Bundesamt für Sicherheit im Gesundheitswesen

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Guidance for Companies seeking National Scientific Advice by the Austrian Federal Office for Safety in Health Care (BASG) on the development of medicinal products

This guidance document is intended to provide applicants with detailed information on the operational procedure of National Scientific Advice (NASA) by the Austrian Federal Office for Safety in Health Care (BASG). Applicants are kindly requested to follow the recommendations provided below to enable an efficient and timely advice procedure.

1. Introduction

BASG offers National Scientific Advice to applicants, addressing scientific questions arising during the development of medicinal products. A NASA can be requested both before and after authorisation of a medicinal product. The following topics are in the scope of an advice procedure:

- Manufacturing and quality of medicinal products (chemical, pharmaceutical, biological development)
- Planning and execution of nonclinical trials (e.g., pharmacology, toxicology)
- Planning and execution of clinical trials
- Biostatistics
- Pharmacovigilance and risk management

2. General guidance

The basis for providing Scientific Advice are the Austrian Medicines Act (*Arzneimittelgesetz, AMG*) and applicable European and international directives and guidelines (e.g., EMA, EC, ICH) in their current version or, if relevant to the discussion, draft documents under revision by the scientific community or competent bodies.

BASG offers Scientific Advice in face-to-face discussion meetings. In addition to clearly specified questions, the applicant is requested to detail his position and to provide an up-to-date background documentation to support the issues of discussion (see also section 3.3).

During the Scientific Advice procedure, only questions that are accompanied by detailed study outlines or development programs will be discussed. Regulatory questions and questions as to whether specific study results are suitable to obtain marketing authorisation for the product in question, are outside the scope of the NASA process.

Also, please keep in mind that only questions submitted in advance can be discussed with during the meeting, which has a maximum duration of 2 hours. In the interest of the Applicant, the number and scope of the questions should therefore be adequate for discussion within a 2-hour time frame.

The Scientific Advice is associated with fees and will be offered subject to availability of resources at the time the questions are submitted. Follow-up Scientific Advice, i.e., advice given subsequent to previous advice on the same product or question, is in principle possible. A prerequisite for follow-up Scientific Advice is that new plans (e.g. updated study protocols) or new scientific knowledge have become available, thus justifying an additional advice procedure.

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3. Overview of the Scientific Advice procedure

	Applicant sends email including • Application form • List of Questions, including a justification of the Applicant's position, to the following email-address: scientificadvice@basg.gv.at.
Within 4 business days after receipt of documents	BASG • Validates the application • Checks for availability of resources and expertise • Prepares and mails a Letter of Agreement, including: ➢ Formal approval ➢ Notification of the earliest possible meeting date ➢ Notification of the latest possible date for the submission of the final dossier (i.e., complete documentation for review) ➢ Fee calculation
	• If applicable, Letter of Refusal
Within 5 business days after notification of meeting date	Applicant sends a scanned copy of the legally signed Letter of Agreement (confirmation of meeting date and acceptance of fee) • by email to: : scientificadvice@basg.gv.at
	• Alternatively, the applicant withdraws the request in writing.
3 weeks before the meeting at the latest	Applicant submits dossier • electronically (by email scientificadvice@basg.gv.at)
1 business day before the meeting at the latest	Applicant sends an electronic version of the presentation prepared for the meeting: • by email to: scientificadvice@basg.gv.at
Scientific Advice meeting with Applicant	Applicant • presents the questions
	'Question-by-Question' discussion during the presentation
Within 5 business days after the meeting	Applicant • prepares draft meeting minutes and • sends these to BASG/AGES by email: scientificadvice@basg.gv.at
Within 10 business days after receipt of the draft meeting	BASG / AGES experts • review the draft meeting minutes and prepare the final meeting minutes.

minutes	• email a copy of the final meeting minutes to the Applicant.

3.1. Application

All applications have to be made in writing (email to: scientificadvice@basg.gv.at).
The applicant is asked to use application form F_Z105_Antrag_NASA, which is available for download from https://www.basg.gv.at/en/medicines/prior-to-authorisation/national-scientific-advice/

Also, the applicant is asked to attach a List of Questions, including a justification of the applicant's position.

3.1.1. Application form

The following explanations might be helpful for completion of the application form:

Item 2	Name and further details of company/organisation/consortium applying for Scientific Advice
Item 5	If the application is submitted by a legal representative of the Applicant (e.g., a consultant), a letter of authorisation specific to the consultant and procedure in question should be submitted together with the complete dossier.
Items 6 and 7	If applicable, the Applicant is asked to attach any minutes from former advice procedures with other regulatory agencies. Also, please indicate whether available documents are in draft or final status.
Item 8	More than one box can be ticked.
Item 9	At the time of application, the ATC code and/or indication might not be unequivocally clear. In this case, provisional information should be provided.
Items 10 and 11	If the drug/product is approved inside or outside the EU, the Applicant is asked to attach (to the final dossier) a short summary of the approval status in each country and the wording of the approved indication(s).
Item 14	Please compile a list of all documents attached to the application form.

3.1.2. List of Questions

When submitting the application form, the applicant is asked to attach a document containing a List of Questions, including justifications of the applicant's positions. A template for this List of Questions is available for download from www.basg.gv.at/arzneimittel/vor-der-zulassung/nationale-wissenschaftliche-beratung. However, the applicant is free to choose another format.

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During validation of the application, the scope and number of questions will determine the further course of the advice procedure. First, a decision will be made whether the proposed set of questions provides a meaningful basis for the advice procedure. Second, the need for or availability of expertise will be evaluated internally, and a provisional date for the advice meeting will be chosen.

During the advice meeting, only questions actually contained in the List of Questions will be addressed. Should it become necessary to add to or change the set of questions after validation of the application, please contact BASG/AGES (scientificadvice@basg.gv.at) to discuss whether an updated version of the List of Questions may still be submitted for the scheduled advice meeting or whether the meeting should be postponed. Please note that, in the absence of a pre-meeting notification, any new information first presented during the Scientific Advice meeting cannot be taken into consideration.

Questions should be clear and specific, and one question should not mix different issues. The number of questions should be chosen in such a way that all issues can be covered in a 2-hour meeting.

The goal of the advice procedure is to discuss the plans and proposals submitted by the applicant. Therefore, each question should be accompanied by a summary of the plans and proposals developed by the applicant. In some cases, it may be useful to present alternative scenarios addressing a specific issue of the development process.

3.2. Letter of Agreement

Within 4 business days after receipt of the request for Scientific Advice, BASG will formally validate the application. Please note that a request for Scientific Advice can only be accepted subject to resources available at BASG/AGES. As a rule, requests for Scientific Advice will be dealt with in the order of receipt.

The applicant will be notified in writing on whether the application has been accepted or refused. Final acceptance of an application is subject to submission of the final dossier within the specified time frame.

A Letter of Agreement will be transmitted to the applicant. This letter will specify both a date for the Scientific Advice meeting and the latest acceptable date for submission of the final dossier. Furthermore, a fee calculation will be included (see also section 4).

The applicant is asked to send a scanned copy of the legally signed Letter of Agreement to BASG / AGES by email scientificadvice@basg.gv.at. By doing so, the applicant declares acceptance of the estimated costs of the Scientific Advice (see also section 4).

3.3. Dossier and List of Participants

The dossier should contain information needed to address the questions asked. The structure and content should be suitable to the questions submitted.

Content of the dossier:

- List of Questions, including the position of the Applicant (in WORD and PDF format)
- Background information on the drug substance/product and indication(s)
- Any relevant literature referenced in the dossier
- List of the Applicant's participants (including their functions)
- If applicable, minutes of Scientific Advice obtained from other competent authorities
- If applicable, relevant documents on the authorisation status of the drug substance/product in other countries
- If applicable, other relevant documents, e.g., study protocols
- If applicable, letter of authorisation (for applications submitted by a legal representative of the Applicant)

In case of changes to the list of participants after the application has been submitted, please inform BASG/AGES by email in a timely manner.

The dossier should be submitted electronically (by email: scientificadvice@basg.gv.at) no later than **3 weeks** before the agreed Scientific Advice meeting date.

3.4. Advice meeting at BASG/AGES

The advice meeting is scheduled for a maximum of 2 hours. The meeting will be chaired by a BASG representative.

After a round of welcome and introduction, the applicant shall give a presentation of the background and issues of the advice request. The presentation should be given in such a manner that sufficient time is available for discussion. Experience has shown that discussing each question immediately after it has been presented by the applicant is the most efficient approach ('question-by-question' principle).

The applicant is asked to submit the file for the presentation no later than one day before the advice meeting (email to scientificadvice@basg.gv.at).

It should be noted that, aside from BASG/AGES experts assigned to the project, BASG/AGES assessors or administrators not directly involved in the procedure may attend the advice meeting for training or information purposes. As a matter of course, all attending participants are bound to strict confidentiality.

3.5 Meeting minutes

The applicant is asked to prepare a draft version of the meeting minutes. To permit efficient finalisation of the advice procedure, the applicant is asked to email the draft in the form of an electronic MS Word file no later than 5 working days after the meeting to scientificadvice@basg.gv.at.

The meeting minutes should summarise both the discussion and the answers given by BASG/AGES representatives. There is no need to present the detailed course of the discussion.

The minutes should include: date, place and duration of meeting, name and contact details of applicant, name of product (if available), active ingredient, and a list of participants.

BASG will review the draft minutes and may change them as deemed appropriate to produce a final version of the meeting minutes. This final version will be sent to the applicant within 10 working days after receipt of the draft version. The Applicant will receive an electronic (PDF) version signed and dated of the final meeting minutes.

4. Fees

Each Scientific Advice requires payment of a fee. For the valid fee please refer to https://www.basg.gv.at/en/about-us/fees/ or http://www.basg.gv.at/en/about-us/fees/official-announcements.
If the advice meeting has to be cancelled for reasons attributable to the applicant or if the applicant fails to submit the final application in time, i.e., no later than 3 weeks before the Scientific Advice meeting, BASG shall be entitled to invoice for services already rendered.