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Change history

Version	Valid and binding as of:	New minor version	Description, comments (by author)	Author's initials
01	**01.01.19**		**Implementation of TPO4**	**dts**

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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:

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

Meetings for applicants will be held if the requirements listed in this Guidance document 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.

Applicants can still voluntarily request a *Pipeline Review* in connection with a Scientific Advice or Presubmission Meeting. This will focus on new, future applications (and extensions thereof) which, given a time horizon of one year, are eligible in particular for the fast-track authorisation procedure (FTA), the procedure with prior notification (PPN) or a temporary authorisation. The aim is to optimise resource planning for both parties.

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

The conditions referred to in this Guidance document ensure consistent, transparent and efficient implementation of meetings with applicants.

During a **Scientific advice meeting,** questions concerning the development of a medicinal product are conclusively resolved. These may be questions on the quality of active pharmaceutical ingredients and pharmaceutical products, for example, on the planning and organisation of preclinical investigations and clinical trials, and on aspects of pharmacovigilance and the risk management plan. The information provided by Swissmedic during a Scientific advice meeting does not pre-empt the evaluation of the content of the documentation associated with applications for authorisation.

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 stages in the development of the medicinal product (e.g. when designing studies, drawing up the pharmacovigilance plan etc.).

Presubmission meetings conclusively resolve 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, guidance documents, 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 the content of an authorisation application.

Clarification meetings enable the applicant to clarify specific issues with Swissmedic, where there is a justified requirement for clarification arising from the “List of Questions (LoQ)” sent to the applicant. To ensure efficiency, the applicant can table concepts and proposals prior to the meeting.

Examples of such situations include:

- Discussion and explanation of questions form the LoQ where these have not been clearly understood by the applicant.

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- Clarification of questions regarding the applicant's intended response strategy to simplify the process of preparing responses to the LoQ. At the same time, this approach should allow the Swissmedic Case Team –proactively and with an eye to the duration of the procedure – to ensure the best possible assessment of the intended answers whilst also enabling planning of procurement of any additional expertise required.

The Clarification meeting involves no review of the content of the answers to the LoQ.

2 Scope

This Guidance document deals 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 general formal requirements are specified in the Guidance document *Formal requirements HMV4* and the accompanying Directory *Overview of documents to be submitted HMV4*.

In the case of a procedure with prior notification, please refer to the Guidance document *Procedure with prior notification HMV4*.

3 Procedure

3.1 Request for a meeting for applicants

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

3.1.1 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 3.2, 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 or written response
- Proposed dates (within four to eight weeks of receipt of the application)

3.1.2 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 3.2, 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 or written response
- Proposed dates (within four to eight weeks of receipt of the request)

3.1.3 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 3.2 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.

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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 justify its reasons in writing.

3.2 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 ordered so that they correspond to the subject areas set out in the form *Company meeting HMV4*
- The questions must be formulated in a way that avoids any ambiguities. The number of issues to be raised should be appropriate for the duration of the meeting (with the usual maximum being 1 hour 30 minutes)
- For Clarification meetings, the documents should 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 has further questions before the meeting, it should contact the responsible Case Manager.
If the situation changes significantly between the submission of the proposed list of issues and the anticipated date of the meeting, the applicant should inform the responsible Case Manager immediately and clarify the subsequent steps to be taken.
The revised list of issues plus all related documents must be submitted to the Case Management 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 with the necessary background information. The information should refer directly to the issues raised. The scope should reflect the issues raised, be short and concise, and be designed to facilitate efficient processing by Swissmedic.

3.3 Preparation of the meeting

3.3.1 Examination of the application for the meeting

If the administrative or content requirements for holding a **Scientific advice meeting or Presubmission meeting** are fulfilled, Swissmedic will inform the applicant accordingly.

In the event of formal shortcomings, Swissmedic will ask the applicant to correct these shortcomings. If they are not successfully resolved within the time prescribed in the letter, Swissmedic will reject the request for a meeting, providing a written explanation to the applicant.

3.3.2 Style of meeting

Swissmedic will come to an agreement with the applicant regarding the style of the meeting (written response, person-to-person, telephone or video conference), after examining the documents and depending on the complexity of the matter.

3.3.3 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 formally correct request.

On confirmation of the date of the meeting, Swissmedic will also ask the applicant to send a list of participants, stating their respective functions, to the responsible Case Manager. Swissmedic will simultaneously name the members of its meeting delegation. The applicant must notify the responsible Case Manager, of any changes to the list of participants and should do so prior to the date of the meeting, without being so requested by Swissmedic. Swissmedic will also notify the applicant of any changes to its delegation prior to the date of the meeting.

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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.

3.4 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:

1st Welcome and brief introduction of participants
2nd Presentation by the applicant of the issues raised, including a short overview of the key facts and background
3rd Potential brief opinion by Swissmedic's expert representatives
4th Discussion
5th 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
- Name and function of participants
- 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 responsible Case Manager 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.

4 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 (FeeO-Swissmedic; SR 812.214.5).

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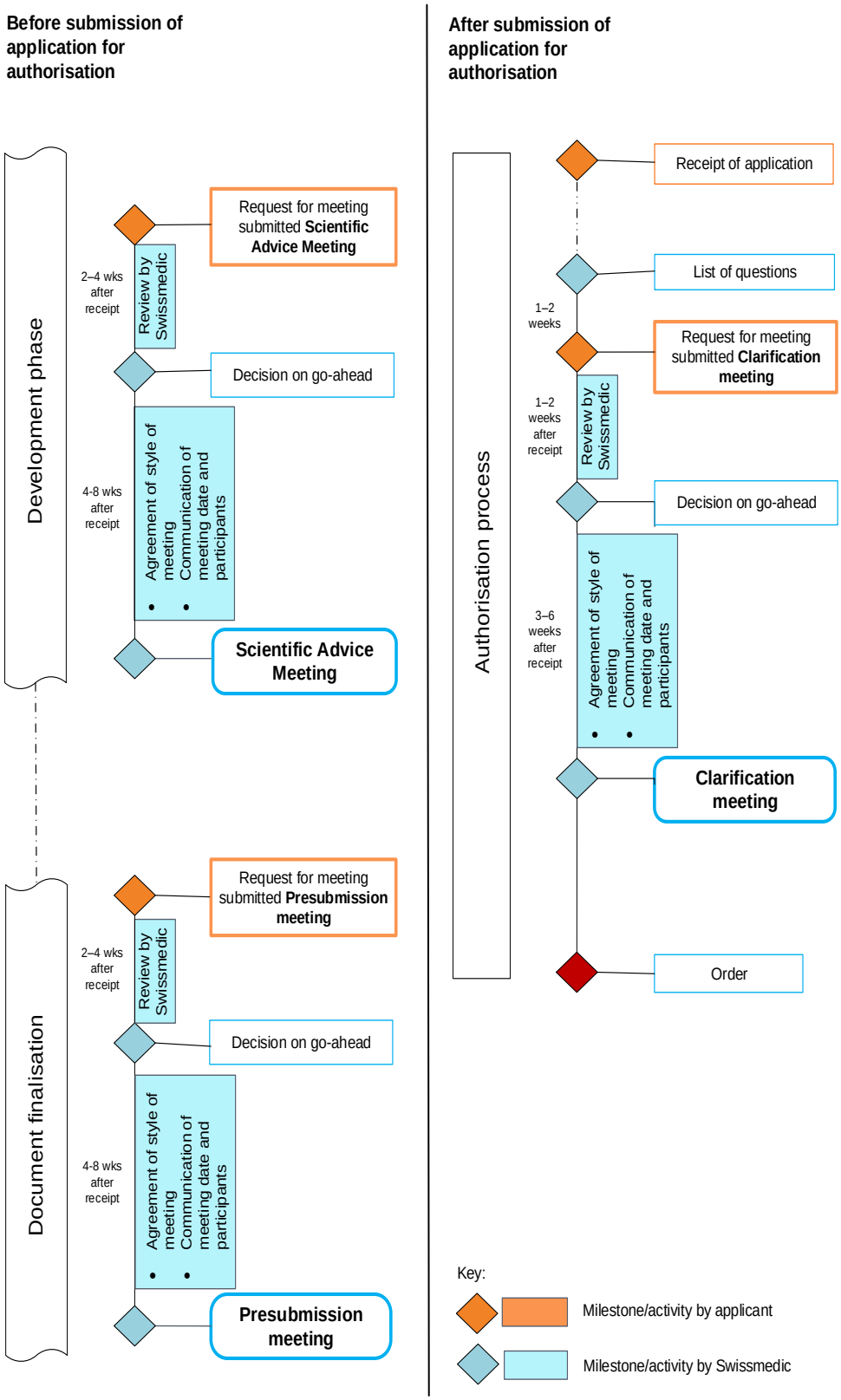
5 Appendix

5.1 Flow diagram



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