The formal arena

The Scientific Advice provides procedural and scientific support to developers of medicinal products within the responsibility of the PEI.

Please be aware that the Scientific Advice will not provide an in-depth assessment of data and must not concern decisions from finalized procedures, pending applications or ongoing legal proceedings.

Briefing document

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

Extent: **not more than 40 pages**. 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[1] (otherwise the meeting will have to be postponed). Later modifications and additional questions cannot be addressed in the Scientific Advice meeting.

Do's

- Include general background information on the medicinal product
- 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 specific questions
- After each question, include your position and the rationale

Exemplary question:

Does the PEI agree that the proposed animal model is a relevant model 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.

[1] The PEI reserves the right to arrange a meeting only after receiving the briefing document.

Don'ts

- Unstructured/incomplete documents
- Repetitive and dissolute information
- Open questions
- Questions that are out of scope of the advice (see above)
- Questions suggesting pre-assessment
- Questions related to conceptional 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

The PEI offers a check of accuracy for your meeting minutes, when you submit the minutes to the PEI within 2-3 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 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

Don'ts

- Include additional questions, statements, data, information, figures
- Provide only bullet points or notes
- Quote statements with names of individuals

Contact

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