How to Guide for Patient Advocacy Groups to Submit Patient Evidence

Introduction

One of the mandates of the *Transparent Drug System for Patients Act* is to put in place a public drug system that is more responsive to patients. To this end, two patient members have been appointed to the Committee to Evaluate Drugs (CED). The issue of patient impact has also been included in the CED Terms of Reference as one of the key considerations for drug reviews.

Despite these initiatives, the patient perspective for specific diseases can remain limited to the views and knowledge of those represented on the CED. Patient evidence is not routinely available or brought forward during drug reviews. Systematic inclusion of patient evidence should be considered during CED discussions of drug reviews and evaluations.

The Ministry is now accepting submissions of patient evidence from registered patient advocacy groups on drugs that will be undergoing review by the CED. This guide contains important information on the submission process.

What does the Ministry require from patient advocacy groups?

The Ministry and the CED have clinical evidence, economic analysis and opinions from practicing specialists available in their drug reviews. However, patients' perspectives on the disease and treatment options are not available. The Ministry is not specifically looking for individual testimonials but a collective approach whereby concerns from a group of patients and caregivers are brought forward. Thereby, patient advocacy groups are invited to submit patient evidence provided by their members. This allows the Ministry and the CED to assess the information regarding the daily lives of patients and their caregivers, information that is not available in the medical literature.

To determine the validity of a patient advocacy group, the Ministry is asking all interested patient advocacy groups to register. This allows the Ministry to determine whether the patient advocacy group has patient and/or caregivers as members and can effectively communicate with their members. In addition, the patient advocacy group is asked to declare any conflict of interests and a confirmation of authorship on each submission of patient evidence to verify that the submission is unbiased towards the drug discussed and that there is no involvement from manufacturers.

How can patient advocacy groups register with the Ministry?

Interested patient advocacy groups can register with the Ministry. Only submissions from registered patient advocacy groups will be accepted by the Ministry. However, the Ministry does not endorse any specific patient advocacy group.

Interested patient advocacy groups can either register prior to making a submission or at the time of their first submission. The registration form can be mailed, emailed or faxed

to the ministry. The ministry will notify the patient advocacy group on the status of the registration via mail, fax or email upon receipt of the registration.

Once registered, the patient advocacy groups will be listed on the Ministry's webpage in alphabetical order. Individual patients and/or caregivers will be redirected to the webpage to contact the appropriate patient advocacy group.

How do patient advocacy groups provide the submission of patient evidence?

The patient advocacy groups are encouraged to check the website for the updated Drug Review Schedule for a list of drugs that will be undergoing review. The Ministry will not be notifying each patient advocacy groups independently on upcoming drug reviews. It is the responsibility of the patient advocacy groups to provide a submission by the posted deadline date on the drug of interest.

Each patient advocacy group can make only one submission per drug listed. However, patient advocacy groups can make submissions for multiple drugs pertinent to the group.

The patient advocacy groups are encouraged to use the Submission of Patient Evidence form provided on the website and at the end of this guide. The form can be mailed, emailed or faxed to the Ministry.

A glossary is available on the Ministry's website to provide patient advocacy groups assistance in defining the various terms used by the Ministry.

What should the submission of patient evidence include?

A. General information:
    1. Conflict of interest declaration - The author and the patient advocacy group must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. Examples of conflicts of interest include, but are not limited to,
        a. Financial support from the pharmaceutical industry (such as educational/research grants, honoraria, gifts, and salary;
        b. Affiliations or personal/commercial relationships with drug manufacturers or other interest groups

    2. Confirmation of authorship. The author must confirm that the submission provided is entirely their own work and did not involve assistance or input from other interested persons or parties (e.g. pharmaceutical companies).

B. Impact of the disease/condition
    1. Describe what symptoms the patients deal with. Identify which symptoms are the most bothersome for most patients and which symptoms are tolerable.

    2. Describe how the symptoms affect daily activities of living and/or describe how the disease impacted the patient's lifestyle. Example: the pain in the fingers does not allow patients to dress without assistance.

C. Treatment Outcomes

1. Identify the most important symptom(s) patients would like drug treatments to help.

2. Identify the symptom(s) that the currently available drug treatments help with.

3. Identify the symptom(s) that the currently available drug treatments do not help with

4. Identify the symptom(s) that the new drug treatment should help with.

5. Describe how the new drug treatment will impact the patients or caregivers current daily routine or lifestyle. Example: the new drug treatment is taken/given once a month instead of daily so that patients no longer need to remember daily to take the current drug.

6. Identify any other financial implications that the current drug treatments and the new treatments have. Example: the current drug treatments that comes in syringes require the patients to drop off the used syringes at a pharmacy whereas the new drug treatment comes in a tablet.

D. Patient evidence on the new drug

This section is meant to gather information from patient members who have used the new drug

- as part of a clinical trial or
- as part of the manufacturer's compassionate release program or
- paid for by third-party private insurer or
- paid for by the patient/family out of pocket

The information provided in this section should in describe

- how easy it is for patients to take or for caregivers to give the new drug
- the symptom(s) the new drug alleviates and the symptom(s) that are not alleviated
- the side effects that are tolerable and the side effects that are not tolerable

What happens to the submission at the Ministry?

Once a submission is received by the ministry, the patient advocacy group will be notified of the receipt by mail, fax or email.

After the deadline for each drug, the ministry will collect the submissions from all the patient advocacy groups for that drug and summarize the information. The information will be presented to the CED by the CED patient member during the discussion of the drug.

The CED will take into consideration this information as well as the clinical evidence, the cost effectiveness and Ontario's budget impact analysis when making their

recommendation. The Executive Officer will then make a final funding decision on the drug based on these recommendations.

The CED recommendation and final funding decision by the Executive Officer will be posted on the website. Each patient advocacy group who made a submission on the drug will not be notified individually of the outcome of the drug review. The patient advocacy groups are encouraged to check the website on a regular basis to review the CED discussion and final funding decision. The ministry will not be formally accepting appeals or rebuttals on the final funding decision from patient advocacy groups.