

## Formal requirements – Briefing document/Meeting minutes

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### Briefing document



*Content:* **stand-alone document** specific for the Scientific Advice, containing all relevant information required to address the included questions.

*Extent:* **not more than 40 pages** without Annexes. Please be aware that an exceeding document is generally not accepted.

*Annex:* only for additional information, e.g. tables, study synopses etc. that are relevant but not essential for the advice.



*Submission:* **3 weeks before** the meeting at the latest<sup>1</sup> (otherwise the meeting will have to be postponed). Later modifications and additional questions cannot be addressed in the Scientific Advice meeting.



#### Do's

- Include a table of contents
- Description of the medicinal product or treatment concept
- Description of the manufacturing process (flow diagram)
- Brief description of the quality, non-clinical and/or clinical development
- Include relevant reference documents/publications, where available
- Include specific questions
- After each question, include your position and the rationale

#### Exemplary question:

Does the PEI agree that the proposed animal models are relevant for our proposed pharmacodynamic and biodistribution non-clinical studies?

**Applicant's position:** Scientific justification of the model, support by literature data, efforts to e.g. generate a homologous model, etc.



#### Don'ts

- Unstructured/incomplete briefing document
- Repetitive and dissolute information
- Include Open questions
- Include Questions that refer to ongoing clinical trial authorization/amendment procedures
- Include Questions that would require assessment of data packages
- Include Questions related to funding and conceptual or strategic product development

#### Exemplary inappropriate questions:

Which proof-of-concept model would be acceptable for the PEI? Why?

Does the PEI consider the clinical data to be sufficient for marketing authorisation?

## Meeting minutes

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The PEI offers a check of accuracy for your meeting minutes, when you submit the minutes as MS Word document to the PEI within 2 weeks after the meeting.

Please be aware that minutes that do not meet a certain level of quality (see below) or are sent to the PEI later than 4 weeks after the meeting may not be eligible for this check.



### Do's

- Keep the sequence and wording of questions as in the briefing document
- Summarize the advice outcome for each question in complete sentences.
- Adhere closely to the topics discussed in the meeting, including the applicant's and the PEI's point of view (institute's position indicated as "PEI")
- Indicate page numbers, date
- Add list of participants (PEI will complement the list, where needed)
- The minutes are written in present or past tense and in indirect speech.
- Submit your draft minutes document as MS Word file



### Don'ts

- Include additional questions, statements, data, information, figures
- Provide only bullet points or notes
- Quote statements with names of individuals
- Minutes in table format are not suitable

**! For further orientation please see the attached template !**

## Contact

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**In case of any queries please contact the Innovation Office:**

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