



*Canadian Agency for
Drugs and Technologies
in Health*

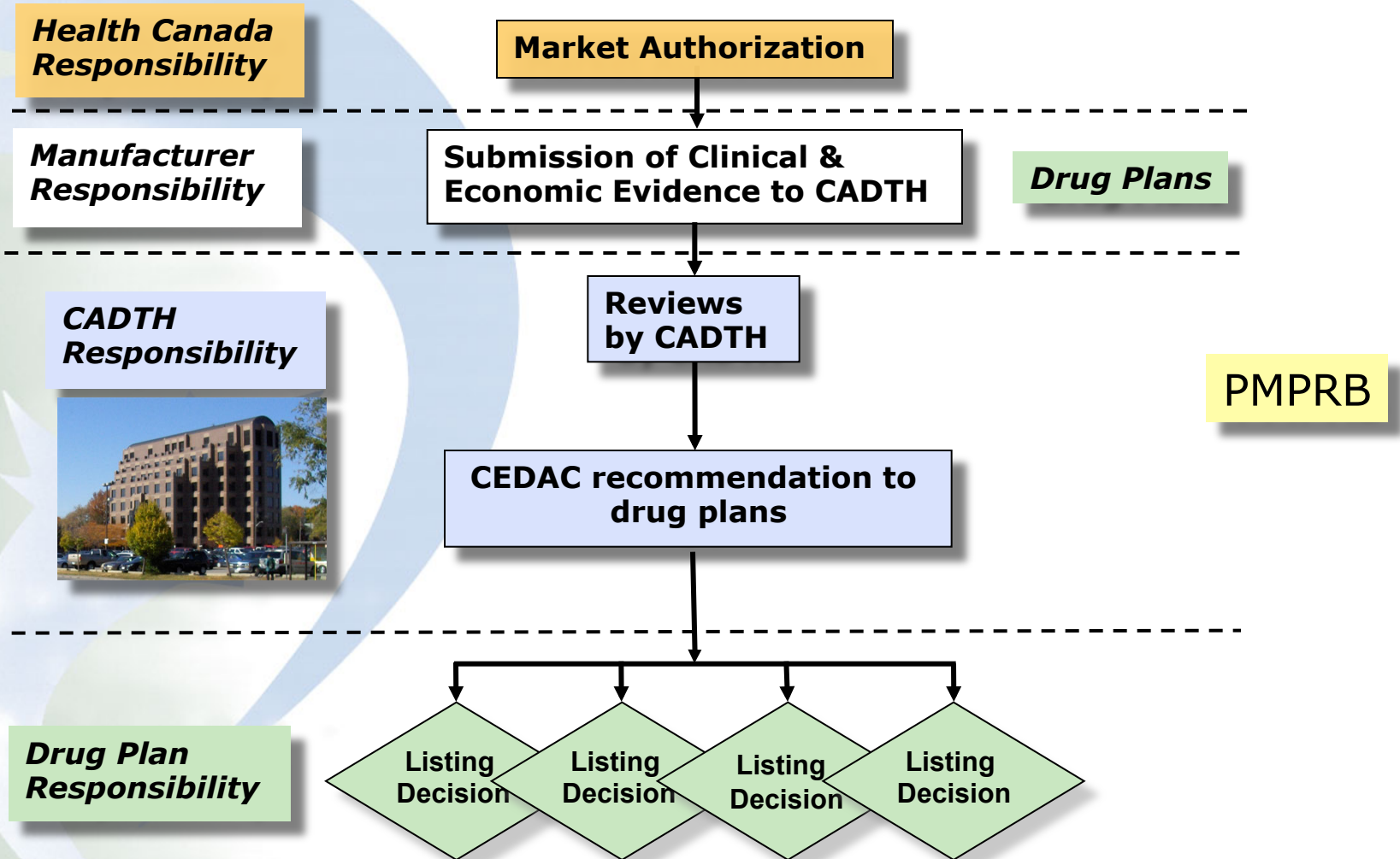
*Agence canadienne
des médicaments et des
technologies de la santé*

Patient Group Input to CADTH's Common Drug Review

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Drug Review in Canada



Expert Committee Recommendations

➤ **Based on multiple types of evidence:**

- safety, efficacy and effectiveness of the drug compared to current accepted therapy
- therapeutic advantages and disadvantages relative to current accepted therapy
- cost-effectiveness relative to current accepted therapy
- **patient perspectives** obtained through patient input

New Process for Patient Input

- **Launched in May 2010 for CADTH Common Drug Review**
- **Input systematically incorporated throughout review process to maximize impact**
- **Seeks information via Canadian patient groups**
- **Respects existing review time frames for CDR**

How to Provide Input?

- **Template for patient group submissions (6 pages)**
 - to facilitate submissions of relevant and consistent content
 - to meet CADTH/expert committee needs as well as needs of other jurisdictions using patient input
- **See www.cadth.ca for**
 - template, guide, online submission function
 - list of submissions with “Calls for Patient Input”



Template for Submitting Patient Group Input to the Common Drug Review (CDR) at CADTH

Section 1 – General Information

Name of the drug CADTH is reviewing and indication(s) of interest	
Name of patient group	
Name of primary contact for this submission	
Position or title with patient group	
Email	
Telephone number(s)	
Name of author (if different)	
Patient group's contact information:	
Email	
Telephone	
Address	
Website	

CADTH may use the above information to contact individuals if comments need clarification.

Information about the Common Drug Review (CDR) program and the Canadian Expert Drug Advisory Committee (CEDAC) may be found in the [CDR section](#) of the CADTH website. For information regarding patient input to CDR and CEDAC, please see the “[Patient Input](#)” section, particularly the [Guide for Patient Group Input to the Common Drug Review at CADTH](#). Should you have any questions about completing this form, please contact CADTH by telephone 613-226-2553, ext. 1233 or email patientinputinquiries@cadth.ca.

- This template form should be used by patient groups to submit patient group input.
- Individual patients should contact a patient group that is representative of their condition to have their input added to that of the patient group.
- Please ensure that the input is in English and that it is succinct and clear. Please use a minimum 11-point font and do not exceed six (6) typed pages (approximately 3,500 words). You may delete the instructions and examples under each heading for more space.
- The patient group input for this drug must be submitted by the deadline date posted on the [Patient Input](#) page of the CADTH website to be used in the CDR process.
- **Due to the tight time frames for providing patient input, using the “Submit” link in the table on the [Patient Input](#) page is the recommended submission method.** Alternatively, the completed template may be faxed to CADTH:
Fax: 613-226-5392
Attention: CADTH, CDR Program
- The information provided in this submission will be shared with the publicly funded drug plans that participate in CDR to use in their decision-making and may be included in publicly available documents. Personal information will not be publicly available.

What Information is Meaningful?

- **Real world information** on the impact of a condition on patient's daily life and that of their families
- **Patient perspectives** on currently available therapies and experiences or expectations for new therapy
- Information representative of the **majority of patients** (supporting examples okay)
- Scientific evidence not required - **unpublished studies** may be included
- Conflict of interests declared for transparency (does not preclude consideration of input)

When to Submit Input?

- Posted on CADTH website and E-alert “Calls for Patient Input” sent to subscribers
 - When manufacturers files a submission to the CDR
 - When manufacturers give advance notice of pending submission
- 3 weeks to respond (extra 2 weeks if advance notice is voluntarily given by drug manufacturer)

Calls for Patient Input

Please see the aforementioned “[Steps for providing patient input](#)” before making a patient group submission. The following table lists all drug submissions received by CADTH and pending submissions when the manufacturer has provided notification.

Brand name	Generic name	Manufacturer	Indication	Project Number	Date submission received	Patient input deadline	Submit patient input
Zenhale (inhalation aerosol)	Mometasone furoate & formoterol	Merck Canada	Asthma maintenance (adults, children 12 or older)	TBD	2011-02-14 (Tentative)	2011-03-08 (Tentative)	Submit
Nucynta CR	Tapentadol	Janssen Inc.	Pain, moderate to moderately severe	S0224	2011-02-01	2011-02-24	Submit
Restasis ophthalmic emulsion	Cyclosporine	Allergan Inc.	Moderate to moderately severe dry eye disease	S0222	2010-12-17	2011-02-07	<i>Closed</i>
Celsentri	Maraviroc	GlaxoSmithKline	HIV-1, treatment naïve (adult)	S0221	2010-12-08	2011-01-31	<i>Closed</i>

How is the Patient Input Being Used?

➤ Patient group information is:

- collated and summarized by CADTH staff
- used by CADTH review team (summary and original input)
- included in review report
- sent to expert committee (summary and original input)
- presented by public members at expert committee meeting
- included in expert committee deliberations
- reflected in expert committee recommendations
- shared with drug plans for their use in decision making

Experience to Date (Feb 11, 2010)

- **“Calls for Patient Input” issued on 22 drugs**
- **46 patient group submissions have been received**
- **Between 0 and 10 patient input submissions per drug have been received**
- **Manufacturers have given advance notice for 13 of the 22 submissions filed**
- **Assessment of 42 patient submissions for 14 drugs**
- **Experience limited—only 3 drug submissions have completed full review cycle**

Experience to Date (cont' d)

➤ **Examples of impact on reviews**

- resulted in use of international clinical expert as patient input identified limited clinical experience in Canada
- resulted in re-examination of cost information
- clarified the burden of the lifestyle restrictions caused by one medical condition
- provided insight into value placed on injection frequency by patients and caregivers

Suggestions For Future Submissions

- **Provide patient experiences vs “textbook”**
 - Gathered via interviews, surveys, e-mail, chat rooms
 - Anecdotes help bring information alive
- **Provide clear expectations for new drug**
- **Follow patient input template**

Next Steps

- **Continuous assessment of patient input submissions**
- **An evaluation of the process**
 - to determine impact on reviews and recommendations
 - to determine if requested information needs to be changed
 - to determine if approach requires changes
- **Development of training initiatives**
- **Development and use of new methodologies in collecting and using patient input**

An evolving process.....

The CDR patient engagement process will evolve as new methodologies and avenues for engaging patients emerge.

For More Information



www.cadth.ca