

Health Canada Public Consultation on the Notification of Drug Shortages

Submission by the Canadian Arthritis Patient Alliance (CAPA)

Arthritis is a term used to refer to more than 100 related conditions. It can strike any one at any point in their lives, including children and young adults. The common feature of the many different forms of arthritis is the chronic joint pain, stiffness and swelling leading to disability and poor quality of life. For those whose arthritis is not well controlled, day to day activities, such as self-care, walking, cooking, caring for children, working, attending school and social activities becomes impossible. Support of a caregiver, often taken on by spouses, parents and other family members, becomes a necessity.

In order to effectively manage their condition, patients need an adequate supply of medication at all times. People with arthritis have encountered supply issues with both newer and older medications. It takes us weeks or months to find the right combination of drugs to keep the disease at bay. In addition, medications can take weeks or months to start working effectively and to their maximum effect. Therefore, if patients experience a drug shortage, switching to other medication, destabilizes our health and could lead to a flare of the disease.

Issues

The creation of the *drugshortages.ca* website is an important first step in ensuring patients are notified of a drug shortage. However, there are a number of issues which need to be addressed to ensure patients are properly notified of a drug shortage.

- Patients have only received notification of a drug shortage once we fill our prescription at the pharmacy. Often, a drug shortage notification does not occur until we are physically at the pharmacy. One patient reported that she drives 40 minutes to her pharmacy to obtain her arthritis medications. A return trip to the pharmacy to obtain the necessary supply of medications causes an additional burden on the patient.
- When a shortage does occur, patients spend large amounts of time calling different pharmacies in order to get their prescription filled. In many cases, patients are contacting multiple pharmacies, suppliers and companies and no one understands the cause of the shortage or when the medication might become available.
- As with any policy, there are unintended consequences and behaviours to patients experiencing drug shortages. If a patient experiences a drug shortage once, they may not be overly concerned about the situation. However, if patients experience repeated drug shortages, patients will lose confidence in the drug supply system (some already do). As a result, we can expect patients to stockpile their own medications in order to avoid a drug shortage situation. For example, some patients with arthritis keep their previously used

bottles of injectable methotrexate for subsequent dosing. This might go against generally accepted safety practices but patients are doing this to keep a supply of methotrexate on hand.

- Another impediment to patients gaining access to their medication is the strict refill policies of insurance companies and public formularies. Often insurance doesn't let us fill drugs until we get closer to exhausting our current supply. This is becoming increasingly the case with pay-direct cards. This may exacerbate the drug shortage situation.
- The average patient, and even patient advocacy associations, are not aware of the *drugshortages.ca* website. The primary contact for patients is their local pharmacy. Upon using the website, there is a lack of patient specific information and the information is not complete (e.g. no anticipated resupply date). Improvements could be made so patients could set up a profile in order to be notified of a shortage of identified medications. Consultation should occur with patients in order to make the website more patient-centred.
- Shortages reported on the website may not directly impact the patient depending on whether the patient currently has sufficient medication at home or whether the pharmacy has sufficient inventory. This highlights whether the drug shortage notification is driven by the right provider. The local pharmacist is best placed to respond to individual patient needs. They can report to patients when an actual shortage will impact them directly.

Options/Solutions

A number of changes need to be made to the approach to effectively supply drugs to patients as well as the notification of drug shortages:

- The necessary players need to start working collaboratively earlier in the process to avoid drug shortages altogether. Patient notification of drug shortages is paramount however measures need to be taken earlier in the system to avoid shortages. If a shortage does occur and impacts the patient, patients ultimately pay the price in terms of their health and well-being.
- Any drug supply system needs to provide necessary information to the patient, based on their particular circumstances. Pharmacists need to take a more active role in ensuring patients medications are ready for them even before they request them. For patients with chronic illness, like arthritis, forecasting should be relatively straightforward as we often take the same medications for years. This approach would be providing exemplary customer service and put the patient first. Therefore, when problems are found then the patient can be notified accordingly. Ideally, the patient would be notified prior to re-filling their prescription.

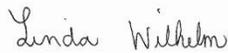
- Mandatory reporting of drug shortages for all medications is recommended. Patients come first and our health is directly affected when a shortage occurs. We can't rely on voluntary actions when patient's health and well-being is at stake.
- Manufacturers should be required to provide sufficient advance notification that a drug will no longer be produced. Patients and healthcare providers should be provided with sufficient notice to ensure alternate manufacturing and licenses can be granted or another supplier is found. There have recently been significant issues with the supply of older medications used in the treatment of Juvenile Idiopathic Arthritis, more specifically Aristopan and Naprosyn suspension.
- Patients need to be involved in any future discussions. Consideration should be given to including patients in the stakeholder working group and any other consultations or meetings.

In closing, we would like to thank you for the opportunity to provide comments on the current and possible changes to the approach to drug shortages. We would be happy to further discuss our comments and suggestions with you at any time.

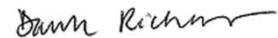
Kind regards,



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Canadian Arthritis Patient Alliance

www.arthritispatient.ca