Guidance for companies requesting scientific advice

This guidance document addresses a number of questions that users of the scientific advice procedure may have. Since September 2004 a new working party of the CVMP – the Scientific Advice Working Party (SAWP-V), has been set up in accordance with the requirements of the legislation, with the remit of providing scientific advice on any requests forwarded to it.

The guidance document provides an overview of the procedure to obtain scientific advice and gives guidance to applicants in preparing their request.

It will be updated regularly to reflect new developments and to include accumulated experience.

The Agency emphasises the importance of meetings with companies asking for scientific advice, especially in case of a first request for scientific advice. These scientific advice pre-submission meetings (which should take place at least 1-2 months prior to the anticipated date of submission of the request) are a vital opportunity for companies to obtain advice from the Agency on structure and content of the request as well as on procedural aspects, in order to maximise the benefits of the procedure.

Scientific advice pre-submission meetings will also enable companies to establish contact with the Agency staff closely involved with the request as it proceeds.

This guidance document explains the scope and nature of scientific advice.

It will enable companies to submit requests which are in conformity with the SAWP-V requirements and which can be validated speedily.

Furthermore, companies will be guided through the different steps of the procedure and receive important information for the preparation of a possible oral explanation to the SAWP-V.
Instructions for users

To obtain the information on a certain topic, simply click on the highlighted key word. We trust that the information, linked to the key word, answers most of your queries.

If you seek further information on any of the included topics and/or want to apply for a scientific advice pre-submission meeting please contact: VetScientificAdvice@ema.europa.eu

Note

It should be highlighted that this document has been produced for guidance only and should be read in conjunction with “The rules governing medicinal products in the European Union, Volume 6A, Notice to Applicants”.

- "Scientific advice to be given by the CVMP for veterinary medicinal products" (SOP/V/4016)
- Explanatory note on fees payable to the Agency (effective 1 April 2012) – see page 27 for veterinary scientific advice fees

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1. What is the legal basis/scope for the provision of scientific advice?

According to Regulation (EC) No 726/2004, one of the tasks of the Agency is, where necessary, advising companies on the conduct of various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products. Article 56(3) of Regulation (EC) No 726/2004 provides that the Committee for Medicinal Products for Veterinary Use (CVMP) shall establish a standing working party with the sole remit of providing scientific advice to undertakings.

Normally, advice is provided in the form of scientific guidelines which are already published on the Agency website at the following address: http://www.ema.europa.eu

It is the Committee for medicinal products for veterinary use (CVMP) responsibility to give scientific advice to industry by answering specific questions based on the documentation provided by the company in the light of the current scientific knowledge.

Scientific advice will be given by the CVMP based on the report and recommendations of the SAWP-V on questions concerning specific issues relating to the establishment of MRLs, the quality, the safety and clinical development of veterinary medicines.

Scientific advice is restricted to purely scientific issues. It covers the whole development process and can be used to provide advice on protocols for clinical trials. National Authorities throughout the EU however retain the competence to review trials on their territory and it should be remembered that there may be additional national requirements.

Regulatory aspects should be the matter of a separate request. The regulatory and administrative questions will be answered by the Agency secretariat directly (see pre-submission guidance for users of the centralised procedure, http://www.ema.europa.eu).

Scientific advice received from the Agency is valid throughout the EU, for all veterinary medicinal products irrespective of the route of authorisation (centrally or decentrally).

Companies seeking advice under Article 56 of Council Regulation (EC) 726/2004, as amended, must note that any advice given is not binding on the Agency with regard to any future marketing authorisation application of the product concerned but will be taken into account in the marketing authorisation.

References:

- Regulation (EC) No 726/2004
- Scientific advice to be given by the CVMP for veterinary medicinal products, (SOP/V/4016)
2. Is my medicinal product eligible for receiving scientific advice?

Scientific advice may be requested for all veterinary medicinal products, as defined in Directive 2001/82/EC, irrespective of eligibility for the centralised procedure or not.

It may also be requested regarding the establishment of maximum residue limits (MRLs) for pharmacologically active substances in accordance with Regulation (EC) No 470/2009, or even in respect to the question whether a substance would be pharmacologically active or not.

If companies are established outside the European Economic Area (EEA), it is advisable to nominate a contact point within the EEA to facilitate communication between the Agency and such companies.

References:

- Directive 2001/82/EC, as amended
3. When can a company request scientific advice?

What is the content of the request for scientific advice?

Scientific advice should be requested during the initial development of the medicinal product (before submission of the marketing authorisation application or the application for the establishment of MRLs), and also, during the post authorisation phase, principally where guidance is needed in selection and design of tests for product development and for general advice on the design of clinical trials.

Requests for scientific advice will not usually be accepted during assessment of the marketing authorisation application (e.g. if rapporteur/co-rapporteur are already appointed).

Scientific advice may be requested where a prospective applicant asks for interpretation of a scientific aspect of an existing guideline. Following the provision of scientific advice the CVMP may consider whether adjustments/modifications to existing guidelines are advisable. In cases where an applicant chooses to deviate in their development plan from existing guidance available (whether in the form of guidelines or Ph. Eur. monographs), it is also possible to seek scientific advice from the SAWP-V, provided a justification for such a request is forwarded.

The question(s) posed by the applicant should be as precise and clear as possible. Such question(s) should address specific scientific issues concerning:

- quality aspects (e.g. specific issues concerning tests to be performed during the development of chemical or biotechnological products);
- any safety aspect including establishment of MRLs and other safety related areas including consumer, environmental and operator safety;
- clinical aspects (specific issues concerning the clinical development programme, e.g. endpoints, trial duration, target population, choice of comparator etc.).

The questions should be prospective and concern the future development of a medicinal product. Each question should be formulated in such a way that it would be readily comprehensible when read in isolation. The applicant should indicate their intended path, along with the justification for this, taking into account guidance where available. SAWP-V will then, in the response, provide a justification for their position also whether in agreement or not with the applicants position. Questions should not ask for general advice normally, for example, to how to design a study but should show how the applicant intends to design the study and their justification for the choices made. Scientific advice is not a pre-assessment of studies already conducted to be included in a proposed marketing authorisation.

The scientific advice is restricted to scientific issues and purely regulatory aspects will therefore be dealt with separately (see pre-submission guidance for users of the centralised procedure, http://www.ema.europa.eu). It is understood that scientific issues and regulatory aspects may be linked and consequently responses may be provided at the same time.

References:

- Regulation (EC) No 726/2004
- Regulation (EC) No 470/2009
- The rules governing medicinal products in the European Union, volumes 6A and 8, Notice to Applicants
- Scientific advice to be given by the CVMP for veterinary medicinal products, (SOP/V/4016)

4. What is the structure of the request for scientific advice?
The request (one electronic or hard copy) should be presented as follows:

- Cover letter as template for letter of intent published on the Agency website - to be submitted as a word file
- Questions + company’s position (in word format)
- Annexes (references other supporting data)

4.1 The template for the letter of intent includes

- name of company
- contact person details
- description of the product or substance
- invented name (if available)
- INN
- company’s code
- pharmacological classification (ATCvet code)
- eligibility for centralised procedure as appropriate
- type of request: quality/safety (including MRLs)/pre-clinical/clinical
- initial/follow-up
- payment of fees details
- justification for request (e.g. no guidance available, new area of development)
- intended indication
- mention of previous scientific advice received (national EU authorities, other relevant international authorities)
- detailed table of contents
- type of request e.g. new or follow-up or for (minor use minor species) MUMS/Limited markets
- SME status if applicable

4.2 The questions are ordered to address specific scientific issues (quality/safety/clinical issues/MRL)

Each question is followed by the company’s position and justification(s), together with cross-references to the relevant parts of the annexes.
4.3 The annexes include

- background information (product profile, investigators’ brochure)
- information relating to the questions (e.g. relevant study protocols – as detailed as possible)
- bibliographical data (references)
- content of previous scientific advice received (national EU authorities, other relevant international authorities)
- relevant guidelines (other than CVMP guidance documents)
- contract agreement when the request is submitted by a consultant on behalf of the company
5. **What are the fees for scientific advice?**

HAVING REGARD to Council Regulation (EC) No 297/95 on fees payable to the Agency, as amended by Council Regulation (EC) No 2743/98, Commission Regulation (EC) No 494/2003 and Council Regulation (EC) No 1905/2005, and in particular Article 11(1) and (2) thereof, on fees payable to the Agency and following the adoption of the Implementing Rules by the Agency Management Board (EMEA/MB/356866/05), the Agency is applying the fees as published on our website:


The following definitions shall apply for the determination of fees:

1. **quality development**: chemical, pharmaceutical and biological testing.

2. **safety development**: toxicological and pharmacological tests including establishment of MRLs.

3. **clinical development**: studies in animals, including clinical pharmacological trials designed to determine the efficacy and safety of the product, for the target animal.

4. **initial request**: request for scientific advice introduced prior to the submission of an application for marketing authorisation.

5. **follow up to initial request**:
   - request to reconsider the advice already given in the light of new information available to the applicant or
   - requests for advice after the marketing authorisation has been granted.

6. **MUMS dossier requirements**:

   For assessing compliance of a proposed data package with relevant guidelines on data requirements for veterinary medicinal products intended for minor uses or minor species.

The ranges and classification that shall apply for fees for scientific advice related to medicinal products for veterinary use are published on the Agency’s website. Fees can change and applicants are advised to check the website for current fee levels.

**Scientific advice fees - MUMS/limited markets**

Free scientific advice may be granted in respect of supporting the research and development of veterinary medicinal products destined for MUMS/limited markets. Products that are classified by CVMP as intended for MUMS/limited markets with the financial incentives announced are given free scientific advice. Financial incentives are given to support products where no alternative product is authorised for that specific indication in a particular species and the market is considered to be limited. Requests for classification may be submitted to CVMP by completing the template on the Agency website and full details of the policy are also published.


**Note**

Fees for scientific advice will be invoiced by the Agency to the applicant, at the address detailed in the template for the letter of intent as received, once the application is started. No fees are requested prior to validation of the request.
6. How and to whom shall I submit my request for scientific advice?

Dates of SAWP-V meetings?

If no scientific advice pre-submission meeting was requested, the SAWP-V secretariat should be notified about the intent to submit a scientific advice at least one month before the anticipated date of submission.

The deadline for receiving the complete request (structure and content according to SAWP-V requirements) at the Agency is **15 days** before the start of the SAWP-V meeting (minimum two weeks before the CVMP week). The date should be confirmed in advance with the SAWP-V secretariat. The SAWP-V meets on the first day of the CVMP meeting each month apart from August.

However companies are invited to submit, if possible, their request at an earlier stage. This enables a possible revision of the request, which might be necessary following the validation performed by the SAWP-V secretariat, before the deadline has expired.

The complete request should be forwarded to the Agency electronically via email, Eudralink or as a paper copy. For electronic submissions there is no requirement to submit a paper copy.

The request should be **mail to**: vetscientificadvice@ema.europa.eu

The secretariat of the SAWP-V will be in charge of validation and processing of the request. The secretariat will be the contact point for the applicant for any discussion concerning the validation of the request and questions concerning the procedure for obtaining scientific advice. A project manager will be appointed once the application is validated and that person is in charge of managing the scientific advice procedure and will be the contact point for applicants for any questions related to the planned/ongoing procedure.

Following the SAWP-V meeting the applicant will be informed of the appointment of the co-ordinator and the project manager, (applicants will receive the co-ordinator's contact details together with the timetable for the procedure).
7. How shall my request be validated?
The request for scientific advice is validated by the secretariat with regard to

- SAWP-V receipt of the complete request within the required deadline (see also "How and to whom shall I submit my dossier")
- structure and content of request (according to SAWP-V requirements)

If one of these criteria is not according to requirements set out in this pre-submission guidance, the request will not be validated and shall be postponed.

**Once the first stage of the validation is completed, the request will be forwarded to SAWP-V members 2 weeks prior to the start of the SAWP-V meeting.**
8. What is the procedure for providing companies with scientific advice (timetable)?

The scientific advice provided to companies is the result of a collegial work from the co-ordinator, the SAWP-V experts, and the CVMP. The draft report is prepared by the co-ordinator and may then be submitted to relevant CVMP working parties for comments, if appropriate, and finally to the CVMP for adoption.

At the end of the validation of the request for scientific advice by the SAWP-V secretariat, the following steps shall be taken for evaluation of the request:

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<th>Days (no working days)</th>
<th>Action</th>
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<tr>
<td>D-15 (Monday, two weeks before start of the SAWP-V)</td>
<td>Deadline for submission of the complete scientific advice request. Date to be confirmed with SAWP-V secretariat.</td>
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<tr>
<td>D-14</td>
<td>The validated scientific advice request is forwarded by the SAWP-V secretariat to the SAWP-V members.</td>
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<tr>
<td>D 0 (SAWP-V)</td>
<td>The SAWP-V formally accepts the request for scientific advice. A co-ordinator is appointed from among the members of the group. The co-ordinator may appoint other experts to assist in the procedure. The timetable is agreed.</td>
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<tr>
<td>D+20 (One week before the SAWP-V)</td>
<td>The co-ordinator sends the first report to the SAWP-V secretariat (Note: this report is not made available to the applicant). The report is forwarded for comments to the SAWP-V members and the relevant working parties, if appropriate on the recommendation of the co-ordinator.</td>
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<tr>
<td>D+30 (SAWP-V)</td>
<td>The first report of the co-ordinator is discussed in the SAWP-V. The SAWP-V decides at this stage, whether it is necessary to invite the applicant for an oral explanation on whether further clarification is necessary. The advice may be adopted by SAWP-V on D+30 and forwarded to CVMP for consideration.</td>
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Two scenarios are possible:

**Scenario I (SAWP-V decides that an oral explanation is necessary)**

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<th>Days</th>
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<td>D+30 (SAWP-V)</td>
<td>A list of issues to be clarified by the applicant at the oral explanation is adopted and sent to the applicant.</td>
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<tr>
<td>D+60 (SAWP-V)</td>
<td>The oral explanation of the applicant to the SAWP-V.</td>
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<tr>
<td>D+75 (15 days prior to the SAWP-V)</td>
<td>The co-ordinator sends the revised report to the SAWP-V secretariat (Note: this report is not made available to the applicant). The report is forwarded by the secretariat for comments to the SAWP-V members and the experts, who were nominated by the co-ordinator to participate in the oral explanation.</td>
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<tr>
<td>D+90 (SAWP-V)</td>
<td>The revised co-ordinator’s report is discussed by the SAWP-V. The advice letter, prepared by the secretariat, to be sent to the applicants adopted by the CVMP, and sent to the applicant immediately following the CVMP meeting.</td>
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Scenario II (SAWP-V decides that there is no need for an oral explanation)*

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<td><strong>D+45</strong></td>
<td>The co-ordinator sends the draft report to the SAWP-V secretariat (Note: this report is not made available to the applicant). The report is forwarded by the secretariat for comments to SAWP-V members.</td>
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| **D+60**     | The revised co-ordinator’s report is discussed by the SAWP-V.  
               | The final advice letter to be sent to the applicant is adopted by the CVMP at the meeting immediately following the SAWP-V meeting and sent to the company immediately following the CVMP meeting. |

* Clarification in writing can be sought from the company at D+30 in which case responses are required.

Scientific advice will usually be given on either D+30 or D+60 of the procedure. The timetable is agreed at the start of the procedure based on the complexity of the questions asked and the need to involve other working parties/experts. Where the applicant has requested parallel scientific advice with the FDA/other regulatory authorities, this will be taken into account in the timetable for the procedure and is more likely to extend to 90 days.

The SAWP-V secretariat will forward the final advice letter, signed by the Chair on behalf of the CVMP, to the applicant by mail (signed copy) and electronically following the CVMP meeting.
9. What is the procedure for appointment of a co-ordinator?

What is the role of such a co-ordinator?

Will the co-ordinator be the rapporteur for a subsequent centralised marketing authorisation application or application for the establishment of MRLs?

At the start of the procedure (day 0) (see also "timetable for obtaining scientific advice"), a co-ordinator will be appointed.

In order to ensure a fair repartition of the workload a procedure for allocations of requests for scientific advice to co-ordinators has been put in place, which is comparable with the procedure for the appointment of rapporteurs and co-rapporteurs in the centralised procedure and establishment of MRLs.

In regard to the appointment of such co-ordinators applicants are asked not to express their preferences regarding co-ordinator; appointments are based solely on availability of appropriate expertise and equal opportunity.

The Agency has a policy on the handling of conflicts of interests for its scientific experts, including committee members. Experts can only be involved in the Agency’s activities if they have signed a declaration of interests form and the Agency has assessed his or her interests. All proposed members for its scientific committees have their declarations of interests screened before their formal nomination.

The appointment of rapporteurs/co-rapporteurs for subsequent centralised and MRL applications is decided separately from any previous appointment of scientific advice co-ordinators. Rapporteurs are appointed by CVMP based on available expertise and experience and may or may not be the same person as the co-ordinator for the scientific advice. However the recommendations of the scientific advice procedure will be taken into account. A copy of any scientific advice given is included in the marketing authorisation.

Following the SAWP-V meeting, the applicant will receive a letter indicating the name of the appointed co-ordinator and the responsible Secretariat contact point for correspondence.

The SAWP-V secretariat is the contact person for the applicant in all matters related to the procedure and should be informed about any direct interaction, or correspondence between the applicant and the co-ordinator.

What is the role of the Co-ordinator?

Additional experts may be nominated by the co-ordinator and (in some cases) nominated by other SAWP-V members. A network of experts ensures that the adequate experts are available to participate in the scientific advice procedure, including attendance at oral explanations.

The co-ordinator is responsible for the provision of reports in response to the scientific advice requests taking into account the timetable for evaluation of such requests. These reports are considered as working documents only and will not be released to applicants. If necessary, the co-ordinator may ask the applicant for any additional documents or clarification where on review additional information is needed to reach a conclusion.

The co-ordinator will compile questions and comments from the SAWP-V and other CVMP Working Parties where appropriate.

The co-ordinator will propose to the SAWP-V to hold an oral explanation with the applicant and will draft the list of issues. The oral explanation will be chaired by the co-ordinator.
10. How do I prepare for an oral explanation?

At D+30 or (+60) of the scientific advice procedure (see also “timetable for obtaining scientific advice”) the SAWP-V will discuss the co-ordinator’s first report. It will be decided at this stage, whether it is necessary to invite the company for an oral explanation.

The applicant may request an oral explanation in the initial request for scientific advice. In general such requests will be granted. However, the decision to invite the applicant will be made by the SAWP-V on a case by case basis following the identification of outstanding issues which need to be clarified by the company.

A detailed list of issues (including pertinent background information reflecting the SAWP-V discussion) to be clarified by the applicant during the oral explanation will be adopted (D+30) and sent to the applicant following the SAWP-V meeting, together with the invitation and the draft meeting agenda.

The list of questions is divided in two categories:
- issues to be dealt with as a priority during the oral explanation;
- points for clarification to be answered in writing by the applicant prior to the oral explanation.

The oral explanation will always take place at the EMEA, usually at D+31 or D+61, during the SAWP-V meetings.

The applicant will be informed of the exact timing 15 days before the oral explanation.

Applicants should ensure at the beginning of the scientific advice procedure, that, in case they are invited for an oral explanation, their relevant experts will be available in order to participate in such meetings.

The applicant will be asked to provide a list of participants 10 days prior to the oral explanation and inform the secretariat about the technical requirements for the presentation.

Applicants are requested to send to the secretariat copies of all relevant visual materials they intend to present not later than two days before the meeting.

In most cases, there will be a 30-40 minute discussion with the applicant (including the presentation given by the applicant). This is usually be preceded by an internal expert meeting.

All participants will be introduced by the chairman of SAWP-V.

Applicants are advised to restrict their presentation to a maximum of 20 minutes in order to allow sufficient time for discussion with the group.

The presentation should focus exclusively on the outstanding issues.

Following the meeting with the applicant, there will be usually an internal debriefing meeting (up to 15 minutes) in order to further discuss areas, where divergent views were expressed and to draw conclusions.

The applicant will be asked to remain available in the Agency premises until the end of the debriefing meeting in case further points (mainly procedural) have to be clarified or agreed.
11. Is the Scientific Advice given binding?

Applicants seeking scientific advice under Article 56(3) of Council Regulation (EEC) No 726/04, as amended, must note that any scientific advice given is not legally binding with regard to any future clinical trial approval or marketing authorisation application of the product concerned, neither on the Agency/CVMP nor on the applicant.

The answer given by the CVMP is based on the question and documentation submitted without prejudice to evolution and state of the art developments and the subsequent opinion of the CVMP. This sentence is repeated in each advice letter sent to the company.

Furthermore, companies should note that the advice provided is without prejudice to applicable legislation relating to the particulars and documents, which must be submitted in support of a marketing authorisation application or an application for the establishment of MRLs. It is also without prejudice to any intellectual property rights of third parties.

When providing scientific advice, the SAWP-V does not pre-empt the outcome of the evaluation of any subsequent marketing authorisation application or application for establishment of MRLs. However, recommendations given by the CVMP in any scientific advice procedure will be taken into account in the assessment of any future applications. Details of any scientific advice given are included in the dossier at submission for a marketing authorisation.

Advice will be given in good faith but circumstances could change especially in the case of early advice or subsequent scientific developments. In some cases, e.g. as a result of scientific developments, an alternative approach to that advised may be appropriate.

In this case it is recommended to companies to request a follow up to the initial scientific advice given.

However where companies choose not to apply the advice, they are requested to clearly justify their position in the expert report of any subsequent marketing authorisation application or application for establishment of MRLs.

Likewise the CVMP will provide argumentation during the evaluation of the marketing authorisation application or application for establishment of MRLs when diverging from its position following the provision of scientific advice.
12. Is clarification or a follow up of the advice possible?

In general, applicants are encouraged to keep the SAWP-V secretariat informed about the status of the development of a product, for which scientific advice has been issued.

**Request for clarification:**

In the event that applicants feel that part of the advice provided is not readily comprehensible without further explanation, it is possible to ask for clarification. This also applies in case the applicant feels that the advice given does not reflect the request put forward by the applicant initially. This should be done in writing preferably within 6 months, addressed to the secretariat with copies to the co-ordinator. The co-ordinator will draft a reply to be endorsed by the SAWP-V and also by CVMP prior to sending the response to the applicant. The secretariat will keep a record in the file. The quality and extent of advice given will be dependent in part on the detail and clarity of the questions submitted in the original application. Informal contact with the co-ordinator may be foreseen within the boundaries of the scientific advice procedure to allow the applicant to clarify minor points.

There is no fee involved in this request.

**Request for follow up:**

Companies may ask for a "follow up" to the initial request for scientific advice.

A follow up to the initial request can be requested

- to reconsider the scientific advice or part of the scientific advice already given in the light of new information available to the company following completion of studies

  or

- after a marketing authorisation has been granted.

When submitting a follow up to the initial request for scientific advice, the applicant should make reference to the previous scientific advice received and highlight the issues to be considered.

The applicant will be asked to forward new information and all supporting documents in accordance with the SAWP-V requirements regarding structure and content of the scientific advice request (documents already submitted at the time of the initial request do not have to be included in the follow up request).

The applicant should submit the request for a follow up to the initial request within the required deadline: receipt of request at the Agency at D-15 (two weeks before start of the SAWP-V meeting). The date should be confirmed with the SAWP-V secretariat.

The fees for a follow up request are given in the reply to question 5 of this document and are published on the Agency website.

Fees will be invoiced once the procedure has started.

The procedure (timetable) in place for provision of a follow up scientific advice follows in theory the same as the procedure for the initial request.

If necessary, the applicant will be invited for an oral explanation.
The appointment of the co-ordinator for the follow up request is made independently from the appointment of the co-ordinator for the original request and therefore, such co-ordinator may not be the same as for the initial request.

The requests will be allocated to SAWP-V members according to availability of appropriate expertise and equal opportunity.
13. Will scientific advice be published?

Link between scientific advice and European Public Assessment Report (EPAR)

Scientific advice given by the CVMP for a medicinal product is considered confidential and will not be made public. However, following each CVMP meeting, a reference to any scientific advice adopted by the Committee is published in general terms in the CVMP press release. Once a marketing authorisation has been issued by the European Commission for any veterinary product assessed under the centralised procedure an EPAR is published which may contain reference to areas where scientific advice has been given and an indication of whether this advice has been followed or not.

The SAWP-V will monitor the scientific advice requests to identify where new guidelines or an update of earlier guidelines are needed. They will forward these recommendations to CVMP.

The CVMP will decide on the need for the development of general guidance to industry in form of notes for guidance etc. for certain scientific areas where scientific advice is frequently requested.
14. When and how shall I ask for a pre-submission Scientific Advice meeting?

The SAWP-V emphasises the importance of meetings with applicants, especially in case of a first request for scientific advice.

Pre-submission scientific advice meetings are a vital opportunity for applicants to introduce their proposed requests and to discuss the possibility of asking for scientific advice in different areas.

Advice can be obtained on how to identify and present the questions to be included in the request for scientific advice with a view to obtaining satisfactory answers.

More detailed information, not yet addressed in this guidance document, can be obtained regarding e.g.:

- content of the request for scientific advice (scope of questions);
- structure of the request (separating regulatory/scientific issues);
- all questions concerning the procedure for obtaining scientific advice (see timetable).

Pre-submission scientific advice meetings will also enable applicants to establish contact with the SAWP-V secretariat closely involved with the application as it proceeds.

Pre-submission scientific advice meetings can take place at any time during the development, but should take place at least 1-2 months prior to the anticipated date of submission. Pre-submission meetings may be also requested with the SAWP-V. These meetings with the SAWP-V at their monthly meetings, will solely address scientific matters and are reserved for particularly novel requests where such a meeting would be mutually beneficial to discuss an application prior to submission.

There are no fees for these meetings.

Applicants are requested to send a meeting request together with relevant background information (issues to be discussed, draft product profile, overview of the development plan, proposed attendees etc.) to the following contact point at least 3 weeks before the anticipated SAWP-V meeting date:

vetscientificadvice@ema.europa.eu
15. What is the procedure for requesting parallel scientific advice with the FDA/other regulatory authorities?

Parallel scientific advice between the Agency/FDA/other regulatory authorities may be requested by the applicant. Requests should be made at the time of initial submission and the applicant is responsible for liaising with both authorities in relation to their individual submission dates in order that the final scientific advice may be finalised in a similar timeframe. The SAWP-V will make every effort to ensure that its timetable is followed and that the advice is given within a maximum of 90 days.

For these requests please contact the SAWP-V secretariat directly giving an overview of the request to be submitted along with the status in the other regulatory authority. The Agency will then liaise with the other regulatory authority to propose a suitable timeframe for the request. Separate reports will be provided by each regulatory authority clearly indicating where agreement has been reached and where differences remain due to regulatory/legal/other requirements in a region.
16. How to request a fee reduction for Small and Medium-Sized Enterprises (SME)?

Pursuant to Article 70.2 of Regulation (EC) No 726/2004 of 31 March 2004, SMEs are eligible for fee reductions, fee deferrals and conditional fee exemptions in accordance with Regulation (EC) No 2049/2005 of 15 December 2005. This includes fee reductions for scientific advice. There is also the possibility to defer payment of the fees payable for the application for marketing authorisation and pre-authorisation inspections, and receive a conditional fee exemption where scientific advice has been given and the application for marketing authorisation is not successful (i.e. does not result in the grant of a marketing authorisation).

It should be noted that fee reductions can only be considered once the applicant has been assigned SME status by the Agency. Successful SME applicants wishing to request a fee reduction should address a letter of intent (by email to smeoffice@ema.europa.eu) to the SME Office. This request for a fee reduction should be submitted as early as possible, at least 2 weeks in advance of the request for scientific advice. There is no need to provide the full request to the SME office.

Where an SME applicant could, in respect of the same fee, also benefit from other reductions provided for in Community legislation, the provisions which are most favorable to the applicant will apply. Cumulative fee reductions for a given fee and a given applicant will not be accepted.

Further information on the level of fee reductions available to SME applicants and how to apply for SME status and submit a letter of intent for requesting fee reductions for fee reduction is provided on the Agency website.


SME status must be in place at the time of validation of the request for the fee incentives to apply. They cannot be applied retrospectively.