NICE and CADTH Parallel Scientific Advice

**Briefing Book**

[Company/Manufacturer’s Name]

[Name of Product (including chemical name, designation, generic and trade names):]

[Intended indication:]

[Company/Manufacturer’s Contact person and contact details:]

This annotated template should be read in conjunction with the relevant guidelines that can be found on the NICE Scientific Advice website.

OFFICIAL-SENSITIVE-COMMERCIAL-CONFIDENTIAL

[Date: Month, Date, Year]

# TABLE OF CONTENTS

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# LIST OF TABLES AND FIGURES

Insert here

# LIST OF ANNEXES

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|  |  |
| --- | --- |
| Annex | Title |
|  |  |
|  |  |
|  |  |
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|  |  |

# LIST OF ABBREVIATIONS

|  |  |
| --- | --- |
| Abbreviation | Full name |
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#  RATIONALE FOR SEEKING ADVICE

Response

# NAME OR CODE NAME OF PRODUCT

Response

# BACKGROUND INFORMATION

## 3.1. Lay Summary

Response

## 3.2. Overview of the Disease

Response

## 3.3. Treatment Options and Relevant Guidelines

Response

## 3.4. Current Unmet Need

Response

**3.5. Regulatory Scientific Advice**

|  |  |  |
| --- | --- | --- |
| Agency | Date or Expected Date | Minutes attached (yes/no) |
| MHRA |  |  |
| Health Canada |  |  |
| EMA |  |  |
| FDA |  |  |

**3.6 Scientific Advice from other Health Technology Agencies**

|  |  |
| --- | --- |
| Country and Agency | Date or Expected Date |
|  |  |
|  |  |
|  |  |

# 4. DATA CURRENTLY AVAILABLE ON THE PRODUCT

## 4.1. Mode of Action or Pharmacological Class

Response

## 4.2. Proposed Dosing Regimen and Route of Administration

Response

## 4.3. Indication and Target Population

Response

## 4.4. Regulatory Status

Please indicate when marketing authorisation is expected. Does the product have marketing authorisation in other indications? In the table below, please provide the expected date for marketing authorisation.

|  |  |  |
| --- | --- | --- |
| Indication | MHRA | Health Canada |
| Intended indication |  |  |
| Other indication #1 |  |  |
| Other indication #2 |  |  |

## 4.5. Summary of Patient Engagement (if available)

Response

## 4.6 Clinical Data Available to Date

Response

5. PRODUCT VALUE PROPOSITION

Response

# 6. PROPOSED CLINICAL DEVELOPMENT PROGRAMME

Response

# 7. PROPOSED ECONOMIC ANALYSIS

Response

# 8. QUESTIONS AND COMPANY’S POSITION TO NICE and CADTH

## Questions on the proposed clinical evaluation

**Question 1:**

Company’s Position

**Question 2:**

Company’s Position

Add further questions and company positions as needed.

## Questions on the proposed economic evaluation

**Question *n*:**

Company’s Position

**Question *n*:**

Company’s Position

Add further questions and company positions as needed.

# 9. QUESTIONS TO NICE ONLY

Please add no more than 2 questions to NICE only.

**Question *n*:**

Company’s Position

**Question *n*:**

Company’s Position

# 10. QUESTIONS TO CADTH ONLY

Please add no more than 2 questions to CADTH only.

**Question *n*:**

Company’s Position

**Question *n*:**

Company’s Position

# 11. REFERENCES

Insert here