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# CONSULTING CANADIANS ON DRUG SHORTAGE NOTIFICATION IN CANADA



## WHAT WE HEARD



*This document presents an overview of input received in response to several in-person and online consultations held by Health Canada between May and July 2014. This input does not necessarily reflect the views of the position of the Government of Canada.*

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## Drug Shortages — A Multi-Stakeholder Approach

Drug shortages are a complex, pressing global issue with serious implications for the health and well-being of Canadians.

Addressing drug shortages is a multi-stakeholder responsibility, requiring the coordinated involvement of all players across the drug supply chain.

Since August 2012, the Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) has advanced collaborative work on drug shortages organized under three integrated pillars:

The early notification and communication of drug shortage information is 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.



# Voluntary Drug Shortage Notification in Canada

Drug shortage notification occurs when manufacturers and importers provide information to the public about anticipated or actual drug shortages due to temporary supply disruptions or permanent discontinuances in production. When fulsome information on drug supply disruptions is provided early, it can help the drug supply system and the healthcare system respond appropriately. It can also help patients and health

care practitioners make informed choices about treatment.

In March 2011, the Minister of Health first called for voluntary public notification of shortages by industry. In response to this call, industry established [www.drugshortages.ca](http://www.drugshortages.ca), a publicly available industry website for companies to post information on drug shortages and discontinuances.

Companies are expected to provide advance notification of all anticipated or actual drug shortages and discontinuances of human pharmaceutical and biological drugs authorized for sale and marketed in Canada, including public and private market vaccines on a **voluntary** basis.

Notification of drug shortages by industry on [www.drugshortages.ca](http://www.drugshortages.ca) is encouraged by the Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) as outlined in the **Protocol for the Notification and Communication of Drug Shortages**.

The MSSC, launched by Health Canada and the Province of Alberta in August 2012, brings together federal, provincial and territorial governments, industry, group purchasing organizations, distributors and health professional associations to work together on drug shortages. For more information on the MSSC and on the progress that it has achieved in addressing drug shortages, please visit **Health Canada's Drug Shortages Webpage**.





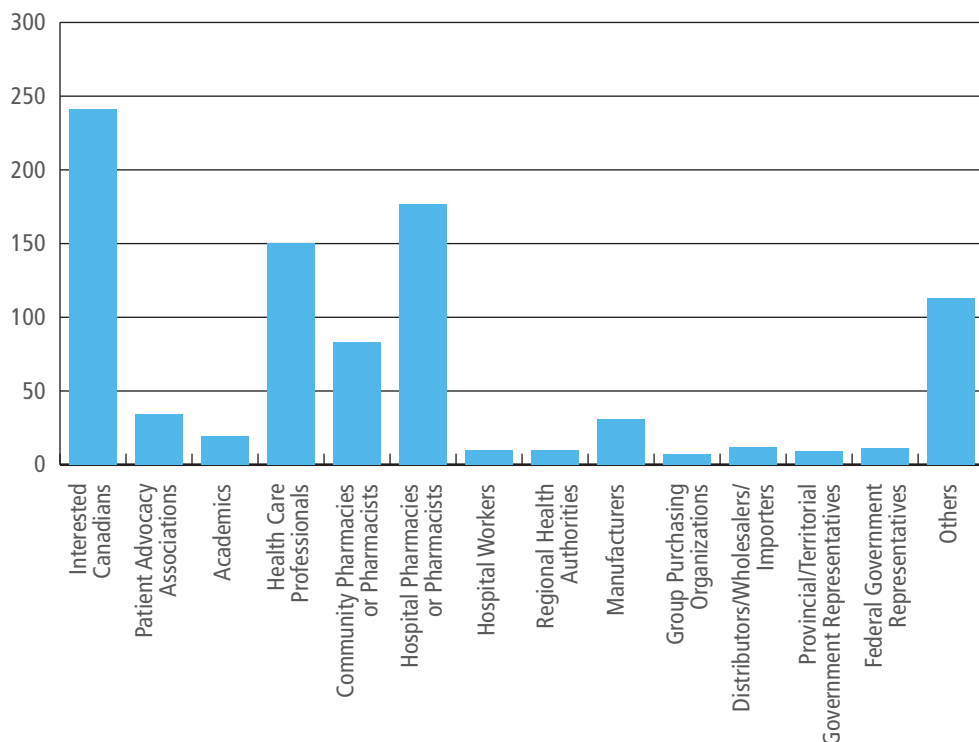
## Consultations on Drug Shortage Notification

From May to July 2014 Health Canada led extensive public consultations on the current voluntary notification system, and on whether a voluntary or mandatory notification approach is necessary for Canadian patients, and those who care for them.

### *Consultations:*

- **Targeted stakeholder consultations** with industry/manufacturers, provinces/territories, patients/advocates, academics, wholesalers, group purchasing organizations, distributors, and health care professionals.
- **Online public consultations** generating over 800 responses from interested Canadians and respondent groups.
- **International consultations** with the US Food and Drug Administration, the Australian Therapeutic Goods Administration, and the European Medicines Agency.

## Online Public Consultation Respondents



The majority of respondents to Health Canada's online consultation identified themselves as interested Canadians (27%), followed by hospital pharmacies or pharmacists (20%) and health care professionals (17%).

Consultations considered the extent to which notification is, or could be more **timely, comprehensive, and reliable** and the extent to which the current voluntary notification system is working for Canadians.

- » **Timely** — manufacturers and importers are expected to provide advance notification of all anticipated drug shortages or discontinuances in order to ensure that patients and the healthcare system have as much time as possible to react;
- » **Comprehensive** — it is expected that the information provided by manufacturers and importers is comprehensive so that patients and other stakeholders have the information they need to make informed decisions to prevent and mitigate shortages;
- » **Reliable** — it is expected that information provided by manufacturers and importers on [www.drugshortages.ca](http://www.drugshortages.ca) is reliable and kept up-to-date so that patients and health care providers can make the best decisions possible.

# WHAT WE HEARD

## *Timely, Comprehensive and Reliable*

It was clearly heard from consultations that the current voluntary approach has many challenges; it is not timely, comprehensive nor reliable, and mandatory drug shortage notification overseen by Health Canada is required.

*Examples of what we heard:*

**TIMELY:** While there is greater transparency in the system and a significant number of manufacturers and importers are posting notices of shortages to the website, it appears that many drug suppliers are providing notification only after a shortage is underway. As a result, patients and their caregivers are not given the warning they require to make timely plans for alternative treatments or medications.

““ *There is no forewarning that an actual drug shortage is imminent, drugs are just suddenly unavailable with unreliable guesses as to when they will become available, if ever again. The system is broken —Community pharmacy/pharmacist* ””

**COMPREHENSIVE:** Since the inception of [www.drugshortages.ca](http://www.drugshortages.ca), industry associations have made efforts to continually improve the quality and comprehensiveness of information, however, information is generally incomplete (ex. no information on the cause of the shortage, therapeutic alternatives or the likely duration), not always kept up to date, and insufficient to support mitigation efforts.

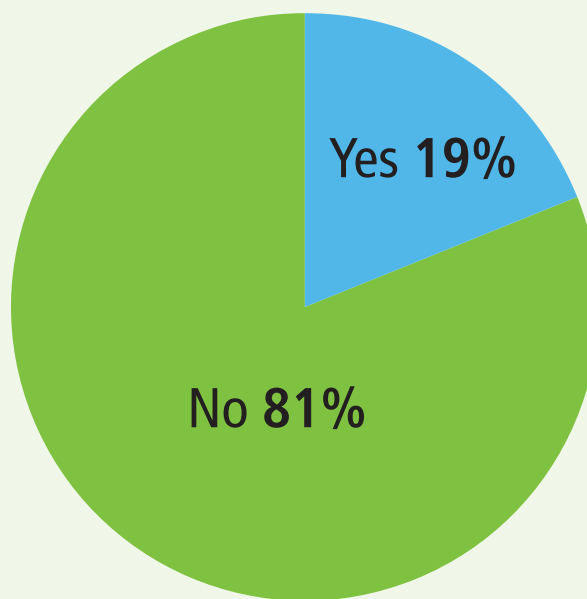
““ *Due to the voluntary nature of reporting by pharmaceutical companies, I do find that the information is not complete, and the anticipated date of availability is rarely correct. —Health care professional* ””

**RELIABLE:** While the quantity and quality of information posted on [www.drugshortages](http://www.drugshortages) has continuously improved based on suggestions from stakeholders across the health care system, there remains a general lack of trust in the voluntary system, and the information posted.

““ *On several attempts to access shortage information, I had to call the manufacturers to confirm the shortage as the website did not state that there was a shortage —Community pharmacy/pharmacist* ””

**Q.**

**Is the current notification system meeting the objectives of being timely, comprehensive and reliable?**



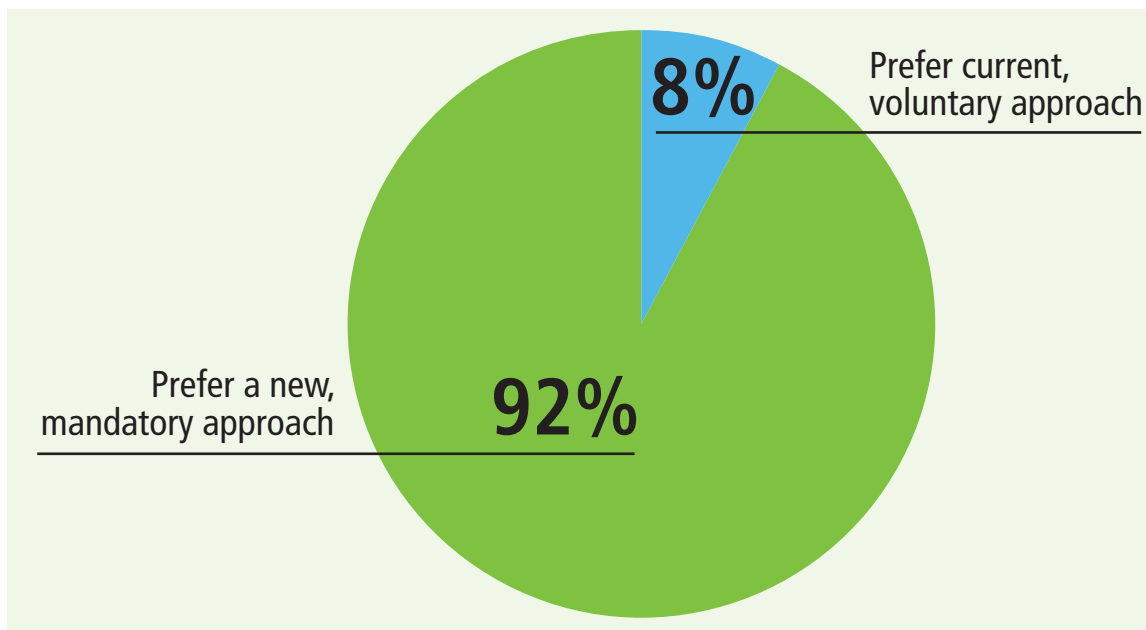


## Voluntary Versus Mandatory Notification

The current voluntary approach to drug shortage notification in Canada means that companies provide notification of drug discontinuances or shortages on a voluntary basis (i.e., no legal obligations). The expectation is that all drug shortages and discontinuances, anticipatory and actual, will be voluntarily publically posted.

A mandatory approach to drug shortage notification would mean that companies are required, through regulation, to provide notification of drug shortage or discontinuances.

The majority of respondent groups indicated that the current voluntary approach was not working well, and showed **preference for a mandatory approach to notification**.



“Patient safety is the only important issue here. The mandatory approach is the only way to proceed. —Community pharmacy/pharmacist”

*“This affects the lives of Canadians. The current system isn’t working for my patients. We need standards mandated and legislated, so that companies follow suit.”*

*—Academic*

*“Voluntary or mandatory is not as important as providing comprehensive information that will help in decision making without guessing.”*

*—Hospital pharmacy/pharmacist*

*“The voluntary system is not working. While mandatory notification does not guarantee delivery, penalties and sanctions can spur a more rigidly monitored response by manufacturers/distributors.”* —Patient advocacy association

*“The listed information represents the most accurate information known to the manufacturer at that point in time... This information includes: availability of other manufacturers and stock supply, availability at other pharmacies and other supply chain sources, etc...”* —Manufacturer

*“The voluntary system that is currently in place is not working well...we need to have more timely notification so appropriate planning can be done in advance of a shortage.”* —Hospital pharmacy/pharmacist



*“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. The main focus should be on the problem, not the symptoms.”*

*—Interested Canadian*

*“I support rules, not suggestions“. —Health care professional*

*““ It should be mandatory with explicit directions to drug manufacturers/distributors on their requirements. It is too dangerous to be optional.” ”*  
*—Community pharmacy/pharmacist*

*“...when patient care is at risk, a mandatory approach is needed to ensure full compliance...” —Patient advocacy association*



# WHAT DO CANADIANS WANT?

Canadians want notification to be more **timely**, **comprehensive**, and **reliable**.

**TIMELY:** Canadians want to receive more timely notification of shortages and discontinuances.

“*Posting of information should be as soon as a company is aware a shortage may occur, not when the shortage happens.*”  
—*Interested Canadian*

**COMPREHENSIVE:** Canadians want to receive accurate and complete information across all information fields, including information on therapeutic alternatives, drug re-supply dates, and the reason for a shortage.

“*There needs to be more awareness about the current system that is in place. Furthermore, if approximate availability dates were added to the system that would provide more insight into how long it is expected to be short.*” —*Community pharmacy/pharmacist*

*“I need to know more than just the shortage. I need to know what alternatives exist.”* —*Hospital pharmacy/pharmacist*





**RELIABLE:** Canadians want increased monitoring by Health Canada of postings, and commitments by industry to provide trustworthy information.

“ Posting shortages to a website is not enough, there needs to be someone actually monitoring the shortages, finding out what the companies are doing to prevent or address the shortages. —Interested Canadian ”

**OTHER:** Canadians and stakeholders want greater transparency around Health Canada’s role and new and enhanced mitigation and prevention tools to tackle drug shortages.

## For More Information on Drug Shortages

Please visit [www.hc-sc.gc.ca/dhp-mps/prodpharma/shortages-penuries/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/shortages-penuries/index-eng.php)