1 January 2025

EMA/571070/2023

European Medicines Agency

Portfolio and Technology Meeting

Briefing Document

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1. Portfolio and Technology discussion
   1. Summary

[Provide background and rationale for seeking a Portfolio and Technology meeting briefly describing the scope of the topics for discussion.]

* 1. Topics for discussion (maximum 8)

[Topics for discussion should be clearly identified and phrased. The scope should be carefully considered to ensure an open discussion within the remit of the Portfolio and Technology meeting.

Each topic for discussion should contain a corresponding, separate Applicant’s position, including a justification of the chosen approach.

Each topic for discussion should be followed by clearly stated question.

Topics for discussion should be numbered sequentially.

**Title Topic 1**

{text}

**Question**

{text}

**Applicant’s position**

{text}

**Title Topic X**

{text}

**Question**

{text}

**Applicant’s position**

{text}

**Title Topic X**

{text}

**Question**

{text}

**Applicant’s position**

{text}

* 1. Background information

[Give a comprehensive scientific overview of the key features of the portfolio and technologies to be discussed at the meeting, providing detailed information on the current challenges and highlighting innovative aspects of the development.

Describe the potential impact of the proposed portfolio / technology on current regulatory practice and guidelines, if applicable.

All key information about the topic should be included here as well as in the Applicant’s position in Section 1.2, which should function as a ‘stand-alone’ argument.

Sources of data and major findings:

[This section is intended to provide a brief overview and critical analysis/interpretation of the portfolio / technology development programme (including relevant experimental data if applicable). Consider including evidence from published literature, if applicable.]

Remaining gaps and a brief overview of how these will be addressed (if applicable):

[Describe the remaining gaps and how these will be addressed.]

* 1. Supplementary information

List of references

[If applicable add here the list of references.]

List of annexes

[Annexes should include any information potentially relevant to the questions]