Guidance document
Controlled Substances Company Meetings

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1 Introduction and objective

To support companies subject to the law, and in the interest of efficiency, Swissmedic organises meetings for licence holders or applicants for the mutual exchange of information and to clarify questions relating to requirements and procedure. This support is provided for companies in possession of, or in the process of applying for, an establishment licence issued by Swissmedic for the handling of controlled substances or the cultivation of cannabis for medical purposes.

The aim of these meetings is to clarify in advance issues relating to narcotics control by those subject to the law, in order to discuss regulatory aspects and solution strategies that fall within the remit of Swissmedic's Narcotics Division. Companies will then be able to factor in the information obtained during project implementation. However, the feedback obtained from Swissmedic during a Controlled Substances Company Meeting (company meeting) does not preclude further review of a submitted application.
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. The meetings can take place face-to-face at Swissmedic premises or virtually.

1.1 Objective

In this guidance document, Swissmedic lays out transparently for licence holders and applicants the rules and processes that are to be observed in connection with company 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 Narcotics Division held in connection with an issue relating to narcotics control. Possible issues arise from projects connected with an application for a new or amended establishment licence for the handling of controlled substances or for the cultivation of cannabis for medical purposes. Issues can also arise from legal obligations resulting from the establishment licence, if these fall within Swissmedic's remit.

The meeting provides a further opportunity to discuss questions with Swissmedic experts in addition to the existing option of discussing questions raised during a "Scientific GMDP Meeting" (Guidance document I-321.AA.01-A05e) or a "Meeting for applicants for authorisation procedures" (Guidance document ZL105_00_003_WL).

This guidance document covers the documents to be submitted, meeting preparation (decision on how the meeting is 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 company meeting must be submitted in writing to Swissmedic 4-8 weeks before the desired date using the form "Application_Controlled Substances Company Meeting" 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
- Intended participants from company:
- Details of establishment licence or whether an application for a new or amended establishment licence has been submitted
- Issue to be addressed by the company 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 or other Swissmedic divisions that have taken place or are planned
- Several suggested dates for the meeting (within 4-8 weeks of receipt of the application for a discussion) and the requested duration of the meeting (between 1 and 2 hours)
- Suggested form of the meeting: Face-to-face at Swissmedic (Freiburgstrasse 139, Bern) or video conference
- Language (German or English)
- Other mandatory documents (to be submitted by 2 weeks before the meeting at the latest):
  - Agenda and company presentation on the issue
  - Participants from company (if any changes have been made)
- Other optional documents:
  - Additional documentation and background information
  - Records of feedback from other authorities or Swissmedic divisions

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 company meeting can proceed from a subject matter perspective or whether the conditions for the 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 should be discussed in another setting (e.g. association), or is connected with a GMDP issue and should therefore be discussed in a "Scientific GMDP Meeting" (see Guidance document I-321.AA.01-A05e). 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 2-week 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.
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 2 weeks 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 an agenda and company presentation and any other outstanding documents to Swissmedic by 2 weeks prior to the date of the meeting at the latest. If the company has requested a video conference meeting, it will additionally receive an e-mail containing a link for participation in the video conference. 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 Controlled Substances Company 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 contact person from the Narcotics Division.

2.3 Duration of the Controlled Substances Company 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 from 1.0 to 2.0 hours.

2.4 Procedure for Controlled Substances Company Meetings

The company meetings take place face-to-face at Swissmedic premises, Freiburgstrasse 139 or by video conference. Meetings will be led by the responsible Swissmedic representative from the Narcotics Division.

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 form 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 issues and aspects discussed
- Further action

The applicant must send the draft minutes to Swissmedic in Word format by 2 weeks after the meeting at the latest. Swissmedic will normally review the minutes within 2 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 (either digitally or handwritten) 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, including preparation. 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).

Change history

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