



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 October 2020
EMA/CVMP/11887/2020
Veterinary Medicines Division

Guidance for applicants requesting scientific advice

Introduction

The Scientific Advice Working Party (SAWP-V) of the Committee for Medicinal Products for Veterinary Use (CVMP) 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.

Scientific advice is available to applicants including commercial enterprises, research organisations and academics to support veterinary medicinal product development. The guidance document provides an overview of the procedure to obtain scientific advice and gives guidance to applicants in preparing their request. Its aim is to enable applicants to submit requests which are in conformity with the SAWP-V requirements.

If you seek further information on any of the included topics, please send an email to vetscientificadvice@ema.europa.eu.

It should be highlighted that this document has been produced for guidance only and should be read in conjunction with applicable policies and legislation.

References and useful links

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004;
- Directive 2001/82/EC of the European Parliament and of the Council of November 2001;
- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC;
- Mandate, objectives and rules of procedure for the CVMP Scientific Advice Working Party (SAWP-V) (EMA/CVMP/SAWP/676117/2010);
- Standard operating procedure on Scientific advice to be given by the CVMP for veterinary medicinal products (SOP/V/4016);

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



- Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the Agency, as amended by Council Regulation (EC) No 2743/98 as amended;
- Commission Regulation (EC) No 2049/2005 of 15 December 2005;
- Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals - Preliminary risk profiling for new antimicrobial veterinary medicinal products (EMA/CVMP/CHMP/682199/2017) (https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/answer-request-european-commission-updating-scientific-advice-impact-public-health-animal-health-use_en-0.pdf);
- Explanatory note on fees payable to the European Medicines Agency (<https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency>).

Questions

1. What is the [legal basis/scope](#) for the provision of scientific advice?
2. Is my veterinary medicinal product [eligible](#) for receiving scientific advice?
3. [When](#) can an applicant request scientific advice?
4. What is the [content](#) of the request for scientific advice?
5. What is the [structure](#) of the request for scientific advice?
6. When and how can I ask for a scientific advice [preparatory meeting](#)?
7. What are the [fees](#) for scientific advice and when should they be paid?
8. How and when shall I [submit](#) my request for scientific advice?
9. What is the procedure for requesting [parallel scientific advice](#) with the FDA?
10. How shall my request be [validated](#)?
11. What is the procedure for appointment of a [coordinator](#) and what is the [role](#) of the coordinator?
12. What is the [procedure](#) and timetable for providing applicants with scientific advice?
13. How do I prepare for an [oral explanation](#)?
14. Is the given scientific advice [binding](#)?
15. Is a [clarification](#) or a [follow-up](#) to scientific advice possible?
16. Will scientific advice be [published](#)?
(Link between scientific advice and [European Public Assessment Report \(EPAR\)](#))
17. What is the procedure for requesting [preliminary risk profile](#) (PRP) assessment for new antimicrobial veterinary medicinal products?

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 applicants 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 CVMP shall establish a standing working party with the sole remit of providing scientific advice to undertakings.

CVMP is responsible to give scientific advice to industry by answering specific questions based on the documentation provided by the applicant in the light of the current scientific knowledge.

CVMP gives scientific advice 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 efficacy/clinical development of veterinary medicines, as well as bioequivalence studies for generic medicinal products and a Preliminary Risk Profile (PRP) assessment for new antimicrobial veterinary medicinal products.

Scientific advice is restricted to purely scientific issues. It covers the whole development process and can be used to provide general advice on protocols for clinical trials. However, national competent authorities throughout the EU 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 the users of centralised procedure at <https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/veterinary-pre-submission-qa-introduction>).

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

Applicants 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 evaluation of marketing authorisation application.

Advice is also provided in the form of scientific guidelines which are published on the Agency website.

2. *Is my veterinary medicinal product eligible for receiving scientific advice?*

Scientific advice may be requested for any veterinary medicinal product, as defined in Directive 2001/82/EC (and from 28 January 2022 in the Regulation (EU) 2019/6), irrespective of eligibility for the centralised procedure.

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 included in the veterinary medicinal product would be pharmacologically active or not and therefore requiring or not an MRL evaluation (in case of veterinary medicinal products intended for food-producing animals).

Moreover, preliminary risk profile (PRP) assessment of new antimicrobial or antimicrobial veterinary medicinal products can be requested through the scientific advice procedure (please see section 17 for more details).

If applicants 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 applicants.

3. When can an applicant request scientific advice?

Scientific advice can be requested during the initial development of the veterinary medicinal product (usually before submission of the marketing authorisation application or an application for the establishment of MRLs) or during the post-authorisation phase, where guidance is needed e.g. in selection and design of tests for product development, and for general advice on the design of clinical trials.

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 the available guidance (whether in the form of guidelines or Ph. Eur. monographs), it is also possible to seek scientific advice from the SAWP-V, provided that a justification for such a deviation is supplied.

4. What is the content of the request for scientific advice?

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

- quality aspects (e.g. specific issues concerning tests to be performed during the development of any veterinary medicinal product);
- safety aspects (e.g. establishment of MRLs and other safety-related areas including consumer, environmental and user safety);
- clinical aspects (specific issues concerning the clinical development programme, e.g. endpoints, trial duration, target population, choice of comparator, target animal safety);
- bioequivalence studies for generic medicinal products;

A request to the SAWP-V can also be made for preliminary risk profile assessment of new antimicrobial or antimicrobial veterinary medicinal products.

The questions should be prospective, i.e. 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 conjunction with the corresponding *Applicant's position*. The applicant should indicate their intended path, along with the justification for this, taking into account guidance where available. In response, SAWP-V will provide a statement whether it is in agreement or not with the applicant's position, and it will also provide a justification for their position. Questions should not ask for general advice, for example 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 and intended to be included in a marketing authorisation application.

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

5. What is the structure of the request for scientific advice?

The request (one electronic copy) should be presented as follows:

- *Request for Scientific Advice (SA)* form, including questions and the Applicant's position (template published on the Agency website), to be submitted in Word format;
- Annexes (references, product profile, (draft) study protocol(s), study reports or other supporting data), as applicable. PDF format is preferred.

The questions should be ordered to address specific scientific areas (quality/safety/MRL/clinical development/bioequivalence/preliminary risk profile).

Each question should be followed by the applicant's position. Relevant concise justification of the position should be provided. However, extensive amount of information from reference documents (e.g. draft study protocols, study reports, etc.) should not be included in the request, but provided as annexes.

The annexes can include (as applicable):

- Letter of Authorisation (mandatory, if the request is submitted by a consultant on behalf of the applicant)
- Background information (e.g. product profile, draft SPC)
- Information relating to the questions (e.g. relevant study protocols – as detailed as possible)
- Bibliographical data (references)
- Content of previous scientific advice received (from the national competent authorities in the EU or other relevant international authorities)
- Relevant guidelines (but no need to provide copies of CVMP guidance documents).

6. When and how can I ask for a scientific advice preparatory meeting?

The SAWP-V offers *scientific advice preparatory meetings* with applicants (please note these meetings are different from the *pre-submission meetings*). Applicants requesting scientific advice for the first time may find this option especially useful. Scientific advice preparatory meeting is an opportunity for applicants to introduce their proposed scientific advice request and to obtain advice on how to identify and present their questions in such a way as to obtain optimal answers.

More detailed information can be provided on e.g.:

- scope of questions in the request for scientific advice
- structure of the request (separating regulatory and scientific issues)
- all questions concerning the procedure for obtaining scientific advice.

It is recommended that scientific advice preparatory meeting takes place approximately 1 month prior to the intended date of submission of a scientific advice request.

There are no fees for these meetings.

Applicants can request preparatory meeting using the electronic submission form in IRIS (*Procedural information* section) and specify their preferred week for the meeting. In such a case please upload the proposed list of issues/topics to be discussed and the list of proposed attendees (mandatory), and any relevant background information (optional; e.g. draft product profile, overview of the development plan, presentation slides, etc.) in the *Documents from Applicant* section of the electronic submission form in IRIS.

7. What are the fees for scientific advice and when should they be paid?

Full details on all fees, classification and reductions that shall apply for fees for scientific advice related to veterinary medicinal products are published on the Agency website

(<https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency>).

Fees can change and applicants are advised to check the website for current fee levels. Fees for scientific advice will be invoiced by the Agency to the applicant, to the address recorded in the IRIS system, once the validation is complete. No fees are requested prior to validation of the request.

Scientific advice fees - MUMS/limited market and SME applicants

Free scientific advice may be granted to support research and development of veterinary medicinal products destined for minor use/minor species (MUMS)/limited market. Products that are classified by CVMP as intended for MUMS/limited market with the financial incentives announced are given free scientific advice. Financial incentives are given to support development of products for food-producing species where no alternative product is authorised for that specific indication in a particular species and the market is considered to be limited. Full details of the policy and further guidance on how to request such classification are published at <https://www.ema.europa.eu/en/veterinary-regulatory/research-development/minor-uses-minor-species-limited-markets>.

Financial support is available to applicants with assigned SME status by EMA according to Commission Regulation (EC) No 2049/2005 of 15 December 2005, including fee reduction for scientific advice.

Where an applicant could, in respect of the same fee, benefit from both reductions from MUMS and SME incentives, the provisions which are most favourable to the applicant will apply. Cumulative reductions for a given fee and a given applicant will not be accepted. Further guidance on requesting SME registration and related incentives is available on the Agency website (<https://www.ema.europa.eu/en/human-regulatory/overview/supporting-smes>).

MUMS/limited market and/or SME status must be in place at the time of submission of the SA request for the fee incentives to apply. They cannot be applied retrospectively.

8. How and when shall I submit my request for scientific advice?

If no scientific advice preparatory meeting was requested, the deadline for receiving the complete request (structure and content according to SAWP-V requirements) at the Agency is **22 working days** before the start of the SAWP-V meeting at which the applicant would like the SA procedure to start. The SAWP-V usually meets one day before or on the first day of the CVMP meeting each month apart from August. The dates of CVMP meetings can be found at

https://www.ema.europa.eu/en/documents/other/cvmp-meeting-dates-2019-2020-2021_en.pdf.

Please be aware that the deadline for submission of SA request may be affected by EMA holidays (<https://www.ema.europa.eu/en/about-us/contact/business-hours-holidays>).

However, applicants are invited to submit, if possible, their request at an earlier stage. This provides more time for possible revision of the request, which might be necessary for the request to pass the validation.

Scientific advice requests are made through EMA's secure online regulatory & scientific information management platform, IRIS (<https://iris.ema.europa.eu/>). After logging in, press on the button "Create new submission" and, after choosing the applicant type and providing information about the applicant, in the *Submission Type* text field select either "Initial Scientific Advice – Veterinary" (for initial SA requests) or "Follow up Scientific Advice – Veterinary" (for follow-up SA requests). More information on the use of IRIS can be found on the IRIS homepage, <https://iris.ema.europa.eu/>.

The *Scientific advice request template*, found on <https://www.ema.europa.eu/en/veterinary-regulatory/research-development/scientific-advice>, should be completed and then uploaded in the *Documents from Applicant* section of the electronic submission form in IRIS.

The SAWP-V secretariat (vetscientificadvice@ema.europa.eu) will be the contact point for prospective applicants' general questions concerning the procedure for obtaining scientific advice. After the SA request has been submitted, communication between SAWP-V secretariat and the applicant in relation to that request will take place via IRIS.

9. What is the procedure for requesting parallel scientific advice with the FDA?

The applicant may request parallel scientific advice from EMA and FDA. Requests should be made at the time of initial submission of a request for scientific advice and the applicant is responsible for liaising with both authorities in advance 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 submit your SA request to EMA the usual way, using IRIS (please see section 8 above) and notify the SAWP-V secretariat by email (vetscientificadvice@ema.europa.eu) of your intention, giving an overview of the status of the request in the other regulatory authority. The Agency will then liaise with FDA 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.

10. How shall my request be validated?

The secretariat of the SAWP-V will be in charge of validation and processing of the request. The request for scientific advice is validated with regard to:

- SAWP-V receipt of the complete request within the required deadline (see also section 8, "How and when should I submit my request for scientific advice")
- structure and content of the request (according to SAWP-V requirements).

The SA procedure cannot start until the SA request has been validated. Failure to meet validation criteria may cause postponement of the SA procedure for that request to one of the next SAWP-V meetings.

11. What is the procedure for appointment of a coordinator and what is the role of the coordinator?

At the start of the procedure (Day 0), SAWP-V appoints a coordinator. Appointments are based solely on availability of appropriate expertise and equal opportunity. Preferences regarding coordinators expressed by applicants cannot be taken into consideration.

The Agency has a policy on the handling of competing interests for its scientific experts, including committee and working party 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 their interests. All proposed members for the Agency's scientific committees have their declarations of interests screened before their formal nomination.

The appointment of rapporteurs/co-rapporteurs for subsequent centralised application procedure or MRL application is decided separately from any previous appointment of scientific advice coordinators. Rapporteurs are appointed by CVMP based on available expertise and experience, and may or may not be the same person as the coordinator for the scientific advice.

Following the SAWP-V meeting, the applicant will receive a letter indicating the name of the appointed coordinator and the contact person at the secretariat, responsible for correspondence.

The SAWP-V secretariat is the contact body 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 coordinator.

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

The coordinator is responsible for preparing the draft report in response to the scientific advice request, taking into account the timetable for responding to such requests. Draft reports are considered working documents only and will not be released to applicants.

If the coordinator deems it necessary, he/she will compile questions and comments for the applicant from the SAWP-V members and members of other CVMP Working Parties.

The coordinator, if he/she deems it necessary, 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 coordinator.

12. What is the procedure and timetable for providing applicants with scientific advice?

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

After the validation of the request for scientific advice by the SAWP-V secretariat, the request is forwarded to the SAWP-V members. The SAWP-V formally accepts the scientific advice request at its meeting, appoints a coordinator from among the members of the working party and agrees the timetable. This marks the start of the procedure. The coordinator may appoint other experts to assist in the procedure. The applicant is informed of the appointment of the coordinator and the timetable for the procedure following the SAWP-V meeting.

Scientific advice is usually given on a 60-day procedure. The timetable is agreed based on the complexity of the questions asked and the need to involve other working parties/experts, and may be extended to 90 days. Where the applicant has requested parallel scientific advice with the FDA, this will be taken into account in the timetable for the procedure and it is more likely that it will be extended to 90 days.

When the draft report of the coordinator is discussed at the SAWP-V meeting, the SAWP-V decides whether it is necessary to invite the applicant to provide further clarification in the form of written responses to a list of questions or in an oral explanation. In some cases SAWP-V may also decide to extend the procedure or introduce a clock-stop after initial discussion in the working party, if further reflections on questions are needed. The secretariat will advise the applicant about the updated timetable and the procedure for oral explanation.

After final discussion (either at approximately Day 60 or Day 90 of the procedure) the SAWP-V agrees on the scientific advice report, which is then forwarded to CVMP for adoption (usually in the ongoing CVMP meeting).

The SAWP-V secretariat will make the final scientific advice report available to the applicant within IRIS after adoption by the CVMP, following the CVMP meeting. All communication between SAWP-V secretariat and the applicant in relation to a submitted request will take place via IRIS.

13. How do I prepare for an oral explanation?

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 applicant, and which are deemed not possible or not practical to be resolved in writing.

SAWP-V will adopt a detailed list of issues (including pertinent background information reflecting the SAWP-V discussion) to be clarified by the applicant during the oral explanation, and such list will be 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 take place during the SAWP-V meetings. The applicant will be informed of the exact timing 15 days before the oral explanation.

Applicants should ensure that, in case they are invited for an oral explanation, their relevant experts will be available 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 electronic versions of all relevant visual materials they intend to present, no later than five working days before the meeting.

In most cases, there will be a 30- to 40-minute discussion with the applicant (including the presentation given by the applicant). The presentation should focus exclusively on the outstanding issues. Applicants are advised to restrict their presentation to a maximum of 20 minutes in order to allow sufficient time for discussion with the working party. Following the meeting with the applicant, the SAWP-V will further discuss the responses to draw conclusions.

The applicant will be asked to remain available until the end of SAWP-V discussion in case further points (mainly procedural) have to be clarified or agreed.

14. Is the given scientific advice binding?

Applicants seeking scientific advice under Article 56(3) of Council Regulation (EEC) No 726/2004 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 to the Agency/CVMP nor to the applicant.

The answer given by the CVMP is based on the questions and documentation submitted, without prejudice to evolution and state of the art developments and the subsequent opinion of the CVMP.

Furthermore, applicants should note that the advice provided is without prejudice to applicable legislation relating to the particulars and documents that 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 CVMP 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 a scientific advice procedure will be taken into account in the assessment of any future marketing authorisation application(s) for that product. Details of any scientific advice given have to be included in the dossier for submission of a marketing authorisation application.

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 which has been advised may become appropriate. In this case applicants are recommended to request a follow-up to the initial scientific advice given.

However, where applicants choose not to follow 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 given in the scientific advice.

15. Is a clarification or a follow-up to scientific advice possible?

Request for a clarification

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. However, 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. Clarifications will thus be restricted to the advice already given; no new data will be accepted within a clarification request. Clarification should be requested in writing within 6 months after the receipt of the final scientific advice report and addressed to the secretariat (vetscientificadvice@ema.europa.eu). The coordinator 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 of clarification requests. There is no fee charged for clarification requests.

Request for a follow-up

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

A follow-up to the initial request is any subsequent request falling within the same therapeutic indication and initial area(s) as the initial request (area meaning quality, safety, MRL, clinical development, bioequivalence studies or a preliminary risk profile (PRP) assessment). New data can be submitted in a follow-up request.

Applicants may ask for a follow-up to the initial request for scientific advice to reconsider the scientific advice or part of the scientific advice already given in the light of new information available to the applicant following completion of studies, also after a marketing authorisation has been granted.

When submitting a request for a follow-up 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 within the required deadline, i.e. at least 22 working days before the start of the SAWP-V meeting at which the applicant would like the follow-up SA procedure to start. Scientific advice requests are made through EMA's secure online regulatory & scientific information management platform, IRIS (<https://iris.ema.europa.eu/>). For details, please see section 8 (*How and when shall I submit my request for scientific advice?*).

The fees for follow-up requests are published on the Agency website (<https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency>). Fees will be invoiced once the validation is complete.

The procedure in place for provision of a follow-up scientific advice follows the same timetable as the procedure for the initial request. If necessary, the applicant will be invited for an oral explanation. The appointment of the coordinator for the follow-up request is made independently from the appointment of the coordinator for the original request and therefore the coordinator may not be the same as for the initial request.

16. Will scientific advice be published?

Scientific advice given by the CVMP for a veterinary 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 medicinal product assessed under the centralised procedure, a European Public Assessment Report (EPAR) is published. The EPAR may contain reference to areas where scientific advice has been given and an indication of whether this advice has been followed or not.

17. What is the procedure for preliminary risk profile (PRP) assessment for new antimicrobial veterinary medicinal products?

The purpose of the PRP is to consider the antimicrobial resistance risk to public health from the new substance or veterinary medicinal product and the potential need for risk management measures to be applied. The intended benefit is to provide increased regulatory predictability at an early stage of product development.

PRP assessment of a new antimicrobial substance or antimicrobial veterinary medicinal product can be requested within the scientific advice procedure either on its own (in which case part B of the *Request for Scientific Advice (SA)* form has to be filled in) or in combination with scientific questions on other parts of the dossier (in which case both parts (A and B) of the form have to be filled in). The PRP sub-procedure is based on the document *Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals - Preliminary risk profiling for new antimicrobial veterinary medicinal products* (EMA/CVMP/CHMP/682199/2017) (https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/answer-request-european-commission-updating-scientific-advice-impact-public-health-animal-health-use_en-0.pdf).

In assessing a PRP, SAWP-V may consult other working groups (e.g. Antimicrobial Advice Ad Hoc Expert Group (AMEG), Antimicrobials Working Party (AWP), etc.). For this reason, the usual duration of the scientific advice procedure that includes PRP assessment is 90 days.