Drug Shortages

A Guide for Assessment and Patient Management

Canadian Pharmacists Association
Association des Pharmaciens du Canada

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Purpose

It is well known that drug shortages are not uncommon and, in fact, often occur as a part of the routine day for pharmacists.[1,2,3] This guide presents a systematic approach to assess the impact of drug unavailability and subsequent patient management. It can be applied whenever drug shortages are encountered.

This guide is a concise, practical tool for physicians, pharmacists and other prescribers that can be used in any drug shortage situation. The guide was designed to:

- Present an explicit systematic process to use when faced with a drug shortage.
- Highlight the unique position of pharmacists, physicians and other prescribers in delivering a strong, reassuring and consistent message to the public regarding the management of drug therapy in the face of drug availability difficulties.
- Discourage practices of stockpiling or having medications on hand "just-in-case", and to provide tips for communicating with patients.

Introduction

Medication therapy is critical in treating and preventing disease and is an integral part of everyday life for many Canadians. The pharmaceutical supply chain of manufacturers, wholesalers, distributors and pharmacists, as well as physicians and governments, acknowledge the importance of having a continuous supply of medications.

However, it is possible within today's drug distribution system for glitches to occur, such as short-term back orders or long-term drug unavailability. The challenge for health care providers is to provide seamless, equivalent drug therapy at comparable costs. Assessment requires a critical evaluation of the current situation and potential impact of the shortage on patient outcomes.[4]

When an important drug product is not available, practitioners will want to know:

- reasons for the product's unavailability
- when the product will be available
- options for obtaining the drug from alternate sources
- alternate therapies and their cost consequences
- related information needs of health care providers and patients.

Disruptions in the supply of pharmaceuticals may occur due to several reasons, including:

- Unexpected increases in utilization of a drug, resulting in a temporary shortage until manufacturing capacity meets demand.
- Voluntary discontinuation or recalls of a product by a manufacturer. In some situations, other manufacturers market the same drug, but are unaware of the discontinuation, and therefore do not adjust their manufacturing capacity in advance.
- Withdrawal from the market by Health Canada/manufacturer.
- Natural disasters (e.g., ice storms and floods).
- Increased demand due to emergency situations (e.g., mass casualties) or infectious disease outbreaks (e.g., caused by a pandemic influenza).

It is important to acknowledge there may be public concern that Canadians will be without essential medicines.

As front line health care providers, pharmacists, physicians and other prescribers are in a unique position to deliver a reassuring and consistent message to the public, as well as manage any changes to drug regimens required due to a drug shortage. It also provides an opportunity to do a full medication assessment or review to determine overall appropriateness of drug therapy. CPhA has developed this guide to assist in managing patients in the event of a drug shortage.

For drug-specific therapeutic information, pharmacists, physicians and other prescribers are encouraged to refer to drug and therapeutic references (e.g., ***Therapeutic Choices***[5]; ***CPS***[6]; ***eTherapeutics***[7]), clinical practice guidelines (e.g., Canadian Medical Association's CPG Infobase at www.cma.ca/cpgs), or contact a regional drug information centre.

If, in your practice, you are aware of critical drug shortages that necessitate changes to a patient's drug therapy, and have developed a unique way of managing the situation, please share your experience with us. Please call 1-800-917-9489, or email us at info@pharmacists.ca.

CPhA will continue to monitor drug supply issues.

Pharmacists, physicians and other prescribers must use their professional judgement in using this guide to meet the needs of their own practice settings and situations, and to comply with applicable policies and regulations.

This document has been revised from a guide on drug shortages first published by the Canadian Pharmacists Association in 1999, and updated in 2001.

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Managing Drug Shortages

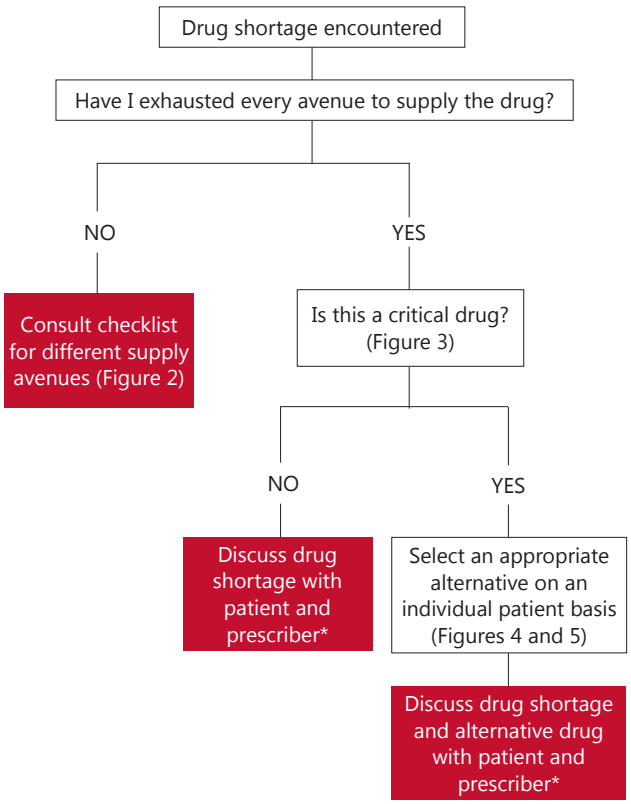
As a general overview of how drug shortages should be resolved, an algorithm (Figure 1) simplifies the management of drug shortages into a number of basic steps and questions.

Pharmacists may find that the contents of this section represent steps that they have already internalized and practice on a day-to-day basis.

The shaded boxes represent the three main steps to resolve a medication shortage:

1. Exhausting every avenue to supply the medication
2. Assessing how critical the drug is for the patient
3. Selecting an alternative medication, if required.

Figure 1. Suggested approach for pharmacists in the management of a drug shortage



** In many provinces, pharmacists are authorized to adapt a prescription or prescribe an alternative dosage form or medication.*

Step 1.

Checking all medication supply avenues

Drug shortages are a day to day reality for pharmacists. If a medication is unavailable, the pharmacist investigates different sources for obtaining the medication. Use the following checklist to double check and document the process for obtaining and supplying medications.

Figure 2. Checklist for medication supply avenues

1. Is the medication interchangeable with any brand name or generic alternatives?
   ☐ Yes ☐ No
2. If the medication is available in other dosage strengths, can the dose be made up using other strengths?
   ☐ Yes ☐ No
3. If the medication is available in a different formulation, can the drug be supplied in this form? Are there any bioavailability differences which require dosage adjustment?
   ☐ Yes ☐ No
4. Can drug supply be obtained through another pharmacy?
   ☐ Yes ☐ No
5. Can drug supply be obtained through your regular wholesaler or other wholesalers?
   ☐ Yes ☐ No
6. Can drug supply be obtained directly from the manufacturer?
   ☐ Yes ☐ No

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Step 2.

Determining how critical a medication is for a patient

If a medication is unobtainable and cannot be supplied to a patient, the pharmacist and prescriber must work together to determine how essential or "critical" the drug is so that the appropriate course of action can be determined. The potential consequences of drug unavailability must be carefully considered for each individual case.

A drug shortage also provides an opportunity to do a full medication assessment or review to determine the overall appropriateness of drug therapy. Use the following series of questions to assess the impact of a drug shortage on a patient, and to document the process undertaken with the patient.

Table 1 and Figure 3 will assist the health care practitioner in determining how critical a medication is:

- **Level 1 drugs:** critical drugs that cannot be missed for even a single dose or day
- **Level 2 drugs:** critical drugs that may be missed for greater than one dose or day, but should be reinstituted as soon as possible since they reduce long-term complications of disease and reduce intolerable symptoms of disease
- **Level 3 drugs:** non-critical drugs that can safely be withheld for a period of time

Table 1: Classification of critical and noncritical drugs and recommended actions

	Level 1	Level 2	Level 3
Description	**CRITICAL DRUG** **Drug should be available for initiation or continuation.** **Drug therapy for disease is essential and cannot be interrupted for even one dose or one day.** **Drug actions may:** • be acutely life saving* (e.g., nitroglycerin for angina attack) • reduce debilitating symptoms of disease or patient morbidity (e.g., opioids for cancer pain) • precipitate dangerous disease events with cessation (e.g., insulin products) **Medications that are not firstline therapies and whose actions are accomplished by alternate therapies are exceptions.*	**CRITICAL DRUG** **Drug should be available for initiation or continuation.** **Drug therapy for disease is important; however therapy may be interrupted for greater than one dose or one day, but should not be interrupted for extended duration.** **Drug actions may:** • be life-saving over time (e.g., diuretics for hypertension) • reduce intolerable symptoms of disease or patient morbidity	**NON-CRITICAL DRUG** **Drug availability is preferred but not crucial.** **Drug therapy is valuable, yet may be interrupted for an extended duration of time.** **Drug use may:** • be based on patient preference only • reduce minor symptoms of disease (e.g., H_2 receptor antagonists for dyspepsia) • be mostly adjunctive (e.g., montelukast in asthma) • add minimal benefit to management of disease • be lifestyle drugs (e.g., finasteride for male pattern baldness)
Action 1+	Use interchangeable product if medication is unavailable. For single source products, go to Action 2.	Use interchangeable product if medication is unavailable.	Use interchangeable product if medication is unavailable.
Action 2+	Switch to an alternative drug within class, if class effect exists. Consult with prescriber.	May consider a switch to an alternative drug within class, if class effect exists. Consult with prescriber.	Switching to an alternative drug within class may not be required. Discuss with patient and prescriber.
Action 3+	Switch to alternate drug class to ensure continued therapy for disease. Discuss with patient. Consult with prescriber.	Substitution with alternate drug class may not be required. Discuss with patient and consult prescriber. Contact patient as soon as medication becomes available.	Substitution with alternate drug class is not required. Discuss with patient and prescriber. Inform patient when medication becomes available.

+In many provinces, pharmacists are authorized to adapt a prescription or prescribe an alternative dosage form or medication.

***Note:** This classification system should be used as a guide only. Professional judgement is required in determining whether the above classification of a particular drug is appropriate for each patient, based on individual patient need and assessment.*

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Figure 3. Steps to determine how critical a medication is for a patient

1. What is the seriousness of the disease?
For what disease/condition is the drug being used?
What are the consequences of untreated disease?

- ☐ Acutely life-threatening (e.g., angina attack)
- ☐ Causes debilitating symptoms leading to decreased quality of life (e.g., cancer related pain)
- ☐ Causes bothersome symptoms with no long-term consequences (e.g., allergic rhinitis)
- ☐ Serious long-term consequences but not currently bothersome (e.g., hypertension)

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2. What is the effect of abrupt withdrawal of the medication on the patient?
On the disease?
On other medications being taken by the patient?

- ☐ Is the medication known to be associated with a withdrawal reaction? (e.g., beta-blockers, SSRIs, anticholinergics)
- ☐ Will abrupt drug withdrawal precipitate a complication of the disease? (e.g., nitroglycerin for angina)
- ☐ Had the patient's medications been adjusted to compensate for drug interactions? Will abrupt withdrawal result in the appearance of any drug interactions? (e.g., warfarin drug interactions)

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3. How essential is the medication in the management of the disease and what are its therapeutic benefits?

- ☐ Acutely life-saving (e.g., nitroglycerin in unstable angina)
- ☐ Cures disease (e.g., antibiotics for community acquired pneumonia)
- ☐ Prevents onset/progression of long-term consequences (e.g., HMG CoA reductase inhibitors for cardiovascular disease)
- ☐ Reduces/controls bothersome symptoms of disease (e.g., sumatriptan, a $5HT_1$ agonist for migraine)

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4. Is the patient currently deriving the benefits of the medication?

- ☐ Is the treatment working? Objective data (e.g., lipid profile)
- ☐ Is the treatment working? Subjective data. What is the patient's perceived efficacy of the medication? (e.g., PPIs for GERD symptoms)
- ☐ Is the medication meeting the patient's goals? (e.g., Analgesics may reduce but not completely eliminate pain in patients with cancer pain. Pain reduction may be an acceptable goal for the patient rather than pain elimination.)
- ☐ Is the patient experiencing any adverse effects from therapy?
- ☐ Is the patient adherent with drug therapy?
- ☐ Is the drug therapy still required?

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Figure 3. Steps to determine how critical a medication is for a patient – *continued*

5. For how long is the duration of the expected drug shortage? Will the drug be unavailable for:

- ☐ one day
- ☐ a few days
- ☐ several weeks
- ☐ unknown

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6. What patient factors may increase or decrease the impact of the drug shortage on the patient?

- ☐ Is the patient anxious about the unavailability of his/her medication?
- ☐ Could this encourage patient non-adherence?
- ☐ Could this result in the patient perceiving the therapy as not important?

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7. For what length of time can the medication be missed without serious detriment to the patient? (See Table 1)

- ☐ Not even a single dose or day
- ☐ Greater than one dose or one day
- ☐ Extended duration of time (several weeks)

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8. Based on the above considerations, how critical is the medication in this situation? (See Table 1)

- ☐ Level 1 critical drug
- ☐ Level 2 critical drug
- ☐ Level 3 non-critical drug

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The final step in the process is for the physician, pharmacist or other prescriber to integrate all the available information to arrive at a rating of how critical the unavailable medication is to the patient. Classifying medications in this manner makes the prioritization of medications more explicit and helps to determine when a substitute medication must be chosen for the patient, or when a temporary shortage of a medication may be acceptable. Table 1 can be used to grade how critical a certain drug may be and suggests actions based on the level of criticalness.

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Step 3.

Selecting an alternative medication

If a drug is critical for a particular patient, select a substitute that will be effective and tolerable therapy for the patient. Figure 4 describes the factors that should be considered in selecting a substitute medication for a patient.

Figure 4. Checklist for selecting an alternative medication

1. **Are there acceptable brand name or generic equivalents available?**

   ☐ Yes ☐ No

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2. **Does the medication belong to a drug category that is known to have a class effect?**

   (e.g., ACE inhibitors, HMG CoA reductase inhibitors)

   ☐ Yes ☐ No

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3. **Are there any alternate drug therapies that may be considered?**

   (Refer to current therapeutic references for possible alternatives)

   ☐ Yes ☐ No

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4. **How well does each alternate drug therapy work?**

   ☐ Does it provide similar efficacy in managing symptoms? (e.g., PPIs are superior to H_2 receptor antagonists for severe symptoms of GERD.)

   ☐ Does it have similar efficacy in improving outcomes of disease? (e.g., Digoxin does not reduce overall mortality of heart failure as ACE inhibitors do.)

   ☐ Has the patient tried any of these alternatives in the past?

   ☐ How well did they work?

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5. **When can the alternate drug therapy be expected to begin working?**

   (i.e., The ideal alternate therapy would begin to work as the effects from the original drug wear off.)

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Figure 4. Checklist for selecting an alternative medication – *continued*

6. What side effects or toxicities may be expected?

- ☐ What are the short-term and long-term toxicities?
- ☐ Do the therapeutic benefits of a medication outweigh its associated toxicities?
- ☐ If used previously, did the patient experience any side effects or toxicities?

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7. Does the patient have any other medical conditions, co-morbidities or contraindications to the alternate drug? (e.g., beta-blockers for asthmatics)

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8. Are there any patient-specific factors that may modify your selection of a substitute drug therapy?

- ☐ Does the patient have any drug allergies?
- ☐ Is the patient pregnant or breastfeeding?
- ☐ Does the age of the patient predispose him/her to certain adverse medication effects?
- ☐ Is this patient unable to metabolize and/or eliminate this drug? (e.g., ACE inhibitors or digoxin in patients with reduced renal function)

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9. What other medications is the patient taking?

- ☐ Do any of these medications interact with potential alternate therapies?
- ☐ Can dose modifications be made to overcome these drug interactions?

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10. Is the alternate drug therapy easily administered?

- ☐ Can this medication be easily integrated into the patient's routine?
- ☐ Is the patient capable of undertaking a new regimen?

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11. Are the alternate drug therapies affordable for the patient?

- ☐ Is the medication covered by the patient's drug plan?
- ☐ Due to the shortage, is the alternate medication on special authorization?
- ☐ Is it more expensive for the patient?

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Step 4.

Initiating a new therapy with an alternative medication or discontinuing therapy temporarily

Figure 5. Checklist for initiating a new therapy or discontinuing therapy

1. **What considerations need to be addressed when discontinuing the original medication?**
   - ☐ Does the medication need to be tapered downward? If so, by how much and how often should the medication be tapered? (e.g., steroid tapering)
   - ☐ What parameters should be monitored to ensure minimal adverse effects from drug termination? (e.g., beta-blocker withdrawal: monitor heart rate, blood pressure, angina symptoms, etc.)
   - ☐ What parameters should be monitored to ensure that the patient is not experiencing any unnecessary ill effects related to loss of drug action on disease? (e.g., diuretics for heart failure stopped: monitor weight, edema, shortness of breath, etc.)

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2. **Should the two therapies be overlapped during the switchover?**
   - ☐ When should the alternate therapy be initiated to provide continuous drug coverage?
   - ☐ How frequently should the new medication be given to ensure continuous drug coverage? (e.g., fentanyl patch switch to oral morphine tablets)

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3. **What considerations need to be addressed when the substitute medication is initiated?**
   - ☐ Does the substitute medication need to be titrated upward? If so, by how much and how often should the medication be titrated? (e.g., carbamazepine initiation)
   - ☐ What parameters should be monitored to assess onset of drug action and adequacy of drug efficacy?
   - ☐ What parameters should be monitored to detect any adverse effects related to the medication or fast titration of medication?
   - ☐ Is the drug covered by the patient's drug plan? If not, is there a special authorization process to allow for its use?

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4. **What are the treatment goals?**
   - ☐ Include patient in determining if treatment goals have been met.

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5. **Does the patient require assistance to undertake a new regimen?**
   - ☐ What is the patient's comfort level with the new therapy?
   - ☐ What friend or family supports are needed to ensure a smooth transition from original medication to alternative?

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Figure 6. Choice of therapy when the original medication becomes available again

1. Should the patient remain on the current medication or switch back to the original?

- ☐ Refer to Figures 3 and 4 to evaluate the original and alternative medications and identify which medication is preferable for the patient.
- ☐ How does the patient perceive the effects of the current medication?

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2. If the patient is to return to the original medication, what factors should be considered?

- ☐ Refer to Figure 5 to identify factors that must be considered in switching medications.

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Communication between Pharmacists, Prescribers and Patients

Open lines of communication between pharmacists, physicians or other prescribers and patients are necessary when dealing with drug supply shortages, so that panic is not unnecessarily created when availability of a drug may be temporarily compromised. The public needs to be reassured that stockpiling of medications in case of a shortage outbreak or other event is unwarranted.

If there is a temporary shortage of a medication, pharmacists should avoid dispensing large quantities of drugs to individual patients and also stock only the inventory that is needed for their dispensary. Overstocking by some community or hospital pharmacies may result in shortages from the manufacturer or wholesaler for other pharmacies. Physicians and other prescribers can also help in such situations by not prescribing large quantities or for long periods.

A team approach between pharmacists, physicians and other prescribers will ensure that a strong and consistent message is delivered to patients. Effective communication and cooperation will become essential when drug shortages do occur. A good working relationship will facilitate a patient-focused, thorough assessment of potential consequences of drug unavailability and development of contingency plans that meet a patient's drug related needs.

Here are some suggested points to share with your patients[3,8,9,10]:

- Reassure patients that they should be able to obtain normal supplies of medication, as they require them.
- In the event that a pharmacy encounters a particular drug shortage, there are a number of alternative sources of medication supply in the drug distribution system.
- Encourage patients to reorder medications when 5-7 days of supply remain (e.g., don't let your supply run out).
- Advise patients not to leave all their medications either at home or work (e.g., carry a few doses with you in case you are delayed. Pharmacists can provide an extra labelled Rx vial for this purpose).
- When travelling, take a few extra days supply with you and carry them with you on airplanes.
- Reinforce that stockpiling of medication is not necessary and that obtaining drugs over the Internet is not recommended.
- The pharmacy supply chain has a demonstrated record of being resilient during many different situations, even emergencies such as natural disasters. Most issues can be quickly and efficiently corrected.

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