the first to inform health care providers about a drug shortage. People are still scrambling to try and find solutions, and in most cases are still just as baffled as to the cause.

The posting of a drug shortage notice on a website should not be the beginning and the end drug shortage management in Canada. The approach needs to change from the current thinking that notification on a website provides a head's up for the health care system to react to the view that ***early notification is required as part of a comprehensive drug shortage prevention and management strategy.***

1. **PREVENTION** – The main focus should be on the problem and not the symptoms. All efforts must be made to identify and address the causes of drug shortages.
2. **MANAGEMENT** – There must be effective strategies to manage anticipated and actual drug shortages. Mandatory early notification should be an important component of a comprehensive and coordinated response.

Improvement is needed in **all** aspects of drug shortage prevention and management. Many Canadians, including people with epilepsy, require a consistent supply of their prescription medication. People should be able to focus on living well with their condition and should not have to worry about the supply of their drug.

Health Canada Public Consultation on the Notification of Drug Shortages May 22 – July 5, 2014

Who can participate in the public consultation?

The public consultation on drug shortages is open to anyone who would like to participate. If you are concerned about drug shortages, this is your chance to share your opinion with the Government of Canada.

Estimated time to complete the consultation:

Health Canada estimates it will take about ten to twenty (10 to 20) minutes to complete the consultation.

The Canadian Epilepsy Alliance expects it will take longer than the estimated time to read through the information and answer the questions. The consultation does not have to be completed all at once. People who are interested in participating can complete the consultation at their own pace.

There are a total of nine (9) questions. Some questions simply require a “yes” or “no” answer. Some questions ask for a short written response (maximum 250 words, less than 1 page).

Different ways to participate in the public consultation:

A. Complete the consultation online

Go to the public consultation information page and click on the “PARTICIPATE NOW” button to answer the questions online.

English: www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_shortages-penuries-eng.php

French: www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_shortages-penuries-fra.php

You can stop at any point while you are doing the online consultation and finish it later:

Click on the “Save and continue later” button

Email the link to your email address OR Bookmark the link

B. Download a copy of the consultation document to your computer and send your responses by email or regular mail

Link to PDF version of the consultation: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/consultation/drug-medic/ds-consult-public-publique-eng.pdf

Once you have answered the questions your saved file can be sent by email OR the file can be printed and sent by Canada Post:

Email: ds_pmconsultation@hc-sc.gc.ca

Mail:

Attention: Drug Shortage Consultations

Strategic Horizontal Policy Division

Health Products and Food Branch, Health Canada

250 Lanark Ave, 4th Floor, Address Locator: 2004D

Ottawa, ON, K1A 0K9

Summary of the Canadian Epilepsy Alliance Perspective

The questions asked in the public consultation are listed on the following pages along with information pertaining to epilepsy and the Canadian Epilepsy Alliance's perspective on drug shortages.

Please Note: This is not the official consultation document

To participate in the consultation go to the Health Canada website:

www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_shortages-penuries-eng.php

In this summary, comments from the Canadian Epilepsy Alliance are in **purple text** and may provide some useful background information for people who are interested in participating in the public consultation. The Canadian Epilepsy Alliance encourages everyone to share their personal experiences and their own views on the current approach to drug shortages in Canada.

The Canadian Epilepsy Alliance would also like to hear from you! Please share your thoughts on drug shortages or your experiences with us by contacting your local epilepsy agency 1-866-EPILEPSY (866-374-5377).

Question 1) For the purposes of this consultation, please indicate the type of group you are representing. **Select "Interested Canadian" unless one of the other categories better describes the group you represent for the purpose of this consultation.**

Following question #1 the consultation document provides background information and links to additional information on these topics:

- What are Drug Shortages?
- The Drug Supply Chain
- Working Together to Address Drug Shortages
- What Causes Drug Shortages?
- Drug Shortage Notification in Canada

Question 2a) Prior to this public consultation, had you visited www.drugshortages.ca? **Answer Yes or No**

Question 2b) If yes, how often and what information were you looking for? Were you able to find it/access it? (maximum 250 words)

If yes, some additional information that could be included in your response is:

- **How did you hear about www.drugshortages.ca?**
- **Why did you visit the website?**
- **Was it easy to find the information you were looking for?**
- **Was it easy to understand the information on the website?**
- **Was there any information explaining what you should do?**

Question 3) Prior to this public consultation, were you familiar with the approach to drug shortage notification in Canada? **Answer Yes or No**

Following question #3 the consultation document provides background information on this topic:

- **How Does the Voluntary Approach to Drug Shortage Notification Currently Work in Canada?**

NOTE: The information provided is how the current approach to notification is expected to work, not how it is actually working.

Question 4a) The notification of drug shortages should be timely, reliable and comprehensive. In your experience, is the current system meeting these objectives? **Answer Yes, No, or Not enough knowledge to make an assessment**

Question 4b) If no, please explain how the current system is not meeting these objectives. (maximum 250 words)

If you have personal experience of ways that the current system is either meeting or failing to meet its objectives, provide those examples when you answer the consultation.

Canadian Epilepsy Alliance perspective:

No. The information is not timely, reliable, or comprehensive. We have no confidence in drugshortages.ca as a one-stop shop for information on drug shortages.

- **Lack of reliability**
 - Some shortages are reported and some aren't
 - When a shortage is reported, the estimated resupply dates appear to be the most optimistic not the most realistic
 - The estimated resupply date may be changed multiple times throughout a drug shortage to increasingly later and later dates
 - Updates are not always made when there is a change in the situation
 - No oversight to ensure information is accurate
- **Lack of timeliness**
 - When a shortage is reported, notification is often made after the drug has already become in short supply
- **Lack of comprehensive information**
 - The drugshortages.ca website does not distinguish anticipated shortages from actual shortages
 - The reason for a shortage is rarely given
 - It is difficult to gauge the potential severity of a shortage...will there be an impact on patients?
 - Information to help people manage a drug shortage is not available
 - The status of alternative drug products is not provided
 - There is no indication of whether a response is being made to address the shortage
- **Lack of an effective communication system**
 - Even when reliable information is posted on drugshortages.ca there is no effective mechanism to communicate this out to health care providers, pharmacists and patients

In Canada, drug companies are expected to provide information on all anticipated and actual drug shortages and discontinuances, as soon as the information is available.

Question 5a) Based on your experience, please explain how the current approach to drug shortage and discontinuance notification has/has not provided you with the information you needed to properly respond to drug shortages. (maximum 250 words)

Did you experience a drug shortage, or a potential shortage? Tell your story.

- **How did you learn about the shortage?**
- **Did you have any advance warning?**
- **Did the current approach to drug shortages help you deal with the shortage?**
- **How did the drug shortage affect you and your family?**
 - **How did you feel?**
 - **How did you manage the situation?**
 - **What challenges did you experience?**
 - **Were there any consequences? (eg changes in seizure control, side-effects or other health consequences, safety consequences, effects on independence, effects on employment, financial consequences, stress, etc.)**

Question 5b) Please explain how you have used the information posted on www.drugshortages.ca. (maximum 250 words)

How did you use the information on www.drugshortages.ca? Was it helpful?

Following question #5 the consultation document provides background information on this topic:

- **Public Notification Register for Drug Shortages & Letters of Non-Compliance**

Question 6) Based on your experience with the current approach to drug shortage notification, in what way(s), if any, should the current approach to drug shortage notification be changed? (maximum 250 words)

Canadian Epilepsy Alliance perspective:

The approach needs to change from thinking that voluntary notification on a website is sufficient to the view that early notification is required as part of a comprehensive drug shortage prevention and management strategy with centralized oversight.

1. **PREVENTION** – The main focus should be on the problem, not the symptoms. All efforts must be made to identify and address the causes of drug shortages.
2. **MANAGEMENT** – There must be effective strategies to manage anticipated and actual drug shortages. Mandatory early notification should be an important component of a comprehensive and coordinated response.

Advance warning as soon as a drug manufacturer becomes aware of a potential supply problem provides important lead time for:

- i. government and industry to work together and possibly avert a drug shortage;
- ii. an ethical distribution plan to be put in place;
- iii. all stakeholders to develop back-up plans.

A comprehensive drug shortage prevention and management strategy should include:

- a greater focus on prevention
- earlier notice of anticipated and actual shortages
- greater reliability of drug shortage notifications
- mechanisms to assess the current status across the whole supply chain
- mechanisms to determine where supply problems are impacting patients
- strategies to assist patients affected by a drug shortage
- transparency of any actions being taken to address a drug shortage
- better ways to communicate information to health care providers and patients
- tools to help patients and their families understand and manage a drug shortage.

Following question #6 the consultation document provides background information on this topic:

- What Are Other Countries Doing?

Select which of the following 2 options you support (voluntary notification or mandatory notification) and explain your reasons:

Question 7a) If you support a voluntary approach to drug shortage notification for the Canadian system, please explain your reasons. (maximum 250 words)

Question 7b) If you support a mandatory approach to drug shortage notification for the Canadian system, please explain your reasons. (maximum 250 words)

Canadian Epilepsy Alliance perspective:

The Canadian Epilepsy Alliance supports a mandatory approach to drug shortage notification.

Questions about drug shortages? Contact your local epilepsy agency or call 1-866-EPILEPSY (866-374-5377)

The voluntary approach has been in place for over 2 years and it is not working.

Industry made a commitment on September 28, 2011 to voluntarily provide notification of current and impending drug shortages on a publicly accessible website.

The current notification system is unreliable. There have been multiple failures to provide advance notice of epilepsy drug shortages over the past 2 years.

There have been some widespread shortages of epilepsy medications across multiple drug manufacturers. Some examples are the 2012 divalproex sodium (Epival) shortages; 2013 clobazam (Frisium) shortages; and 2014 clobazam (Frisium) shortages. Some (but not all) companies eventually provided notice, but AFTER people were already experiencing difficulty getting their prescriptions refilled.

There have been shortages of epilepsy medications marketed by a single manufacturer (eg Celontin shortage). There was no notification on drugshortages.ca when Celontin initially became unavailable in 2012. A notification was finally posted in June 2013, months and months after people had experienced difficulty getting prescriptions refilled.

Late notification defeats the whole purpose of an “early warning” system and makes it unlikely that government and industry could work together to try and avoid a shortage situation, or for stakeholders to better manage a shortage situation.

Some companies do not provide notification at all. For example, two companies that market clobazam in Canada have yet to provide any notification on drugshortages.ca even though their products are currently unavailable.

Other companies fail to provide timely updates. For example, one clobazam manufacturer provided an initial notification on drugshortages.ca on Feb. 26th, 2014 that their product was in shortage, even though a customer service representative with their company confirmed on Feb. 12th that the product was on back-order and had been unavailable for awhile. This same product was still unavailable during the first week of June, but the last update on drugshortages.ca gave an estimated resupply date of April 24th. The manufacturer did not make any updates between mid-March and early June to advise people that the product was going to be unavailable for longer than initially expected.

Industry has had over 2 years to demonstrate their ability to provide voluntary notification of drug shortages and they have failed to do so reliably. It is time to move to a mandatory approach and to integrate the notification information with a comprehensive and coordinated drug shortage strategy.

Question 8a) Please indicate for which of the following drug product categories advance notification of shortages and discontinuances should be provided. [Note: Please check all that apply]

- Critical medicines only (drugs determined to be medically necessary and deemed to have the greatest impact on human health)
- All prescription drugs (e.g., heart medications, antibiotics, and anti-anxiety medications)
- All medicines

Canadian Epilepsy Alliance perspective: All prescription drugs

All Question 8b) Please provide any additional comments you may have, if any, on the question above. (maximum 250 words)

Canadian Epilepsy Alliance perspective:

When pharmaceutical companies have been given a license to market a drug, they must also take on the obligation to ensure supply.

If a supply disruption is anticipated, or if the drug is going to be discontinued, this information must be communicated as soon as the drug manufacturer becomes aware of it.

Consistency and continuity of the drug supply is crucial for people with epilepsy:

- Suddenly stopping an anti-seizure drug can worsen or destabilize someone's epilepsy condition.
- Suddenly stopping an anti-seizure drug can cause prolonged and possibly life-threatening seizures.
- Missing even 1 dose of an epilepsy medication can result in a breakthrough seizure.
 - the consequence of a breakthrough seizure can be loss of independence, loss of a driver's licence, loss of a job, injury, accident or death
- Medication changes, if required, should be made gradually.
- Substitution (switching from one supplier to another of the same drug molecule) of epilepsy medications can be problematic as well.
 - Some people with epilepsy have been advised by their health care provider to remain on the same product (ie not to switch brands).
 - In 2013 the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) issued a new [guidance on epilepsy medications](#) and drug substitution. The MHRA recommends either avoiding substitution or using caution for certain types of epilepsy medications because substitution is associated with "definite concerns" or "possible concerns" for Category 1 and 2 anti-seizure drugs respectively.

For these reasons, it is important that early notification is provided for all anticipated shortages of epilepsy medications, even if the same drug “molecule” might be available from another manufacturer.

Question 9) Please provide any additional comments you may have regarding this document or drug shortage notification processes and/or approaches. (maximum 250 words)

Opportunity to provide additional comments.

To participate in Health Canada’s public consultation go to:

English: www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_shortages-penuries-eng.php

French: www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_shortages-penuries-fra.php

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