NICE and Canada’s Drug Agency

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

Insert here

# List of Tables and Figures

Insert here

# List of Annexes

Insert here

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

# List of Abbreviations

|  |  |
| --- | --- |
| **Abbreviation** | **Full Name** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

# 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 Canada’s Drug Agency

## 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 Canada’s Drug Agency (CDA-AMC) Only

Please add no more than 2 questions to CDA-AMC only.

**Question *n*:**

Company’s Position

**Question *n*:**

Company’s Position

# 11. References

Insert here