swissmedic

Guidance document
Meetings for applicants held with the Authorisation sector

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1 Introduction and purpose

To support companies and in the interest of optimising the authorisation procedure Swissmedic organises meetings for applicants in order to clarify questions relating to content and procedure. These may be held in person, virtually or in writing.

Meetings for applicants will be held if the requirements listed in this Guidance document (WL) are fulfilled and if, as the result of conducting a meeting, the intended exchange of information, knowledge and experience can be achieved efficiently and productively for both parties.

2 Purpose

This WL is intended for administrative entities and therefore does not establish immediate rights and obligations on the part of individuals. This WL 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.

In this WL, Swissmedic makes it clear to applicants and other interested parties what rules and processes it observes in connection with meetings for applicants. The conditions referred to in this WL ensure consistent, transparent and efficient implementation of meetings for applicants.

3 Scope

This WL describes the meeting for applicants in the authorisation procedure, stipulates the documentation to be submitted, the preparation of the advice (decision on the form of implementation, communication and planning before the meeting, if applicable the implementation of the advice in the form of a meeting, the subsequent processing and archiving and the fee levied.

4 Overview of meetings for applicants

4.1 Meetings at the applicant’s request

- Scientific Advice Meeting in the development phase of a medicinal product
- Pipeline Meeting
- Presubmission Meeting prior to submission of an authorisation application
- LoQ Clarification Meeting with a view to producing a prompt, correct and complete response to the List of Questions (LoQ), particularly if major objections exist.

4.2 Meeting initiated by Swissmedic

- Labelling Meeting to clarify remaining individual aspects of labelling following a preliminary decision.

5 Description

5.1 Meetings at the applicant's request

5.1.1 Scientific Advice

In the 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. 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.).

5.1.2 Pipeline Meeting

Companies can request a Pipeline Meeting. The focus is on future new applications and their extensions in the advanced stage of development. A Pipeline Meeting primarily serves to inform Swissmedic regarding the intention to submit within the coming 1 to 3 years. Swissmedic comments as applicable on general scientific and regulatory aspects concerning the product pipeline. However, more in-depth advice and answers to questions are reserved for specific Scientific Advice Meetings or Presubmission Meetings. The pipeline should be presented by a maximum of 10 participants and the scope of the products/product groups presented should be appropriate to the time available (max. 1.5 hours).

5.1.3 Presubmission Meeting

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 legislation, guidance documents, publications in the Swissmedic Journal or other relevant, publicly available documents.Presubmission Meetings are not intended to evaluate the content of an authorisation application.

5.1.4 LoQ Clarification Meeting

LoQ (List of Questions) 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 LoQ 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 LoQ 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.

5.2 Meeting initiated by Swissmedic

5.2.1 Labelling Meeting

Unlike the meetings described above, Labelling 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. The Labelling Meeting is an additional vessel for informal exchange and for the text review letters.The Labelling Meeting is designed to avoid additional text review rounds and enable the review process to be concluded efficiently.

6 Formal aspects and structure of the meeting for applicants

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

In the case of a procedure with prior notification, please refer to the Guidance document *Procedure with prior notification*. For information regarding conducting the Accelerated Application Hearing (AAA), please see the Guidance document *Fast-track authorisation procedure* or the Guidance document *Temporary authorisation for human medicinal products*.

Requests to hold a company meeting must be submitted in writing. The applicant should justify their request for a meeting in a cover letter.

If Swissmedic rejects a meeting, it gives a reason for this in writing.Requests for a meeting for applicants must include the following information and/or documents:

6.1 Meetings at the applicant’s request

6.1.1 Pipeline Meeting

- Contact address in Switzerland
- Draft agenda with details of the therapeutic areas/points to be discussed
- Proposal for the style of the meeting: in person, telephone or video conference or written response
- Proposed dates (between four and eight weeks after the application for a meeting is submitted)

6.1.3 Scientific Advice Meeting

- Contact address in Switzerland
- 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 “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)

6.1.4 Presubmission Meeting

- Registered office in Switzerland (Art. 10 para. 1 let. b and c TPA)
- 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 “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)

6.1.5 LoQ Clarification Meeting

- List of issues with the applicant’s concepts and proposals (the clearly defined and justified opinion) (see section“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 or written response
- Proposed dates for the discussion (within approx. three weeks of receipt of the request)
- The meeting request must be submitted within four weeks of receipt of the LoQ.

6.2 Meeting initiated by Swissmedic

6.2.1 Labelling Meeting

The Labelling 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 (virtual meeting 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.

6.3 Duration of the meetings

The duration of the meeting depends on the type and scope of the questions. Meetings upon company request usually last a maximum of 1.5 hours. The Labelling Meeting usually lasts from 30 min. to max. 1 hour.

6.4 Requirements / 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*
- The questions must be formulated in a way that avoids any ambiguities.
- For LoQ 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 questions cannot be answered conclusively during the meeting, Swissmedic will provide its written opinion following the meeting.

If the applicant has further questions before the meeting, it should contact the responsible Regulatory 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 Regulatory Manager immediately and clarify the subsequent steps to be taken. A revised list of issues may result in the date of the meeting being pushed back.

The documentation submitted with the form should provide Swissmedic's specialist representatives 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.

6.5 Preparation of the meeting

6.5.1 Examination of the application for the meeting

If the administrative or content requirements for holding a Scientific Advice Meeting, Presubmission Meeting or LoQ Clarification Meeting are fulfilled, Swissmedic will inform the applicant accordingly. The request is generally assessed within two to four weeks, or within one to two weeks in the case of the LoQ Clarification Meeting.

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.

6.5.2 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; Labelling Meeting: teleconference or written response), after examining the documents and depending on the complexity of the matter.

6.5.3 Meeting dates/participants

Swissmedic determines the date of meetings taking into account the availability of the specialist representatives and experts from the Divisions concerned.

Meetings for applicants are usually held no later than eight weeks following receipt of the formally correct request. LoQ 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 simultaneously name the members of its meeting delegation. The applicant must notify the responsible Regulatory 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.

6.6 Structure of the meeting

Meetings take place at the premises of Swissmedic. 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 in the template provided by Swissmedic. 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 toSwissmedic in Word format by two weeks after the meeting at the latest. 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.

7 Fees

Swissmedic will invoice the applicant for the costs related to the meeting, based on the administrative and scientific resources involved.

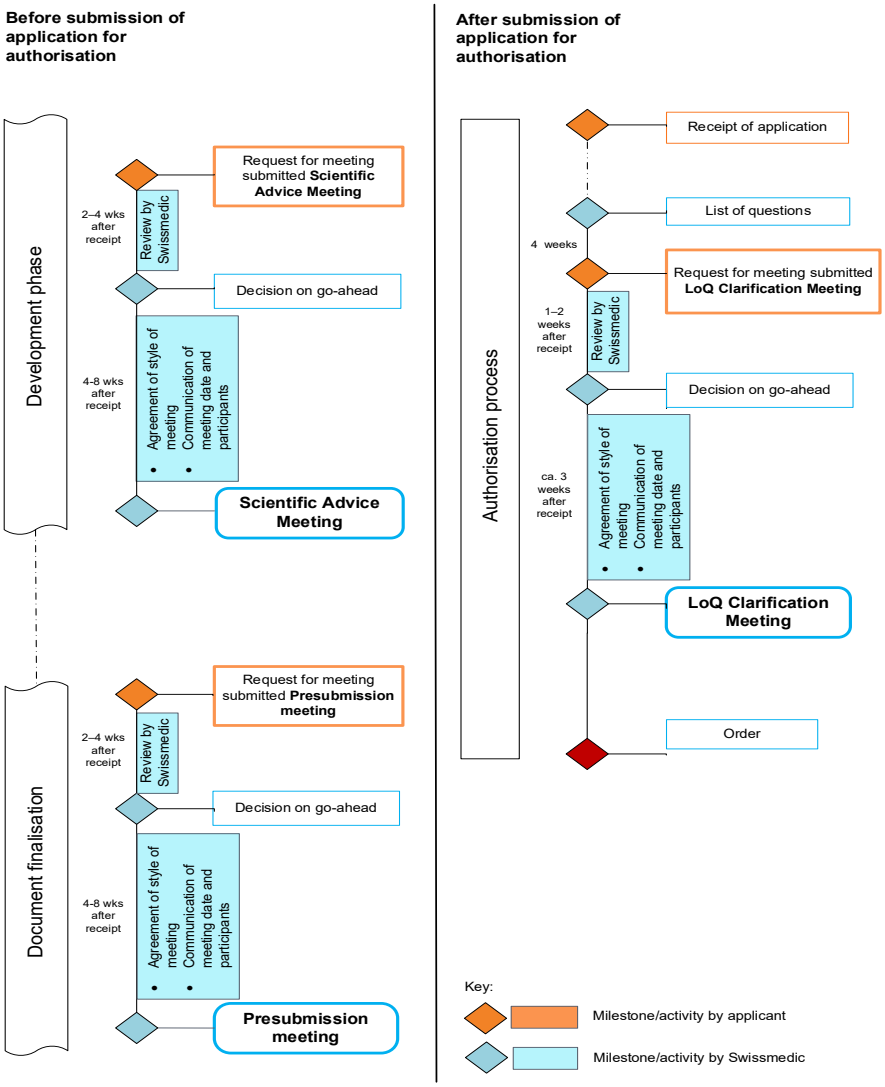
The fees are in accordance with the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5).

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

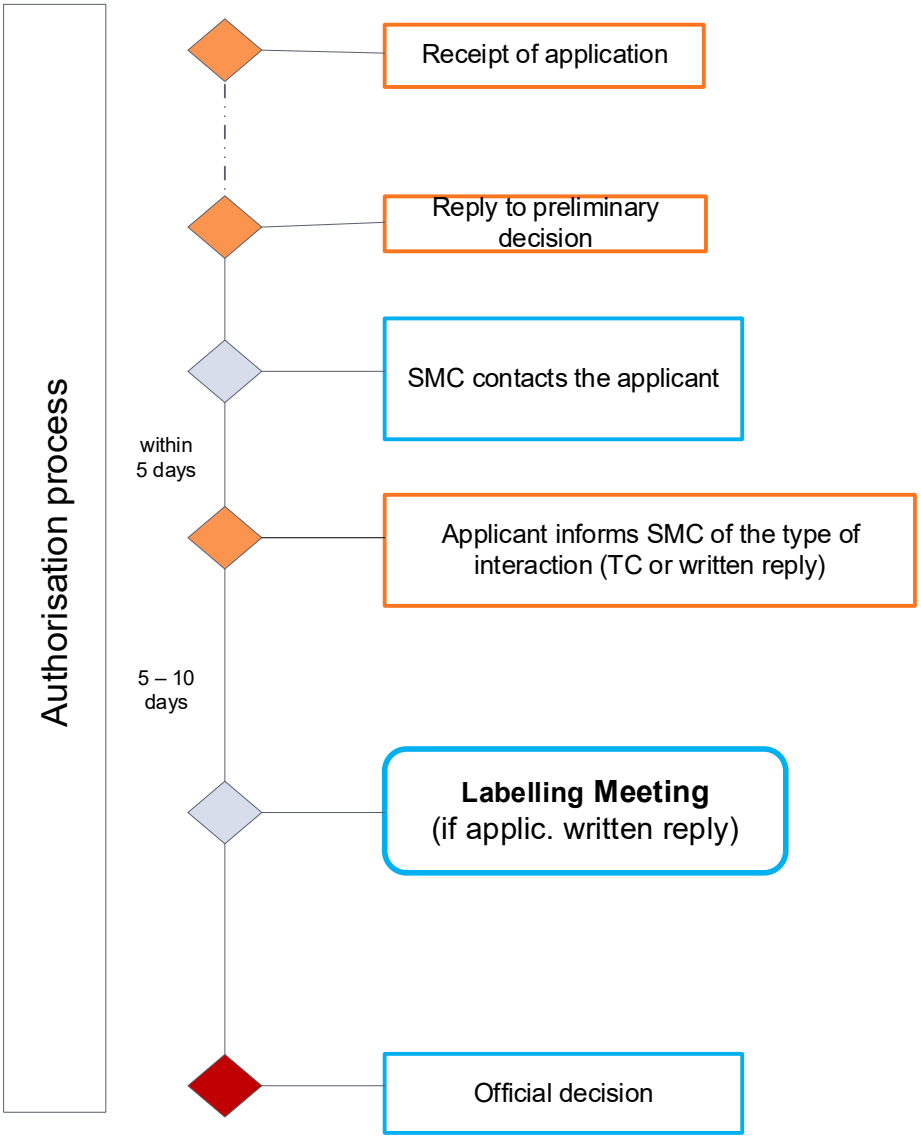
Swissmedic will waive any fee (Art. 12 FeeO-Swissmedic) for holding Scientific Advice and Presubmission Meetings for applications for authorisation of vital medicines according to Annex 1 of the Ordinance on the Essential Human Medicines Reporting Office (SR 531.215.32).

8 Annex 1

Flow diagram



After submission of application for authorisation



9 Annex 2

Preliminary Decision Clarification Meeting for human medicinal products – Pilot

1 Principle of holding the Preliminary Decision Clarification Meeting

A Preliminary Decision Clarification Meeting can be requested **for applications for authorisation or variation of the indication of medicinal products with a new active substance (NAS)**, including the following procedures:

- Fast-track authorisation procedure (FTP)
- Temporary authorisation
- Work-sharing procedure of the Access Consortium (provided Swissmedic has the lead review)
- Procedure in Project Orbis

When submitting a request for a Preliminary Decision Clarification Meeting, the applicant must provide Swissmedic with justification of the purpose of the meeting.

In principle, the following are possible:

1. The applicant has comprehension questions regarding the objections communicated by Swissmedic in the preliminary decision and would like to clarify these[1].
2. The applicant would like advice from Swissmedic on how to present certain facts in the response to the preliminary decision, e.g. as an argument or graphic, in order to best address Swissmedic's objections.

The individual points for discussion requested by the applicant must be listed and justified in the request for a meeting. Swissmedic reserves the right not to agree to hold a Preliminary Decision Clarification Meeting or discuss individual points for discussion.

New data will not be accepted as part of the Preliminary Decision Clarification Meeting and no assessment of the content of new aspects will take place.

The assessment of the planned written response to the preliminary decision and the final decision cannot be anticipated during the meeting.

Aspects that still need to be discussed with partner authorities are excluded from the discussion in international procedures.

For questions regarding a possible resubmission in the case of a rejection, or if the applicant decides to withdraw the application, Swissmedic offers appropriate company meetings after the decision has been issued, which can be requested shortly after the decision.

[1] For example, questions regarding implementation of the requirements and/or conditions given in the preliminary decision, unclear points in the ARA/PD, on the indication wording suggested by Swissmedic or on the modification of the information for healthcare professionals (e.g. warnings / ADRs)

2 Formal aspects

The meeting request must be submitted within two weeks of receipt of the preliminary decision. Preliminary Decision Clarification Meetings are held approx. three weeks after receipt of the request for the meeting.

Preliminary Decision Clarification Meetings generally last for 60 minutes.

To ensure the meeting is efficient, the number of participants should be small. The number of participants in the meeting on the applicant's side should generally be no more than five people.

The list of issues and the briefing documents must be submitted to Swissmedic with the request for the meeting.

Aspects of the procedure not listed here (request, meeting, preparation of minutes, etc.) are based on the descriptions under "LoQ Clarification Meeting", "Preparation of the meeting" and "Structure of the meeting", etc. of this WL.

Change history

Version	Change	sig
3.0	Clarifications regarding company meetings. Description of pilot Preliminary Decision Clarification Meeting.	fg, ble, zsa, pfc, rc
2.1	New layout, no content adjustments to the previous version.	dei
2.0	Extending / optimising meetings for applicants	fg, gf, ru, zsa
1.0	Implementation of HMV4	dts