NICE 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 SA website]*

OFFICIAL-SENSITIVE-COMMERCIAL

[Date: Month, Date, Year]

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# LIST OF TABLES AND FIGURES

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# LIST OF ANNEXES

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# LIST OF ABBREVIATIONS

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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/Expected Date | Minutes attached (y/n) |
| **MHRA** |  |  |
| **EMA** |  |  |
| **FDA** |  |  |

**3.6. HTA Scientific Advice/Early Dialogues:**

|  |  |
| --- | --- |
| Country/Agency | Date/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: [when is marketing authorisation expected? Does the product have MA in other indications?]

## [Please provide Date, Expected Date or NA]

|  |  |  |
| --- | --- | --- |
| Indication | EMA | FDA |
| Intended indication |  |  |
| Other indication #1 |  |  |
| Other indication #2 |  |  |

**4.5. Summary of Patient Engagement (if available):**

Response

**4.6 Clinical Data Available to Date:**

[insert relevant subsections as required]

Response

5. PRODUCT VALUE PROPOSITION:

Response

# 6. PROPOSED CLINICAL DEVELOPMENT PROGRAMME:

[insert relevant subsections as required]

Response

# 7. PROPOSED ECONOMIC ANALYSIS:

Response

# 8. QUESTIONS AND COMPANY’S POSITION:

**Questions on the proposed clinical evaluation**

**Question 1:**

Company’s Position

**Question 2:**

Company’s Position

[Insert further questions here:]

**Questions on the proposed economic evaluation**

**Question *n*:**

Company’s Position

**Question *n*:**

Company’s Position

[Insert further questions here:]

# 9. REFERENCES:

Insert here