CADTH Record of Scientific Advice

[month, Day, Year]

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#

# Scientific Advice Meeting Participants

**Date**

[Spell out month in full: Month, Day, Year]

**[Pharmaceutical Company Name]**

|  |  |
| --- | --- |
| Participant Name | Participant Title |
| [Name] | [Title] |
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**CADTH**

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| Participant Name | Participant Title |
| [Name] | [Title] |
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# Abbreviations

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# Background

CADTH Scientific Advice prepared this report with consultation from external clinical experts and academic leaders to provide guidance on early drug development plans. The briefing book submitted by the company was reviewed, and responses to the questions posed have been summarized, based on a health technology assessment point of view and on relevance to the Canadian health care setting. The Summary of Advice was presented at the in-person Scientific Advice meeting. Discussion at the in-person meeting, together with post-meeting comments, have been added under each question, if applicable.

**Patient Input**

As part of the Scientific Advice process, we interviewed [number] patients and consulted past patient group input submissions to the CADTH Common Drug Review to better understand, from the patient perspective, what is important with regard to drug development. A detailed summary of patient input is provided in Appendix 1.

**Key Highlights from Patient Input**

*[Provide a brief summary, highlighting key aspects including: personal burden of disease and unmet medical need(s); significant impact of symptoms/disease; challenges experienced with current treatments; values and preferences in treatment selection.]*

# Record of Scientific Advice

## Question 1

[Insert question/issue, as stated in the *Briefing Book*.]

*The full company position is not required here.*

###

**Summary of Advice**

[Response]

*CADTH will summarize the Scientific Advice provided in response to Question 1. This may be done in sentences and paragraphs or in bullet form. The intent is to summarize the Scientific Advice provided rather than to document the conversation word for word.*

###

**Discussion and Post-Meeting Comments**

[Response]

*CADTH will use this section to document additional discussion points, as needed. CADTH may indicate “no additional discussion points,” if appropriate. CADTH will clarify any unresolved issues from the meeting and/or add additional thoughts since the meeting occurred.*

## Question 2

[Insert question/issue, as stated in the *Briefing Book*.]

**Summary of Advice**

[Response]

**Discussion and Post-Meeting Comments**

[Response]

## Question 3

[Insert question/issue, as stated in the *Briefing Book*.]

**Summary of Advice**

[Response]

**Discussion and Post-Meeting Comments**

[Response]

## Question 4

[Insert question/issue, as stated in the *Briefing Book*.]

**Summary of Advice**

[Response]

**Discussion and Post-Meeting Comments**

[Response]

## Question 5

[Insert question/issue, as stated in the *Briefing Book*.]

**Summary of Advice**

[Response]

**Discussion and Post-Meeting Comments**

[Response]

## Question 6

[Insert question/issue, as stated in the *Briefing Book*.]

**Summary of Advice**

[Response]

**Discussion and Post-Meeting Comments**

[Response]

*CADTH will extend the template, as needed, to include the remaining questions from the* Briefing Book*.*

# References

1. abc
2. abc

# Appendix 1: Patient Input Summary

**The Approach Taken for Patient Input**

As part of the CADTH Scientific Advice process, we interviewed [number] patient(s) and consulted past patient group input submissions to the CADTH Common Drug Review to better understand, from the patient perspective, what is important with regard to drug development.

CADTH contacted relevant patient groups to help identify interested individual patients who met the following criteria:

* personal experience with [state disease] and treatment with [list standard drug therapy] or other therapies to try to manage the [define symptoms] of this condition
* awareness of other people’s experiences with this condition; for example, moderates a chat group, or volunteers with a patient group or support centre.

A set of questions were developed for the interview. The summary of the interview is provided under each question, along with relevant details from the patient group submission.

**Contributors**

The interview was held [date: Month, Day, Year], via telephone, with the CADTH Scientific Advice team, patient engagement team, and interviewee.

Patient group input from [name of patient group], received for the CADTH Common Drug Review [date: Month, Day, Year] regarding [disease/condition], was accessed.

**Patient Input Summary**

**Personal Experiences**

[Insert interview question.]

**Summary**

[Summary]

**Current Therapies**

[Insert interview question.]

**Summary**

[Summary]

**Quality of Life**

[Insert interview question.]

**Summary**

[Summary]

**Planned Clinical Studies**

[Insert interview question.]

**Summary**

[Summary]

**Additional Information**

[Insert interview question.]

**Summary**

[Summary]