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Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
2.0	15.12.2020	Extending / optimising meetings with applicants	fg, gf, ru, zsa
1.0	01.01.2019	Implementation of HMV4	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:

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. Early Clarification Meeting in order to ensure prompt, accurate and complete answers to a List of Questions (LoQ), especially where major objections exist.
4. Late Clarification Meeting to clarify remaining individual aspects after a preliminary decision (initiated by Swissmedic).
5. Accelerated Application Hearing (AAA) on the decision concerning a planned Fast-Track authorisation Procedure (FTP) and a procedure for a temporary authorisation of human medicinal products.

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) for which scientific data in the late phase of development are available. During a Pipeline Review, Swissmedic gives the applicant a non-binding assessment as to which authorisation procedures might be appropriate for these medicinal products. A Pipeline Review can cover one or more therapeutic areas (e.g. cardiovascular diseases, oncology) and is intended to enable applicants to strategise and optimise their planned submissions at an early stage.

The AAA is conducted for planned procedures focusing on an FTP or a temporary authorisation of a human medicinal product and takes place between 2 and 12 months before the submission of an authorisation application. The aim of the AAA is to achieve planning and procedural certainty for applicants. The AAA procedure is described in detail in the guidance documents *Fast-track authorisation procedure HMV4* and *Temporary authorisation for human medicinal products HMV4*.

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 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 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

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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.

Early Clarification Meetings enable the applicant, in justified cases, to clarify specific issues arising from the LoQ with Swissmedic. Since Swissmedic has already provided the applicant with the annotated Information for healthcare professionals texts with the LoQ, the meetings can also be used to resolve comprehension issues connected with labelling. To ensure efficiency, the applicant can table concepts and proposals prior to the meeting.

Examples of such situations include:

- Discussion and explanation of questions arising from the LoQ, incl. on labelling, where these have not been clearly understood by the applicant.
- Clarification of questions regarding the applicant's intended response strategy, for example
  - Discussing a proposal on the strategy for a restriction of the indication (based on the study data available at the time of initial submission)
  - Discussing a different strategy for the re-analysis required by Swissmedic

The data required by Swissmedic should be submitted with the reply to the LoQ. No new data are accepted during the Early Clarification Meeting. Nor is the content of the data required with the LoQ reviewed. The meeting cannot pre-empt the results of the review or the decision on review phase II.

The Early Clarification Meeting is designed 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.

Late Clarification Meetings are initiated exclusively by Swissmedic. After the answers to the preliminary decision have been reviewed, any remaining individual labelling aspects are clarified in a discussion with the applicant. This is designed to avoid additional text review rounds and enable the review process to be concluded efficiently.

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

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- 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 Early 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 approx. three weeks of receipt of the request)
- The meeting request must be submitted within two weeks of receipt of the LoQ.

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 an Early 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.

3.1.4 Late Clarification Meeting

The Late Clarification Meeting is scheduled exclusively by Swissmedic. Swissmedic informs the applicant in writing of the points to be clarified.

- The applicant informs Swissmedic within 5 days of the type of interaction (teleconference or written reply).
- If the interaction is to take place as a teleconference, the applicant suggests possible meeting dates (within 5 to 10 days after the announcement of the type of interaction)
- If the applicant prefers a written interaction, the replies concerning the points to be clarified should be submitted to Swissmedic within max. 10 days.

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). The Late Clarification Meeting usually lasts from 30 min. to max. 1 hour.
- For Early 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.

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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, Presubmission Meeting or Early Clarification 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; Late Clarification Meeting: teleconference or written response), 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.

Meetings with applicants are usually held no later than eight weeks following receipt of the formally correct request. Early Clarification Meetings are held approx. 3 weeks after receipt of the request for the meeting.

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.

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 (Late Clarification Meeting max. 1 hour). 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

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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).

The costs for the Late Clarification Meeting are covered by the respective flat fees charged for the authorisation procedure.

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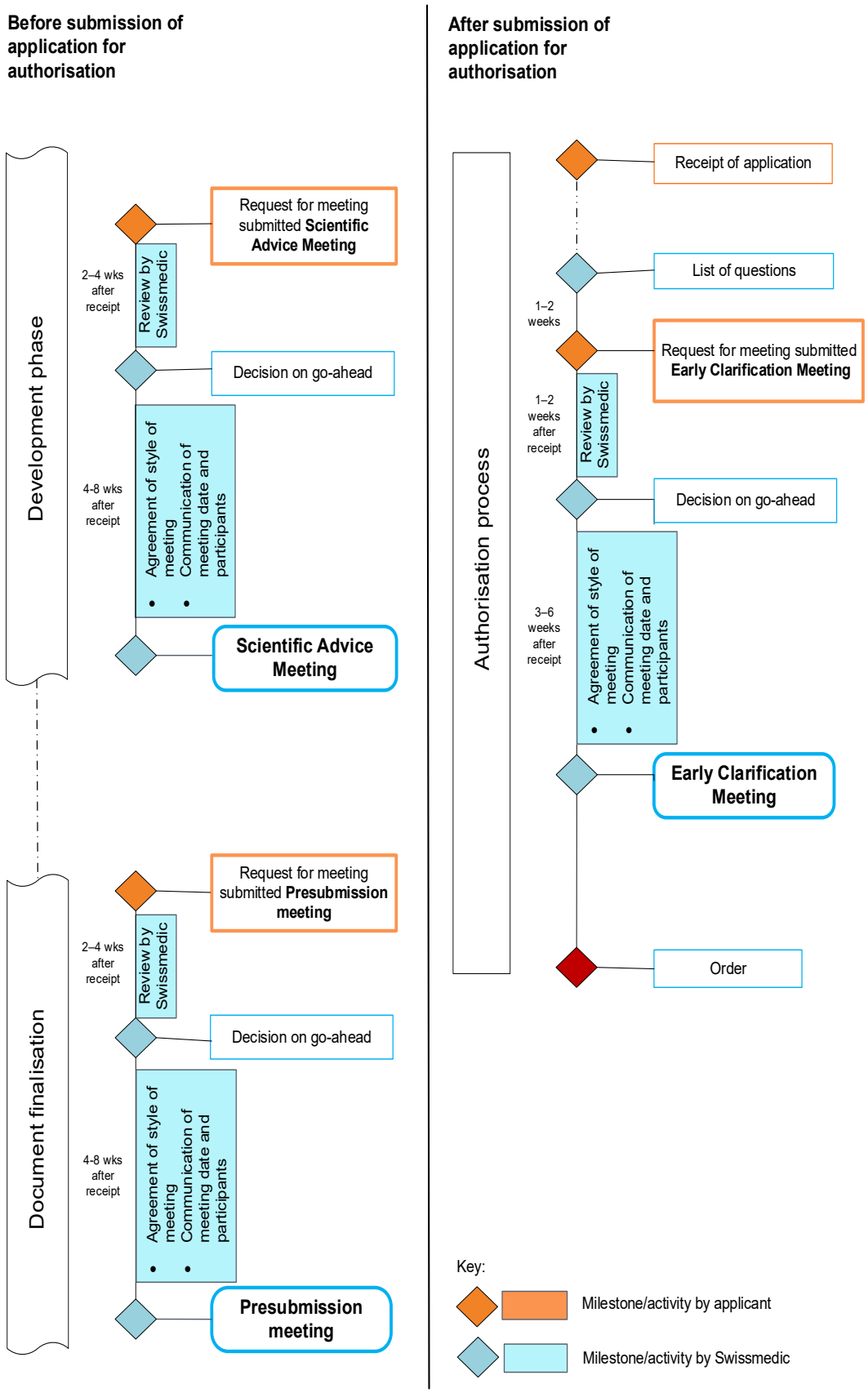
5 Appendix

5.1 Flow diagram



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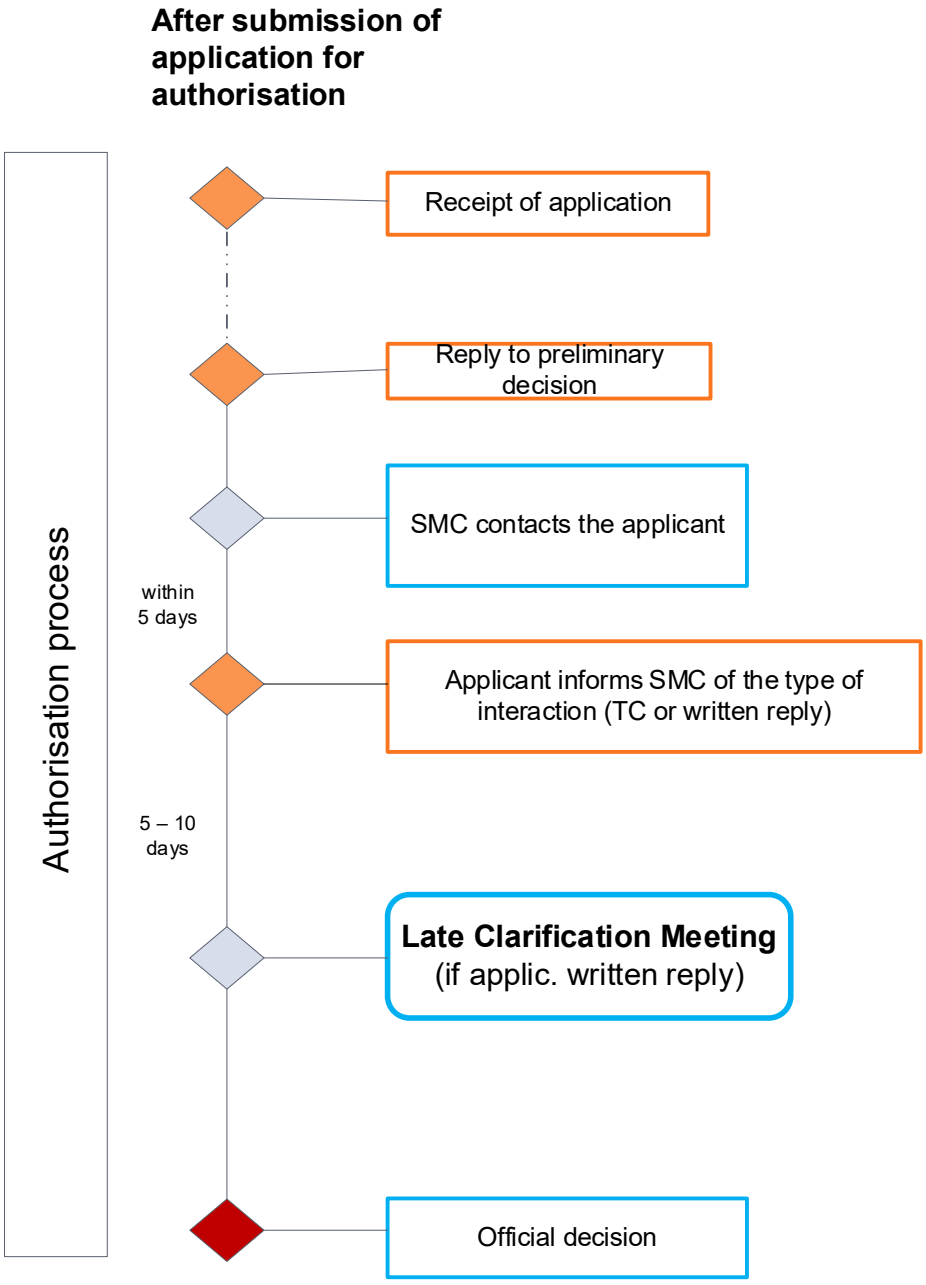

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