Guidance document
MAGHP Scientific Advice

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1 Terms, definitions, abbreviations

1.1 Definition

A scientific advice meeting involves the provision of advice to a company by Swissmedic on the appropriate tests and studies required in the development of a medicine or on the quality of a medicine during a meeting or in a written answer. It takes place during the early phases of application processing (e.g. when designing studies, drawing up the pharmacovigilance plan etc.).

1.2 Abbreviations

CM	Case Management
CR	Clinical Review
MAGHP	Marketing Authorisation for Global Health Products
NRA	National Regulatory Authority
PCR	Preclinical Review
ROD	Regulatory Operations and Development
SHE	Stakeholder Engagement Division
QR	Quality Review
WHO	World Health Organisation

2 Introduction

The description of this scientific advice meeting procedure is aimed at those involved in the developmental phase of a medicinal product intended for submission under the Swissmedic Marketing Authorisation for Global Health Products (MAGHP) procedure.

3 Objective

The objective of a **scientific advice meeting** during the development phase is to respond to specific 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.

No anticipation of the future evaluation of the content of the corresponding documentation (e.g. no decision on approval or deferral of the planned application) is made in a scientific advice meeting.

If questions cannot be answered conclusively during the meeting, Swissmedic will provide its written opinion following the meeting.

In the context of scientific advice concerning a medicinal product intended for submission under the MAGHP procedure, the World Health Organisation (WHO) and National Regulatory Authorities (NRAs) concerned may contribute their opinion and (specific) requirements.

4 Procedure

4.1 Request for a scientific advice meeting

The applicant submits a request for a scientific advice meeting for a medicinal product falling under the MAGHP procedure to Swissmedic, Case Management (CM) Division. This request must include the following information and/or documents:

- Form *company meeting HMV4*
- Information that must be submitted to NRAs in connection with the planned submission for marketing authorisation (NRAs concerned)
- Information on whether WHO should be involved in the procedure
- Consent form to indicate that documentation can be shared with the NRAs concerned and WHO
- 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 4.3.)
- Draft agenda with the issues to be discussed
- Proposal for the style of the meeting: in person, telephone or video conference
- Proposed dates (six to eight weeks after receipt of the request)

4.2 Determination of parties involved

Swissmedic Stakeholder Engagement (SHE) Division initially contacts the NRAs listed in the request as well as WHO to obtain their feedback, if they are interested in actively participating in the scientific advice meeting. This would include access to the documentation on a secure electronic platform as well as nomination of reviewers/experts to be involved in the meeting and/or provision of (scientific) input.

NRAs confirming their interest in active participation will be referred to as “NRAs concerned”. Feedback from NRAs and WHO shall be sent to the SHE Division at Swissmedic.

The Regulatory Operations and Development (ROD) Division will set up the application-specific electronic platform access and will make the documentation for the request available to the NRAs concerned and WHO.

Swissmedic will share the information on request with the NRAs concerned and WHO via the electronic platform.

4.3 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 with the issues stated on the application form (form *Company Meeting HMV4*)
- must be formulated in a way that avoids any ambiguities. The number of issues to be raised should correspond with the duration of the meeting (see 4.5).

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

If the applicant subsequently wishes to raise further questions, it shall seek clarification with the CM Division to ascertain whether, and if so, which additional questions can 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 shall inform the CM 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 CM Division no later than four weeks prior to the date of the meeting. The documentation will be made available immediately on the electronic platform to the NRAs.

The documentation submitted with the form should provide Swissmedic's specialist reviewers and experts responsible for the evaluation, as well as the experts from the NRAs concerned and WHO, 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 efficient processing by Swissmedic, the NRAs concerned and WHO.

4.4 Preparation for the meeting

4.4.1 Examination of the application for the meeting

The CM 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** are fulfilled, Swissmedic will inform the applicant accordingly. A copy of this letter goes to the NRAs concerned and WHO.

4.4.2 Meeting dates/participants

Swissmedic determines the date of meeting taking into account the availability of the reviewers and experts from the divisions concerned. The SHE Division contacts the NRAs concerned and WHO to define who, and how, participants will join the meeting (by teleconference or by personal on-site participation at Swissmedic offices).
A meeting is usually held no later than eight weeks following receipt of the request.

Upon confirmation of the date of the meeting, the CM Division will request a list of participants from the applicant, stating their respective functions. Swissmedic will simultaneously name the participants from Swissmedic, the NRAs concerned and WHO. The applicant must notify the CM Division prior to the meeting of any changes to the list of participants, without being requested to do so by Swissmedic. Swissmedic will also notify the applicant of any changes to its delegation, the participation of NRAS or WHO prior to the date of the meeting.

In the interests of ensuring effective discussion, it should be ensured that the delegations from Swissmedic, the NRAs concerned, WHO and the applicant consist of competent experts and remain as small as possible in number.

4.4.3 Coordination meeting between Swissmedic, NRAs concerned and WHO

Before the meeting with the applicant, Swissmedic, the NRAs concerned and WHO will have a pre-meeting to present and discuss their opinions and to take the opportunity to clarify any diverging points. The pre-meeting is held at least one week before the meeting with the applicant, so that questions emerging during the pre-meeting can still be clarified. The coordination meeting can be conducted by teleconference.

4.5 Structure of the meeting

Scientific advice meetings take place at the premises of Swissmedic. They last up to 2 hours. Swissmedic will chair the meeting.

The agenda follows the list of issues. The meeting proceeds as follows:

- Welcome and brief introduction of participants
- Presentation by the applicant of the issues raised, including a short overview of the key facts and background
- Opinion from expert representatives
- Discussion
- Closure of the meeting with summary and identification of the next steps

4.6 Working language

Since the meeting is attended by the NRAs concerned and WHO representatives it will be held in English.

4.7 Minutes of the meeting

The applicant will draft the minutes of the meeting 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, of Swissmedic, and if applicable of the NRAs concerned as well as WHO for each issue raised
- Next steps

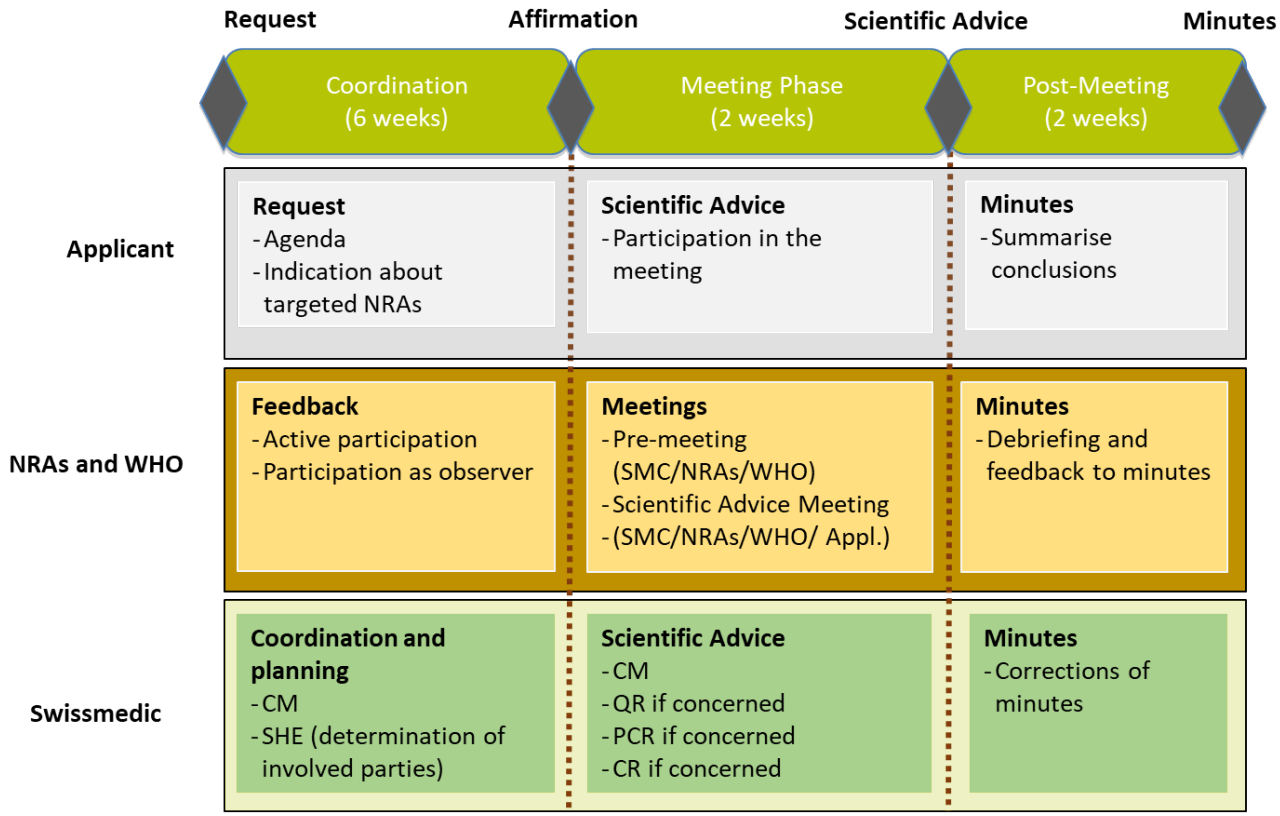
The applicant should send the draft minutes in a secure electronic manner in Word format to the CM Division. Swissmedic will upload the document to the electronic platform. The NRAs concerned and WHO will provide their comments to the minutes to Swissmedic within two weeks. Swissmedic will consolidate the comments, within two weeks of their receipt, and will return the revised minutes to the applicant. The final version of the minutes will also be made available to NRAs and WHO by the CM Division on the electronic platform.

The minutes are based on the current status of knowledge at the time of the meeting. Swissmedic, the NRA concerned and WHO may take subsequent recent developments into consideration at the time the marketing authorisation is assessed.

4.8 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).

5 Annex


Request
Affirmation
Scientific Advice
Minutes
Coordination (6 weeks)
Meeting Phase (2 weeks)
Post-Meeting (2 weeks)
Applicant
Request
- Agenda
- Indication about targeted NRAs
Scientific Advice
- Participation in the meeting
Minutes
- Summarise conclusions
NRAs and WHO
Feedback
- Active participation
- Participation as observer
Meetings
- Pre-meeting (SMC/NRAs/WHO)
- Scientific Advice Meeting
- (SMC/NRAs/WHO/ Appl.)
Minutes
- Debriefing and feedback to minutes
Swissmedic
Coordination and planning
- CM
- SHE (determination of involved parties)
Scientific Advice
- CM
- QR if concerned
- PCR if concerned
- CR if concerned
Minutes
- Corrections of minutes

Change history

Version	Change	sig
1.2	New layout, no content adjustments to the previous version.	dei
1.1	Periodical revision	pal, zeg, wec, ze
1.0	New document	sia, ze