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Guidance document
Scientific GMDP Meetings for establishment licence holders

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List of contents

1 Introduction and objective

To support companies that hold an establishment licence issued by Swissmedic and which are therefore inspected at specified intervals by Swissmedic or a Regional Inspectorate – but also to support applicants for establishment licences – Swissmedic's Inspectorates and Licences Division offers the option of company meetings to clarify GMDP issues arising from amendments and projects involving activities covered by companies' licences. Scientific GMDP Meetings provide an opportunity to discuss questions associated with projects to build new or convert existing production buildings, systems, premises or supply systems, roll out new technologies (e.g. continuous manufacturing, robotic filling lines, rapid microbiological methods, computer-assisted systems that use AI) or launch new manufacturing processes or new product classes at or in existing production facilities / buildings / premises.

The aim of these meetings is to clarify in advance GMDP-related issues facing the companies at an early project stage and discuss regulatory factors and solution strategies that the Agency will generally examine in the course of a subsequent inspection. Companies will then be able to factor in the information obtained during project implementation. However, the feedback obtained from Swissmedic during a Scientific GMDP Meeting does not preclude further content-based review of GMP/GDP compliance in the course of an inspection. If the applicant company is routinely inspected by a regional inspectorate, this can be included in the meeting. In addition, the company is free to contact the relevant regional inspectorate directly to discuss issues relating to GMDP.

Company meetings can 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 and productively for both parties. During meetings, Swissmedic will comment on the content or issues presented, but without playing an advisory role. Scientific GMDP Meetings can take place face-to-face at Swissmedic premises or virtually.

1.1 Objective

In this guidance document, Swissmedic lays out transparently for applicants and other interested parties the rules and processes that are to be observed in connection with Scientific GMDP Meetings. The framework conditions set out in the guidance document ensure that meetings are held in a uniform, clear and purposeful manner.

1.2 Scope

This guidance document describes the procedure for meetings between company representatives and Swissmedic representatives from the Inspectorates and Licences and ATMP Divisions held in connection with a GMDP issue arising from an amendment in accordance with Article 41 paragraph 1 MPLO to the content of the establishment licence or with issues arising from projects connected with the issuing of new licence.

Furthermore, major changes that are notifiable in accordance with Article 41 paragraph 2 MPLO may create issues that are appropriate for discussion in a Scientific GMDP Meeting. Where an issue arises in connection with a major change notification, the company should submit the notification in accordance with Article 41 paragraph 2 MPLO and submit its application for a Scientific GMDP Meeting to Swissmedic at the same time or after submitting its notification. However, there is also the option of

requesting a Scientific GMDP Meeting first, then submitting the major change notification to Swissmedic afterwards.

GMDP issues associated with the manufacture of advanced therapy medicinal products (ATMPs) can also be discussed at Scientific GMDP Meetings. The meeting provides a further opportunity to discuss questions with Swissmedic experts in addition to the existing option of discussing questions associated with an authorisation application as part of a “Meeting for applicants for authorisation procedures” (Guidance document ZL105_00_003_WL) with the medicinal products authorisation department.

Examples of suitable issues for a Scientific GMDP Meeting include:

- Modifications to facilities, equipment or procedures used in the manufacture, testing or import and export of medicinal products, for wholesale trading or for trading abroad with medicinal products or for brokerage or agency activities in connection with medicinal products;
- The roll-out of innovations, e.g. continuous manufacturing, robotic filling lines, rapid microbiological methods or the use of artificial intelligence in computer-controlled systems;
- The introduction of new manufacturing processes or technologies, the introduction of new genetically modified organisms or the introduction of the manufacture of gene therapy products at / in an existing production facility / building / premises.

This guidance document covers the documents to be submitted, meeting preparation (decision on how the meeting is to be held; pre-meeting communication and planning), the decision on whether to proceed and the form of the meeting, minuting, follow-up and archiving, and fees.

2 Company’s application and documents to be submitted

Applications for a Scientific GMDP Meeting must be submitted in writing to Swissmedic 6 to 8 weeks before the desired date using the form “Application_form_Scientific_GMDP_Meeting” (Annex 2) by e-mail or post using the address given in the form.

The application must include the following information or documents:

- Address / contact information of the applicant with a registered office in Switzerland
- Address for correspondence, if applicable
- Details of establishment licence or whether an application for a new or amended establishment licence has been submitted (with reference to application ID, if applicable)
- Information on whether a major change according to Article 41 paragraph 2 MPLO has been submitted
- Issue to be addressed by the Scientific GMDP Meeting: Title/topic and questions with the points to be discussed (questions must be clearly formulated to avoid misunderstandings)
- If applicable, details of discussions of the issue with other authorities that have taken place or are planned
- Several suggested dates for the meeting (within 6-8 weeks of receipt of the application for a discussion) and the requested duration of the meeting
- Suggested form of the meeting: Face-to-face at Swissmedic or video conference
- Language

- Other mandatory documents (to be submitted by 2 weeks before the meeting at the latest):
  - Agenda and company presentation on the issue
  - List of intended participants from company
- Other optional documents:
  - Additional documentation and background information
  - Records of feedback from other authorities

The presentation and any other documentation submitted with the form should provide Swissmedic's specialist representatives and experts with the necessary background information. They should be directly related to the questions raised. The scope should be adapted to the issues, short and concise, and facilitate efficient reviewing and processing by Swissmedic.

2.1 Review of the meeting request

Swissmedic will review the information provided in the form and the documents submitted and decide whether the Scientific GMDP Meeting can proceed from a subject matter perspective or if the conditions for a meeting have not been fulfilled. This may be the case, for example, if the issue does not fall within the scope set out in section 1.2. Similarly, the application for a meeting may be rejected if the issue is not connected with GMDP and should be discussed in another setting (e.g. a round table meeting, meeting with a regional inspectorate) or if the issue is connected with an application for authorisation of a medicinal product/ATMP and should be discussed in a meeting for applicants for authorisation procedures (see ZL105_00_003e_WL Guidance document Meetings for applicants for authorisation procedures). Furthermore, the application will be rejected if the company has not developed its own strategies to resolve the issues (i.e. only wants to obtain advice from Swissmedic).
If the initial review of the application raises questions about its content or if the suggested meeting dates are not possible, Swissmedic will contact the applicant within the 14-day period to clarify the questions and arrange a suitable date for the meeting. Swissmedic determines the date of the meeting taking account of the dates suggested by the company in its application form and the availability of its specialist representatives and experts.
During the initial review, Swissmedic also assesses whether it is necessary to involve a Regional Inspectorate and, if so, which one. If a Regional Inspectorate is to be involved, the meeting date is coordinated with the regional Inspectorate concerned or the company is referred to the competent regional inspectorate.
If Swissmedic rejects the application for a meeting, it will provide reasons for its decision in writing. Otherwise, the applicant will receive written confirmation of the time and date of its face-to-face meeting at Swissmedic's premises or its video conference meeting within 14 days of receipt of its application. Swissmedic will also provide the names of the people attending the meeting on Swissmedic's behalf in the written confirmation. The confirmation will also include a request to the applicant to submit its list of participants and any other outstanding documents to Swissmedic by two weeks prior to the date of the meeting at the latest. If the company has requested a video conference meeting, it will receive an e-mail containing a link for the video conference after it has provided its list of participants. Should it prove impossible to remedy any shortcomings within the time period specified in the letter, Swissmedic will reject the meeting request and provide reasons for its decision in writing.

2.2 Content of the Scientific GMDP Meeting

The meeting will only discuss the list of questions submitted by the applicant. If questions cannot be answered conclusively during the meeting, Swissmedic will provide a written response after the meeting.
If the applicant has further questions in advance of the meeting, it must contact the responsible licence assessor / inspector two weeks before the meeting at the latest.

2.3 Duration of the Scientific GMDP Meeting

The duration of the meeting should be appropriate for the number and scope of the questions and presentation. Meetings requested by companies usually last 1.5 hours to a maximum of 2.0 hours.

2.4 Procedure for Scientific GMDP Meetings

Scientific GMDP Meetings take place face-to-face at Swissmedic premises or by video conference. Meetings will be led by the responsible licence assessor / inspector from Swissmedic.

The agenda will follow the list of questions. The normal procedure for meetings will be as follows:

1) Welcome and brief introduction of participants
2) Request / reminder to company of its duty to keep minutes
3) Presentation of the key facts and background information by the applicant and explanation of the issue
4) Brief response by Swissmedic specialist representatives (if applicable)
5) Discussion
6) Conclusion with summary and definition of further action

2.5 Minutes

The applicant will draft minutes of the meeting in German or English using the template provided by Swissmedic. The outcomes and main points of the discussion should be summarised succinctly and concisely and cover the following:

- Date, duration and type of the meeting
- Names and positions of participants
- Summary of the positions of the applicant and Swissmedic on the GMDP issues and aspects discussed
- Further action

The applicant must send the draft minutes to Swissmedic in Word format by two weeks after the meeting at the latest. Swissmedic will normally review the minutes within two weeks, correct them or add comments, then return them to the applicant for finalisation. The minutes must reflect what was known at the time of the meeting. The applicant will then send the final, signed minutes to Swissmedic as a PDF document, which Swissmedic will then archive with the documents for the application.

3 Fees

Swissmedic will invoice the applicant for the costs incurred in connection with the meeting. The fee will be based on the administrative and scientific work involved. The fee will be invoiced in accordance with the Swissmedic Fees Ordinance (FeeO-Swissmedic; SR 812.214.5).

4 Changes compared to the previous version

- No changes, new document