List of contents
1 Introduction and objective ................................................................. 2
2 Scope .................................................................................................. 3
3 Other valid documents ........................................................................... 3
4 Procedure ............................................................................................ 3
  4.1 Request for a meeting ...................................................................... 3
  4.1.1 Scientific advice meeting ............................................................ 3
  4.1.2 Presubmission meeting ............................................................... 3
  4.1.3 Clarification meeting ................................................................. 3
  4.2 List of issues/documentation ............................................................ 4
  4.3 Preparation of the meeting .............................................................. 4
  4.3.1 Examination of the application for the meeting ......................... 4
  4.3.2 Style of meeting ........................................................................ 5
  4.3.3 Meeting dates/participants ......................................................... 5
  4.4 Structure of the meeting ............................................................... 5
4.4 Fees .................................................................................................. 6
5 Appendix ............................................................................................. 7
  6.1 Flow diagram ................................................................................. 7

Change history

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1 Introduction and objective

In the interest of optimising the authorisation procedure Swissmedic organises the following types of meetings with applicants in order to clarify questions relating to content and procedure:

1. Scientific advice meetings during the developmental phase of a medicinal product
2. Presubmission meetings in advance of the submission of an application for authorisation
3. Clarification meetings in order to ensure prompt, accurate and complete answers to a List of Questions, especially where major objections exist.

Such meetings will be held if the requirements listed in these instructions are fulfilled and if, as the result of conducting a meeting, the intended exchange of information, knowledge and experience can be achieved efficiently for both parties.

The instructions constitute a Guidance document intended for administrative entities and therefore do not establish immediate rights and obligations on the part of individuals. By publishing these instructions, Swissmedic is ensuring transparency for applicants and other interested parties regarding the rules and processes related to meetings with applicants. This guidance sets out in detail the conditions that are associated with such meetings, and serves primarily as a tool to assist Swissmedic in holding these meetings in a consistent manner, while taking procedural efficiency and availability of resources into consideration.

The conditions referred to in these instructions ensure consistent, transparent and efficient implementation of meetings with applicants.

The objective of a Scientific advice meeting during the development phase is to respond, in a binding manner, to specific open questions on the quality of active pharmaceutical ingredients and pharmaceutical products, on the planning and organisation of preclinical investigations and clinical trials, and on aspects of pharmacovigilance and the risk management plan, without anticipating the evaluation of the content of the corresponding documentation.

If questions cannot be answered conclusively during the meeting, Swissmedic will provide its written opinion following the meeting. Scientific advice meetings usually take place during the early phases of processing an application (e.g. when designing studies, drawing up the pharmacovigilance plan etc.).

The aim of Presubmission meetings is to respond, in a binding manner, to applicants’ questions that arise as the documents for an authorisation application are finalised. In general these questions relate to administrative, regulatory and legal issues surrounding the submission of the application which have not already been clarified by legislation, instructions, publications in the Swissmedic Journal or other relevant, publicly available documents.

If questions cannot be answered conclusively during the meeting, Swissmedic will provide its written opinion following the meeting. Presubmission meetings are not intended to evaluate an authorisation application in advance.

A Clarification meeting should enable the applicant to clarify specific issues, where there is a justified requirement for clarification in connection with the “List of Questions (LoQ)” sent by Swissmedic, especially where the LoQ states major objections, and in addition to discuss concepts and proposals previously tabled by the industry.

Examples of such situations include:
- The scientific justification of specific questions where this has not been clearly understood by the applicant.
- Clarification of questions regarding the applicant’s intended response strategy, allowing the applicant to optimise preparation of responses. This approach should allow the Swissmedic Case Team simultaneously to ensure the best possible assessment of the answers provided to them whilst also enabling planning of procurement of any additional expertise required.

The Clarification meeting involves no pre-assessment of the answers to the LoQ.
2 Scope

These instructions deal with the documents that must be submitted, the preparation of the meeting (decision regarding whether a meeting will be held, communication and planning prior to the meeting), implementation of meetings, the post-processing and archiving and in addition the applicable fees.

The following documents are also valid in connection with the execution of the present Guidance document:

3 Other valid documents

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<td>ZL105_00_002d_FO Fragenkatalog zum Antrag Firmenmeetings im Bereich ZL</td>
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<td>ZL000_00_002e_VZ Overview documents to submitted</td>
<td></td>
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<tr>
<td>ZL101_00_001e_WL Procedure with prior notification</td>
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The general formal requirements are specified in the Formal requirements guidance document and the accompanying Table of documents to be submitted.

In the case of a procedure with prior notification, please refer to the information sheet Procedure with prior notification.

4 Procedure

4.1 Request for a meeting

Requests for a meeting must include the following information and/or documents:

4.1.1 Scientific advice meeting

- List of issues: presentation of the issues to be resolved within the context of the Scientific advice meeting, usually provided in the form of a briefing book (see section 5.2, List of issues/documentation)
- Draft agenda with the issues to be discussed
- Proposal for the style of the meeting: in person, telephone or video conference
- Proposed dates (within four to eight weeks of receipt of the application)

4.1.2 Presubmission meeting

- List of issues: presentation of the issues to be discussed within the context of the Presubmission meeting, usually provided in the form of a briefing book (see section 5.2, List of issues/documentation)
- Draft agenda with the issues to be discussed
- Proposal for the style of the meeting: in person, telephone or video conference
- Proposed dates (within four to eight weeks of receipt of the request)

4.1.3 Clarification meeting

- Presentation of the problems in answering the List of Questions and the intended meeting objective (on two to four pages)
- List of issues with the applicant’s concepts and proposals (the clearly defined and justified opinion) (see section 5.2 List of issues/documentation)
- Draft agenda with the points to be discussed
- Proposal for the style of the meeting: in person, telephone or video conference
- Proposed dates for the discussion (within three to six weeks of receipt of the request)
The meeting request must be submitted within two weeks of receipt of the List of Questions. Applications for a meeting between Swissmedic and an applicant must be made in writing. The applicant should justify its request for a meeting in the accompanying cover letter. Examination of the meeting request is usually within two to four weeks of its receipt; in the case of a request for a Clarification meeting, review of the request is usually performed within one to two weeks.

If Swissmedic rejects the application for a meeting, it will inform the applicant and justify its reasons in writing.

### 4.2 List of issues/documentation

A list of issues and the related documentation must be submitted with the application for a meeting. The documents

- must be presented in a way that corresponds to the issues stated on the application form
- must be formulated in a way that avoids any ambiguities. The number of issues to be raised should correspond to the duration of the meeting (with the usual maximum being 1 hour 30 minutes)
- should, in cases where a Clarification meeting is to be conducted, include the applicant’s views and proposals, together with the applicant’s clearly defined and justified opinion.

Only those issues stated in the list will be discussed at the meeting.

If the applicant subsequently wishes to raise further questions, it should clarify with the Case Management Division (or where appropriate the Complementary and Herbal Medicinal Products or Veterinary Medicinal Products Division) whether additional questions can also be discussed.

If the situation has changed significantly between the submission of the proposed list of issues and the anticipated date of the meeting, the applicant should inform the Case Management Division (or where appropriate the Complementary and Herbal Medicinal Products or Veterinary Medicinal Products Division) immediately and discuss the subsequent steps to be taken.

The revised list of issues plus all related documents must, in such cases, be made available to the Case Management Division (or where appropriate the Complementary and Herbal Medicinal Products or Veterinary Medicinal Products Division) no later than two weeks prior to the date of the meeting.

The documentation submitted with the form should provide Swissmedic’s specialist reviewers and experts responsible for the evaluation with the necessary background information. The information should refer directly to the issues raised. Its scope should reflect the issues raised, be short and concise, and be designed to facilitate Swissmedic with the efficient processing of it.

### 4.3 Preparation of the meeting

#### 4.3.1 Examination of the application for the meeting

The Case Management Division (or where appropriate the Complementary and Herbal Medicinal Products or Veterinary Medicinal Products Division) will determine whether the application for the meeting complies with the requirements regarding administrative aspects and content. If the administrative or content requirements for holding a Scientific advice meeting or Presubmission meeting are fulfilled, Swissmedic will inform the applicant accordingly.

For Clarification meetings, Swissmedic will request the applicant to resolve any shortcomings in the application for a meeting within a reasonable period of time. If they are not successfully resolved within this time, Swissmedic will reject the request for a meeting, providing a written explanation to the applicant.
4.3.2 Style of meeting

Swissmedic will come to an agreement with the applicant regarding the style of the meeting (person-to-person, telephone or video conference), after examining the documents and following consultation with the specialist reviewers and experts.

4.3.3 Meeting dates/participants

Swissmedic determines the date of meetings taking into account the availability of the reviewers and experts from the divisions concerned.

A meeting is usually held no later than eight weeks following receipt of the request.

On confirmation of the date of the meeting, Swissmedic will also request that the applicant sends a list of participants, stating their respective functions, to the Case Management Division (or where appropriate the Complementary and Herbal Medicinal Products or Veterinary Medicinal Products Division). Swissmedic will simultaneously name the participants of its meeting delegation. The applicant must notify the Case Management Division (or where appropriate the Complementary and Herbal Medicinal Products or Veterinary Medicinal Products Division), of any changes to the list of participants and should do so prior to the date of the meeting, without being so requested by The Agency. Swissmedic will also notify the applicant of any changes to its delegation prior to the date of the meeting.

In the interests of ensuring effective discussion, the delegations from Swissmedic and the applicant must consist of competent experts and remain as small as possible in number.

4.4 Structure of the meeting

Meetings take place at the premises of Swissmedic. They usually last for a maximum of 1 hour 30 minutes. Swissmedic will chair the meeting.

The agenda follows the list of issues. The meetings usually proceed as follows:

1. Welcome and brief introduction of participants
2. Presentation by the applicant of the issues raised, including a short overview of the key facts and background
3. Potential brief opinion by Swissmedic’s expert representatives
4. Discussion
5. Closure of the meeting with summary and identification of the next steps

The applicant will draft the minutes of the meeting in one of Switzerland’s official languages or in English. This document must summarise the conclusions of the meeting in a brief and precise manner and include the following information:

- Date and duration of the meeting
- Brand name (if available) and description of the active pharmaceutical ingredient(s) (INN) of the medicinal product concerned
- Participants at the meeting, stating their functions
- Summary of the opinion of the applicant and that of Swissmedic for each issue raised
- Next steps

The applicant should send the draft minutes to the Case Management Division (or where appropriate the Complementary and Herbal Medicinal Products or Veterinary Medicinal Products Division) on electronic media, in Word format. Swissmedic will examine the minutes, usually within two weeks, modify them as necessary, and return them to the applicant.

The minutes are to be based on the current status of knowledge at the time of the meeting. Swissmedic may take subsequent recent developments into consideration when issuing its authorisation decision.
5 Fees
Swissmedic will invoice the applicant for the costs related to the meeting, based on the administrative and scientific resources involved.
The fees are in accordance with the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (HGebV; SR 812.214.5).
Appendix

6.1 Flow diagram

Prior to submitting authorisation application

- Submission of request for Scientific advice meeting
  - 2 – 4 weeks after receipt
- Exam by Swissmedic
- Decision whether to hold meeting
  - 4 – 8 weeks after receipt
- Agreement on style of the meeting, date of meeting,/participants

Development phase

- Scientific advice meeting

Finalisation of documentation

- Submission of request for Presubmission meeting
  - 2 – 4 weeks after receipt
- Exam by Swissmedic
- Decision whether to hold meeting
  - 4 – 8 weeks after receipt
- Agreement on style of the meeting, date of meeting, /participants

After submitting authorisation application

- Application received
- List of Questions
  - 1 – 2 weeks
- Submission of request for Clarification meeting
  - 1 – 2 weeks after receipt
- Exam by Swissmedic
- Decision whether to hold meeting
  - 3 – 6 weeks after receipt
- Agreement on style of the meeting, date of meeting, /participants

Authorisation process

- Clarification meeting
- Official decision re. authorisation

Legend:
- Milestones / Activities by applicant
- Milestones / Activities by Swissmedic