Rev. 0

NICE-MHRA Parallel Scientific Advice

Briefing Document Template

[Standard headings in the template should be used whenever possible; if it is considered necessary to deviate from the pre-specified headings to accommodate product-specific requirements, alternative or additional headings/sections may be considered.]

Name of product:

Active substance:

Pharmaco-therapeutic group:

Intended indication(s):

Company:

Contact details:

Version:

Date:

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List of Abbreviations

[Any acronyms or abbreviations used should also be defined the first time they appear in the text.]

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1. Summary

[It is strongly recommended to address all elements outlined below (whenever applicable) for any advice request, regardless of the scope of the questions. This summary will inform the background information section of the final advice letter. An upper limit of 3 pages for the summary is recommended]

**Rationale for seeking advice**

[Describe the scope of the questions and the rationale for the advice request (e.g. clinical/non-clinical/quality/significant benefit/similarity/conditional approval/exceptional circumstances).]

1. Product value proposition

[Describe value propositions and how the trial evidence will be used to support these]

1. Background information

[This section should give a comprehensive scientific overview of the product development program, providing relevant systematic information in sufficient detail, together with a critical discussion. However, it should be kept in mind that any information essential for the justification of a given question should also be sufficiently discussed in the corresponding Company’s position. The proposed list of subsections is neither meant to be exhaustive nor mandatory, since the relevance or applicability of each subsection may vary depending on the scope of the advice request. In this respect, the potential direct or indirect relevance of the information covered in relation to the questions posed should be considered. Additional details can be included in study protocols, study reports, investigators’ brochure provided as annexes. The use of tabulated overviews and graphs is encouraged.]

**Disease to be treated**

[Outline main features of the disease and current standard therapy (referencing relevant guidelines), referring to relevant publications as well as any current unmet need(s)]

**Indication**

Please specify the proposed wording for the intended indication, posology, and any special precautions or recommendations for use of the product (including a possible risk management strategy)]

**Description of the product**

[Include mode of action, chemical structure, pharmacological classification, proposed dosing regimen, route of administration and details of any additional diagnostic tests, medical devices or medical procedures that the use of the new product will incorporate.]

**Non-clinical information**

[Please provide brief information on pre-clinical trials in a tabulated overview, only if these are relevant to the advice sought.]

**Clinical information**

[A tabular overview of all clinical studies (completed, ongoing and planned), should be included. Please try to include study number, protocol synopsis, location(s), trial objectives, trial design, randomisation, blinding, intervention, patient population, inclusion/exclusion criteria, identified subgroups, comparators, endpoints, health-related quality of life (HRQL), duration/follow-up and methods of analyses where applicable. Briefly include outcomes of completed trials, including safety assessments. Whilst the focus should be kept on the intended indication, the development in other indications could be briefly summarised, where relevant.]

**Clinical efficacy**

[A general overview of the clinical development program should be based on a comprehensive discussion of e.g. the main clinical results so far, dose-response, exploratory trials, special populations, supportive and pivotal clinical studies, and any analyses performed across trials (pooled and meta-analysis). The discussion should identify the most important findings and challenges in the clinical development program, and its compliance with legal requirements, relevant clinical guidelines, previous scientific advice (sufficiently justifying any deviations), etc. Information on the geographical distribution of centres participating in the pivotal clinical studies can be reflected in this section.]

**Clinical safety**

[A general overview of the safety profile of the product should be based on a comprehensive discussion of e.g. patient exposure (safety database), adverse events observed so far, serious adverse events and deaths, laboratory findings, safety-related discontinuations, specific safety findings, immunological events, safety in special populations, etc.]

**Regulatory scientific advice**

[If scientific advice has been previously requested from the CHMP, national or non-EU (e.g. FDA)]

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

**HTA scientific Advice/Early dialogue**

[If scientific advice has been previously requested from another HTA body]

|  |  |
| --- | --- |
| Country/Agency | Date/Expected Date |
|  |  |
|  |  |
|  |  |

**Summary of patient engagement**

*[Briefly summarise any interactions or inputs from patients’ groups or representatives]*

|  |  |  |
| --- | --- | --- |
| Patient group | Country/date | Outcome |
|  |  |  |
|  |  |  |
|  |  |  |

**Regulatory status**

[Describe the worldwide regulatory status of the product (e.g. any existing MA, or planned MAA timelines).]

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

**Economic evaluation plans**   
  
[This section is optional if no questions on economic evaluation are submitted.

If plans for the economic evaluation are provided, these should include to the extent possible:

• Description of the proposed model (diagram, modelling approach, time horizon, perspective)

• Data collection plans to inform the model:

* Evidence synthesis/meta-analysis – sources of evidence
* Comparators – MTC and indirect comparisons and evidence available
* Trial endpoints used to derive health outcomes in the model
* Quality of life – source and methods, tools used to measure QoL
* Incorporation of adverse effects
* Resource use – sources and methods, tools used to measure resource utilisation

• Methodological Approaches:

* Extrapolation – assumptions and data sources
* Continuation rules
* Use of surrogate outcomes
* Planned sensitivity analyses

Evidence gaps and model assumptions should be described.]

1. Questions and Company’s positions

[It is recommended that questions are phrased in a way to allow for an unambiguous understanding of the question. The scope should be carefully considered in order to avoid too broad or too narrow questions.

Questions should be ordered in the corresponding section according to the expertise (also multidisciplinary) required for the assessment, and numbered sequentially.

Each question should be followed by a corresponding, separate Company’s position including a comprehensive justification of the chosen approach.

All key information about the topic should be sufficiently discussed, so that the Company position can function as a ‘stand-alone’ argument. Issues to be covered could include the following: context and proposal, other options (potentially) considered together with a critical discussion on the relative merits and drawbacks of various approaches, possible consequences and eventual measures to ameliorate these. In general, an extension of 1 to 3 pages for each Company position is recommended.

Cross-references to the relevant parts of the briefing document or annexes can be included if additional detail is needed to support the argument.]

<A. MHRA-only Questions

**Question 1**

**Company’s position**

**Question 2**

**Company’s position**

<B. MHRA & NICE Questions

**Question {X}**

**Company’s position**

<C. NICE-only Questions

**Question {X}**

**Company’s position**

List of References

List of Annexes

[Annexes should be submitted as separate documents and should include any information potentially relevant to the questions.]