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Veterinary Medicines Division

Questions & answers on Article 82 referral procedures based on Article 129(3)

This guidance document addresses a number of questions which stakeholders, in particular applicants or marketing authorisation holders (MAHs), may have on Article 82 referral procedures based on Article 129(3) to the Committee for Veterinary Medicinal Products (CVMP). It provides an overview of the European Medicines Agency's ('the Agency') practical and operational aspects with regards to the handling of Article 82 referral procedures based on Article 129(3).

Questions and answers are being updated continuously and will be marked by "NEW" or "Rev." with the relevant date upon publication.

Note:

It should be highlighted that this document has been produced for guidance only. Applicants/MAHs must in all cases comply with the requirements of EU legislation.

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Table of contents

Initiation of an Article 82 referral procedure based on Article 129(3)

1. What is the legal basis for an Article 82 referral procedure based on Article 129(3)?

An Article 82 referral procedure based on Article 129(3) follows the provisions of Article 82 of Regulation (EU) 2019/6.

It applies in the event of a risk to public or animal health or to the environment that requires urgent action. The procedure is initiated due to the imposition of temporary safety restrictions on authorised veterinary medicinal products.[1]

The procedure for an Article 82 referral is laid down in Articles 83 and 84 of Regulation (EU) 2019/6.

Reference:

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

[1]When the procedure is not initiated due to the imposition of temporary safety restrictions on authorised veterinary medicinal products, the procedure for an Article 82 referral will apply. Please refer to the Questions & Answers on Article 82 referrals.

2. In which situations can an Article 82 referral procedure based on Article 129(3) be initiated?

An Article 82 referral procedure based on Article 129(3) may be initiated in the event of a risk to public or animal health or to the environment that requires urgent action, at the same time as imposing temporary safety restrictions on authorised veterinary medicinal products.[1]

Those temporary safety restrictions may include:

a) restriction of supply of the veterinary medicinal product;

b) restriction of the use of the veterinary medicinal product;

c) suspension of a marketing authorisation.

Reference:

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

[1]When the procedure is not initiated following the imposition of temporary safety restrictions on authorised veterinary medicinal products, the procedure for an Article 82 referral will apply. Please refer to the Questions & Answers on Article 82 referrals.

3. Who can initiate an Article 82 referral based on Article 129(3)?

An Article 82 referral procedure based on Article 129(3) can be initiated by the competent authorities in the Member States (MSs) or by the European Commission (EC).

The initiator of the referral procedure may, at the same time as imposing a temporary safety restriction(s), refer the matter to the Agency's Committee for Veterinary Medicinal Products (CVMP) by submitting a notification to the Agency.

The notification will identify the issue(s) and question(s) referred to the CVMP for consideration, including a detailed explanation of the issue(s) raised and the regulatory action which is being considered. The notification will be publicly available at the start of the procedure (please refer to Question 9).

Reference:

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

4. Can a Member State take regulatory action during an Article 82 referral based on Article 129(3)?

The competent authority in another Member State (MS) than the one which initiated the referral may, where urgent action is necessary to protect public or animal health or the environment, suspend a marketing authorisation at any stage of the procedure, and restrict the supply and/or use of the concerned veterinary medicinal product on its territory until a definitive decision is adopted.

In this case, the MS informs the European Commission, the Agency and all other MSs no later than the following working day of the reasons for its action.

Reference:

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

5. Which veterinary medicinal products can be involved in an Article 82 referral based on Article 129(3)?

All veterinary medicinal products affected by the issue referred and with a valid marketing authorisation (MA) in the European Economic Area (EEA) will be included in the Article 82 referral based on Article 129(3), regardless of whether the MA was granted nationally (including via the mutual recognition or decentralised procedures) or via the centralised procedure. Ongoing applications for marketing authorisations in the EEA may also be included.

The referral procedure may concern a specific veterinary medicinal product, a range of veterinary medicinal products all containing the same active substance, all veterinary medicinal products belonging to the same therapeutic class (several active substances concerned) or a range of veterinary medicinal products containing different active substances and belonging to different therapeutic classes but concerned by the matter referred.

The applicant(s)/marketing authorisation holder(s) cannot choose whether or not to include their veterinary medicinal products in an Article 82 referral based on Article 129(3). The inclusion of their veterinary medicinal products depends on the scope of the procedure that is defined by the issue(s) raised in the notification.

Reference:

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

6. How are the veterinary medicinal products identified to be part of an Article 82 referral based on Article 129(3)?

Before the start of the referral procedure, the Agency, with input from the national competent authorities of the Member States (MSs) within the European Economic Area (EEA) as necessary, will identify the authorised veterinary medicinal products or the applications for a marketing authorisation concerned by the procedure. Whenever possible, all authorised veterinary medicinal products concerned will be identified using information from the Union Product Database.

At the start of the procedure, a draft list of the names of the veterinary medicinal products identified, together with information on the respective marketing authorisation holder(s), strength(s), pharmaceutical form(s), target species and route(s) of administration will be made publicly available on the Agency's website on the specific procedure page (please refer to Question 9).

From a procedural viewpoint, only those veterinary medicinal products identified at the start of the procedure will be covered by its scope. However, to the extent that other veterinary medicinal products affected by the issue(s) but not identified at start of procedure are authorised in the EEA, or subject to future authorisations by the MSs, the concerned MSs should take due consideration of the scientific conclusions of the procedure and apply them to these veterinary medicinal products.

Reference:

Union Product Database (EMA website) - Link

7. What happens if the veterinary medicinal product involved is only authorised in one Member State?

Upon receipt of the notification, the Agency, based on the information collected from the Union product database and in consultation with the national competent authorities of the Member States within the European Economic Area (EEA), will identify the Member State(s) in which the concerned veterinary medicinal product(s) is/are authorised.

If it is concluded that the scope of the procedure concerns veterinary medicinal product(s) authorised in only one Member State, an Article 82 referral procedure based on Article 129(3) will not be initiated and the issue will be handled unilaterally by the Member State concerned.

Reference:

Union Product Database (EMA website) - Link

8. Can an Article 82 referral based on Article 129(3) be stopped?

Once the referral is initiated and the procedure started, the referral can only be stopped if all applicant(s)/marketing authorisation holder(s) withdraw the concerned applications/marketing authorisations in all Member States. This condition applies regardless of whether the procedure was initiated by the European Commission or a Member State.

9. When and how will an Article 82 referral based on Article 129(3) be announced?

Following receipt of the notification initiating the Article 82 referral procedure based on Article 129(3), the matter will be discussed at the next upcoming plenary meeting of the Committee for Veterinary Medicinal Products (CVMP) and a brief summary will be included in the agenda published at the beginning of that CVMP meeting.

The start of the procedure will be announced as part of the CVMP meeting highlights, which will be published on the next working day following the CVMP meeting during which the matter is considered.

The announcement will specify the issue under consideration and invite stakeholders (e.g. veterinary healthcare professionals, farmers, academia) to submit to the Agency all relevant information for the procedure (please refer to Question 15, Question 19 and Question 20).

Furthermore, following the CVMP meeting, all information related to the start of the procedure will be published on the Agency's website on a dedicated page created specifically for the procedure, including the following documents:

- announcement of the start of the procedure;
- notification triggering the procedure;
- draft list of concerned veterinary medicinal products/active substance(s) and marketing authorisation holder(s);
- list(s) of questions to applicant(s)/MAH(s) adopted by the CVMP (please refer to Question 16). *NB In some cases, a list of questions is not applicable at this stage;*
- timetable for the referral as adopted by the CVMP;
- form for submission by stakeholders.

Reference:

What EMA publishes on medicines and when – Veterinary medicines - Referrals

10. How will the applicants/marketing authorisation holders be informed of the start of the Article 82 referral based on Article 129(3)?

Following the CVMP meeting at which the referral is initiated, all applicants/marketing authorisation holders (MAHs) of the veterinary medicinal product(s) concerned by the Article 82 referral based on Article 129(3) and identified in the product list will be notified electronically (via e-mail/Eudralink) by the Agency. The letter notifying the applicant(s)/MAH(s) of the procedure initiation will include:

- the name and contact details of the Agency's dedicated procedure coordinator for the referral who will be the contact point throughout the procedure, as well as the e-mail address of the procedure mailbox, which should always be copied in all correspondence with the Agency;
- Link to the dedicated page on the Agency's website where the relevant documentation related to the start of procedure is available (please refer to Question 9);
- Template for the letter of representation to be completed by each applicant/MAH involved in the referral to formally appoint a contact person who will legally represent the legal entity throughout the procedure (please refer to Question 11). The Agency may release updated information on the website during the procedure and therefore, applicants/MAHs and other interested parties should continuously check the Agency's website for any relevant updates (please refer to Question 30 and Question 35).

11. Should applicants/marketing authorisation holders identify a contact person to communicate with the Agency during the Article 82 referral based on Article 129(3)?

Before the referral starts, the Agency will liaise with the National Competent Authorities to identify the concerned veterinary medicinal products/applications for a marketing authorisation and their corresponding contact person.

To facilitate the exchange of information during the procedure, the applicant(s)/marketing authorisation holder(s) (MAHs) should inform the Agency at the start of the procedure of the designated contact person for the Article 82 referral procedure based on Article 129(3) by way of a letter of representation.

Applicants/MAHs may, if they wish, be represented by another party (e.g. a consultant), who will be the contact person for the procedure. In this case, the applicant/MAH must inform the EMA procedure coordinator identified in the letter that is sent to the applicants/MAHs when the referral procedure is initiated.

All documentation concerning the Article 82 referral procedure based on Article 129(3) will be sent to the contact person only. The contact details of the person should be clearly stated (name, address, phone and email address) in the letter of representation.

It is the responsibility of the applicant/MAH to notify the Agency of any change that might affect the validity of the letter of representation as soon as possible (e.g. in case of a change of the contact person), and to provide a revised letter of representation in such cases. Receipt of any documents by the contact person will be considered to constitute effective receipt by the applicant/MAH *inter alia* for the purposes of calculating the procedural timelines.

All communication with the Agency related to the Article 82 based on Article 129(3) should be channelled via the contact person only.

12. Can applicants/marketing authorisation holders involved in the procedure group together?

The applicants/marketing authorisation holders (MAHs) can form a group for the purpose of the procedure (irrespective of group/company affiliation) in order to provide a single consolidated response and/or oral explanations to the questions raised by the Committee for Veterinary Medicinal Products (CVMP) during the procedure. In this case, the cover letter accompanying the single consolidated response and/or request for oral explanation should clearly identify the parties responsible for the submission/request.

13. What happens if centrally authorised products/applications are involved in the procedure?

If a centrally authorised product (CAP)/application is involved in an Article 82 referral based on Article 129(3), the applicant/marketing authorisation holder (MAH) will be notified by the Agency of the start of the procedure in the same way as other concerned applicant(s)/MAH(s) (please refer to Question 10). The announcement on the Agency's website will also contain a link to the page of the centrally authorised veterinary medicinal product in the Union product database.

Reference:

Union Product Database - Link

14. Do applicants/marketing authorisation holders have to pay a fee?

Fees are not payable for referrals under Article 82 based on Article 129(3) of Regulation (EU) 2019/6.

References:

Fees payable to the European Medicines Agency

Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products

15. Who can submit data to be considered during the Article 82 referral procedure based on Article 129(3)?

The applicant(s)/marketing authorisation holder(s) (MAHs) concerned by an Article 82 referral procedure based on Article 129(3) will be requested to submit information relevant for the assessment of the matter under consideration, in response to a list of questions adopted by the Committee for Veterinary Medicinal Products (CVMP) during the procedure.

The applicants/MAHs will be informed of the start of the procedure and during the procedure on how and when to submit data.

The applicants/MAHs can present written or oral explanations to the CVMP within the time limit as specified in the procedure timetable, and before an opinion is issued by the CVMP. As a general principle, the oral explanation is based on data that was submitted in advance and assessed by the Committee.

Regardless of whether the applicants/MAHs present written or oral explanations to the CVMP during the procedure, an opinion applicable to all veterinary medicinal products concerned by the procedure will be adopted by the CVMP.

The Committee may also take into account any other information at its disposal which relates to the quality, safety and efficacy, as appropriate, of the veterinary medicinal product(s) concerned and which may help in arriving at its opinion. Member States shall also forward to the Agency's Committee all relevant information relating to the veterinary medicinal products concerned.

In addition, other stakeholders (e.g. veterinary healthcare professionals, farmers, academia) have the right to submit information relevant to the issue under review within the Article 82 referral procedure based on Article 129(3). This is an opportunity given by the provisions of Regulation (EU) 2019/6 for data to be submitted by all stakeholders and considered for the assessment of the issue under consideration. However, this is not a mandatory step of the procedure.

For detailed information on how and when to submit data, please refer to Question 10, Question 16, Question 19 and Question 20.

16. How will data be gathered during the procedure?

In order to address the issue(s) triggering the Article 82 referral based on Article 129(3), the Committee for Veterinary Medicinal Products (CVMP) will review relevant additional data that could be requested by the CVMP in the format of a list(s) of questions or by using data sources available to the Agency and/or to the National Competent Authorities (NCAs) of the Member States.

This data may be gathered from several different sources, e.g., from concerned applicant(s)/marketing authorisation holder(s) (MAHs), veterinary healthcare professionals, farmers, academia, data available to the NCAs.

At the start of the procedure the data considered necessary for the assessment will be identified by the CVMP and announced on the Agency's website. This data will have to be submitted within the specified deadline as published in the announcement of the start of the procedure and indicated in the procedure timetable (please refer to Question 9 and Question 22).

The CVMP may also collect additional data from the applicants/MAHs through further lists of outstanding issues and/or an oral explanation in accordance with an extended timetable, which will be made publicly available (please refer to Question 22 and Question 24).

The CVMP will take into account any other information at its disposal which relates to the quality, safety and efficacy, as appropriate, of the veterinary medicinal product(s) concerned and which may help in arriving at its opinion.

17. Who will perform the assessment?

The assessment of data within the Article 82 referral based on Article 129(3) is the responsibility of the Agency's Committee for Veterinary Medicinal Products (CVMP). At the start of the procedure, the CVMP Chairperson appoints a rapporteur and co-rapporteur(s) (please refer to Question 18) who will perform a scientific evaluation of all data collected within the agreed timelines. Once the appointments have been made, the Agency will inform the applicant(s)/marketing authorisation holder(s).

The CVMP may also consult its working parties, ad-hoc expert groups or a scientific advisory group (SAG) to advise it on specific questions. In such cases, the Committee defines their tasks and specifies the time limit for the completion of these tasks.

All members of the CVMP are equally concerned by the question submitted in the matter referred to the Committee, taking part in the evaluation procedure and the adoption of the opinion, independently of the Member State which has nominated them as CVMP member, and of the situation of the veterinary medicinal product(s) in the Member States.

The assessment of all the available data will result in the CVMP adopting an opinion on the issue reviewed.

18. How are the rapporteur and co-rapporteur(s) appointed?

The Committee for Veterinary Medicinal Products (CVMP) (co-)rapporteurs for an Article 82 referral procedure based on Article 129(3) are appointed by the CVMP Chairperson from amongst its members or alternates (hereafter referred to as CVMP members).

If the procedure was triggered by a Member State, normally the CVMP member or alternate of that Member State will be appointed as rapporteur, and the co-rapporteurship will be opened up to all members. If one centrally authorised product (CAP) is involved in the referral, the CVMP rapporteur already nominated for the initial assessment of the marketing authorisation for the CAP is appointed as co-rapporteur.

If the procedure was triggered by the European Commission, the CVMP rapporteur and co-rapporteur already identified for the CAP(s) are appointed. If no CAP(s) are involved in the referral, the (co-) rapporteurship is opened up to all members.

In both cases, if more than one CAP is concerned, the (co-)rapporteurs for the Article 82 procedure based on Article 129(3) shall be appointed from amongst the (co-)rapporteurs for the CAPs involved in the procedure.

In case of an Article 82 referral based on Article 129(3) concerning several active substances belonging to the same therapeutic class, or where several issues are to be assessed, a lead rapporteur and several (co-)rapporteurs may be appointed.

The CVMP Chairperson will endeavour to apply the criteria of best available expertise for the appointment of the (co-)rapporteurs for each referral procedure.

Reference:

Appointment and responsibilities of the rapporteur and co-rapporteur for procedures regarding veterinary medicinal products

During the assessment

19. How shall the responses be presented?

During an Article 82 referral procedure based on Article 129(3), applicant(s)/marketing authorisation holder(s) (MAHs) and other stakeholders (e.g. veterinary healthcare professionals, farmers, academia) can submit relevant data for the assessment of the issue under review within the specified deadline (please refer to Question 15 and Question 22).

Applicant(s)/marketing authorisation holder(s) (MAHs)

Applicants/MAHs of veterinary medicinal products concerned by the procedure should submit to the Agency all available evidence to support the Article 82 referral procedure based on Article 129(3) in response to the list of questions/outstanding issues and as per the timelines published on the Article 82 based on Article 129(3) procedure page.

It is left to the applicants/MAHs' discretion to choose what kind of data should be provided in response to the questions raised by the CVMP.

Applicants/MAHs of veterinary medicinal products concerned by the referral should submit their responses as follows:

- The data should be presented in a format chosen by the applicant/MAH, since no specific technical format for data exists for veterinary referral procedures. It should be accompanied by a signed cover letter and a written summary answering each question.
- The cover letter must make clear reference to the procedure number.
- The written summary answering each question should follow the numbering as per the CVMP list of questions/CVMP list of outstanding issues (if applicable). Please note that supportive data to the responses submitted (e.g. study reports, literature data) are expected to be provided together with a summary of those data.
- Applicants/MAHs are requested to provide a table of contents listing all the studies referred to in the answers. For published studies, reference to the publication should be made; for each unpublished study (e.g. proprietary data), a clear statement should be provided indicating whether a detailed description of the study and its results cannot be released to the public in accordance with the relevant principles of law governing transparency and the protection of commercially confidential information. Applicants/MAHs should be aware that a brief summary of each study may nevertheless be included in the overall summary of the assessment, which will be published.

Published data can be presented as supportive documentation in response to a specific question if no other data is available.

In case changes to the product information (summary of product characteristics, package leaflet and labelling) are proposed in answer to the CVMP questions, only amendments directly related to the scope of the procedure should be proposed. Any other amendments to the product information should be applied for in separate dedicated procedures.

It should be noted that the responsibility for the quality of the submitted documentation lies with the applicants/MAHs and is crucial to the overall assessment. The information and data contained in the individual submissions will be assessed and reflected in the assessment reports for the procedure. For transparency reasons and in order to respect the right of defence of the applicants/MAHs concerned by the procedure, the Agency will share with all concerned applicants/MAHs the assessment reports after deleting all commercially confidential information.

All submissions are expected to be submitted in English and electronically only (please refer to Question 20).

In case applicant(s)/MAH(s) have formed a group (please refer to Question 12), the cover letter accompanying the single consolidated response and/or request for oral explanation should clearly identify the parties responsible for the submission/request.

Other stakeholders

All submissions from other stakeholders than the applicants/MAHs concerned by the procedure (e.g. veterinary healthcare professionals, farmers, academia), have to be accompanied by a submission form and sent within the specified deadline. The submission form template is available on the procedure page.

Preferably, data submitted should be accompanied by an overall summary of its content and should make reference to the specific CVMP question(s) being addressed (as per CVMP published list of questions numbering).

20. How and to whom shall the responses be submitted?

Applicant(s)/marketing authorisation holder(s) (MAHs)

Responses from the applicants/MAHs should be submitted within the timeline specified in the cover letter to the list of questions/list of outstanding issues and on the procedure page.

It is mandatory that all submissions for referral procedures are sent to the Agency via the eSubmission Gateway or eSubmission Web Client using XML delivery files. Upon successful submission, these portals send automated acknowledgement of receipt. Where no such acknowledgement is received, it must be assumed that the submission failed. Responses for nationally and centrally authorised products (CAPs) submitted via these portals are available in the Common Repository and will be considered delivered to all Committee members, alternates and national competent authorities.

Please note that the initial registration process for these portals may take up to 20 working days, and therefore it is highly recommended to register as soon as possible.

The Agency no longer accepts submissions made by any other means (e.g. Eudralink or e-mail).

For referral submissions related to CAPs, responses should always be submitted individually as the next sequence in each CAP product lifecycle.

For any technical issues contact eSubmission@ema.europa.eu or visit the EMA Service Desk portal (EMA Service Desk).

Should you have any other questions regarding your submission, please contact the dedicated EMA procedure coordinator, copying the relevant procedure mailbox.

Other stakeholders

Other stakeholders than the applicants/MAHs concerned by the procedure (e.g. veterinary healthcare professionals, farmers, academia) can submit to the Agency data relevant to the issue under assessment. Submissions should be sent via email, within the specified timeline, to the address indicated on the procedure page.

References:

eSubmission website

eSubmission registration process

Gateway user guide xml delivery files (europa.eu)

21. How will the data be assessed?

Submissions from the applicant(s)/marketing authorisation holder(s) are directly available in the Common Repository for the Committee for Veterinary Medicinal Products (CVMP) (co-)rapporteurs to assess (please refer to Question 20).

The Agency will provide the data received from other stakeholders (e.g. veterinary healthcare professionals, farmers, academia) to the CVMP (co-)rapporteurs for assessment.

All information gathered will be assessed within an agreed timeframe as published on the Article 82 procedure based on Article 129(3) page (please refer to Question 22). The assessment report(s) prepared by the CVMP (co-)rapporteurs will reflect all data submitted and considered relevant for the review.

The CVMP (co-)rapporteur assessment report(s) will be circulated to all CVMP members for comments.

The CVMP may in some cases require input from additional experts (e.g. a scientific advisory group (SAG), an ad-hoc expert group (AHEG)) to advise it on specific questions in relation to the assessment.

22. What is the timetable for the assessment by the CVMP?

Please note that the timelines below are provided for guidance purposes only and they refer to active days, which correspond to the time the Committee for Veterinary Medicinal Products (CVMP) takes to assess all data gathered. The timelines can be altered in order to reflect the particularities of a specific referral procedure and, in case of a justified urgency, the CVMP may agree on a shorter timetable.

An example of a standard timetable for an Article 82 referral procedure based on Article 129(3) would be as follows:

Article 82 based on Article 129(3) referral procedure - *Timetable for the assessment*	Active day
Notification of a referral to the European Medicines Agency/CVMP	Day 0
Discussion at the first CVMP meeting following receipt of the notification: • Discussion of the question(s) referred • Appointment of the (co-)rapporteur(s)	Day 1

Article 82 based on Article 129(3) referral procedure - *Timetable for the assessment*	Active day
• Adoption of a timetable and CVMP list of questions to be addressed by the applicants/marketing authorisation holders (MAHs), if applicable • Adoption of a CVMP list of questions to be addressed by stakeholders	
Preparation and submission of written explanations by the applicants/MAHs and stakeholders in response to the CVMP list of questions	Clock Stop
Re-start of the procedure following submission of written explanations in line with published submission deadlines	Clock re-start Day 2
Circulation of the (co-)rapporteur's assessment report(s) on the applicants'/MAHs' written responses, including the stakeholders data and on the proposed summary of product characteristics (SPC)/labelling/package leaflet, if applicable	Day 20
Comments in writing from CVMP members on the (co-)rapporteur's assessment report(s) and proposed SPC/labelling/package leaflet, if applicable	Day 25
Discussion at the CVMP meeting: • Discussion of assessment report(s) and comments received from CVMP members; • Adoption of the CVMP opinion, or • Adoption of a CVMP list of outstanding issues to be answered by the applicant(s)/MAH(s) in writing and/or in an oral explanation, and timetable for the next assessment period of the procedure.	Day 30

The Committee shall issue a reasoned opinion within 120 days of the matter being referred to it. The CVMP may extend the time limit for a further period of 60 days to allow for the assessment of further data provided as answers to the CVMP list of outstanding issues, or for an oral explanation, or in cases where the CVMP requires input from additional experts (e.g. a scientific advisory group (SAG), an ad-hoc expert group (AHEG)) to support the CVMP's opinion.

However, the CVMP may suspend the time limit of 120/180 days (clock-stop) in order to allow the applicant(s)/MAH(s) to prepare the responses to the CVMP list of questions, list of outstanding issues or an oral explanation (as appropriate).

As a general rule, a clock-stop of up to three months will apply. For an extension of the clock-stop adopted by the CVMP, the applicant/MAH should send a justified request to the Agency for agreement by the CVMP. The letter specifying the length of the requested extension should be addressed to the CVMP Chairperson, signed and sent electronically to the EMA's procedure coordinator. In preparing the justification, the applicant/MAH should consider the seriousness and urgency of the issue under consideration and the impact the extension may have. The CVMP will consider the request, and if agreed, an extended timetable will be adopted. All applicants/MAHs involved in the procedure will be informed of the CVMP conclusion and an updated timetable, if applicable, will be published on the procedure page.

23. Will I receive the CVMP (co-)rapporteur's assessment report(s)?

All applicant(s)/marketing authorisation holder(s) (MAHs) of veterinary medicinal products concerned by the scope of the Article 82 referral procedure based on Article 129(3) and identified at the start of the procedure will be provided with the Committee for Veterinary Medicinal Products (CVMP) (co-)rapporteur's assessment report(s) electronically via Eudralink.

24. Will I have the possibility to present my views to CVMP in an oral explanation and how is this organised?

The Committee for Veterinary Medicinal Products (CVMP) may decide that there are issues which would benefit from being addressed orally by the applicant(s)/marketing authorisation holder(s) (MAHs). In this case, the applicant(s)/MAH(s) will be duly informed in advance of the issues to be addressed during the oral explanation.

Applicant(s)/MAH(s) may also make a request to the CVMP to present their views in an oral explanation. In such a case, the applicant(s)/MAH(s) should send a written request addressed to the CVMP Chairperson (via the EMA's procedure coordinator) stating the reason(s) and specifying the issue(s) to be addressed during the oral explanation. The CVMP will take due account of the request and will decide whether the oral explanation will be held.

The oral explanation(s) should take place during the assessment phase and usually after the receipt of the CVMP (co-)rapporteur's assessment report(s). Further detailed information on organisational aspects of the oral explanation can be found here.

Applicant(s)/MAH(s) can provide the oral explanation on their own behalf or on behalf of a group of applicants/MAHs.

25. What should I do if the application/marketing authorisation of my veterinary medicinal product is withdrawn or transferred to another applicant/marketing authorisation holder?

Withdrawals

If during the referral procedure a marketing authorisation or an application for a marketing authorisation for a concerned nationally authorised product (including via mutual recognition or decentralised procedures) is withdrawn in any Member State(s), the applicant/marketing authorisation holder (MAH) should inform the EMA's procedure coordinator for the referral procedure without delay. The Agency will then liaise with the national competent authority of the Member State(s) concerned. Following confirmation by the national competent authority of the withdrawal of the application/marketing authorisation, the Agency will inform the former applicant/MAH that this specific application/marketing authorisation will no longer be included in the ongoing referral procedure.

For centrally authorised products, if during the referral an application or a marketing authorisation is withdrawn, the applicant/MAH should inform the EMA's procedure coordinator for the referral procedure without delay. For the withdrawal of marketing authorisations, the appropriate procedure should be followed (please refer to 'notifying a change of marketing status').

Transfers

If during the referral procedure the marketing authorisation for a concerned veterinary medicinal product is transferred to a new MAH, the EMA's procedure coordinator for the referral procedure should be informed without delay.

For nationally authorised product(s) (including via mutual recognition and decentralised procedures), the new MAH should provide a copy of the transfer decision of the relevant competent authority. Following receipt of the transfer decision, the Agency will inform the former MAH that they are no longer included in the Article 82 referral procedure based on Article 129(3), in relation to the marketing authorisation transferred.

For centrally authorised product(s), the former MAH should inform the EMA's procedure coordinator and the appropriate procedure should be followed (please refer to 'transferring a veterinary marketing authorisation': questions and answers).

If during the referral procedure an ongoing application for a marketing authorisation is transferred, the new applicant should provide the official confirmation of the transfer to the EMA's procedure coordinator.

For all transfers, the new applicant/MAH should submit a revised letter of representation to the EMA's procedure coordinator as soon as possible, including information on the new contact person for the referral procedure (please refer to Question 11).

26. What should I do if the name of my veterinary medicinal product changes or if the name and/or address of the applicant/marketing authorisation holder changes or, if my contact person changes?

For nationally authorised products (including via mutual recognition and decentralised procedures), if during the referral procedure the name of the veterinary medicinal product changes, or the name and/or address of the applicant/marketing authorisation holder (MAH) changes or if the contact person changes, the applicant/MAH should inform the EMA's procedure coordinator without delay. The Agency will then liaise with the national competent authority of the Member State(s) concerned. Following confirmation by the national competent authority of the change, the Agency will inform the applicant/MAH that the change has been noted.

For centrally authorised products, if during the referral procedure the name of the veterinary medicinal product has been changed following the appropriate procedure (please refer to 'Changing the (invented) name of a veterinary medicine'); or the name and/or address of the applicant/MAH changes or, if the contact person changes (please refer to 'Notifying EMA of changes to contact persons (veterinary medicines)'), the applicant/MAH should inform the EMA's procedure coordinator without delay.

In all cases, a revised letter of representation should be submitted to the EMA's procedure coordinator as soon as possible, including the new information (please refer to Question 11).

Committee for Veterinary Medicinal Products (CVMP) opinion

27. When will the CVMP opinion be adopted?

The Committee for Veterinary Medicinal Products (CVMP) will adopt an opinion on the matter referred under Article 82 procedure based on Article 129(3) within the agreed timeframe, i.e. within 120 days of the start date of the procedure (please refer to Question 22). The CVMP may extend that period up to 180 days, to allow for the assessment of further data provided as answers to the CVMP list of outstanding issues to be addressed by the applicant(s)/marketing authorisation holder(s) in writing or during an oral explanation and/or in case input from additional experts (e.g. a scientific advisory group (SAG), an ad-hoc expert group (AHEG)) is required before adopting an opinion (please refer to Question 22).

The CVMP opinion will usually be adopted on the last day of the CVMP plenary meeting.

28. Which could be the conclusions of the CVMP opinion?

The Committee for Veterinary Medicinal Products (CVMP) opinion on the matter referred under Article 82 based on Article 129(3) shall include any or a combination of the following conclusions:

a) the application(s) do(es) not satisfy the criteria for authorisation;

b) the marketing authorisation(s) should be maintained or varied;

c) the marketing authorisation(s) should be subject to certain conditions or;

d) the marketing authorisation(s) should be suspended or revoked.

Where the opinion recommends that the marketing authorisation(s) is/are varied, including changes/additions to the information in the summary of product characteristics, labelling and/or package leaflet, the opinion will include the required wording and location for these changes.

Where the recommendation is that the marketing authorisation should be subject to certain condition(s) or should be suspended with condition(s) for lifting the suspension, these conditions will be clearly stated in the CVMP opinion (including timelines and details of the data to be provided). These conditions can include, but are not limited to, requesting the marketing authorisation holder(s) to conduct a post-authorisation study. The assessment of the fulfilment of the condition(s) recommended for nationally authorised products (including via mutual recognition and decentralised procedures) will be the responsibility of the Member States, unless otherwise stated in the CVMP opinion.

The CVMP opinion can be adopted by consensus or by majority vote. In the event of an adoption by a majority vote, the divergent positions of the relevant CVMP members and the grounds on which they are based will be appended to the opinion adopted by the CVMP.

29. How is the CVMP opinion structured?

The Committee for Veterinary Medicinal Products (CVMP) opinion will include:

- a cover page in which the adopted opinion is outlined together with the voting outcome of CVMP;
- a list of the veterinary medicinal products/application(s) for a marketing authorisation concerned, including the names of all identified nationally authorised products (including via the mutual recognition/decentralised procedures) involved in the procedure, active substance(s) and their respective applicants/marketing authorisation holders (MAHs) in each Member State. In case centrally authorised products (CAPs) are involved, their respective Annex A including this information will be attached;
- the scientific conclusions and grounds for the CVMP opinion;
- the wording (in English only) to be included in the relevant sections of the product information (summary of product characteristics, package leaflet and labelling), if applicable (only for nationally authorised veterinary medicinal products, including via the mutual recognition/decentralised procedures);
- the revised product information with agreed wording included in the relevant sections of the summary of product characteristics/labelling/package leaflet, if applicable (only for centrally authorised products);
- the conditions or restrictions imposed on the marketing authorisation(s), if applicable;

- the conditions for lifting the suspension, if applicable;
- any divergent views of CVMP members, in case the opinion is adopted by majority;
- the CVMP assessment report on the evaluation of all the data submitted and the conclusion of the CVMP that led to the adoption of the opinion.

30. When is the CVMP opinion published?

A brief outcome of the Committee for Veterinary Medicinal Products (CVMP) opinion will be included in the CVMP meeting highlights that are released on the next working day following the CVMP plenary meeting.

An overview of the CVMP conclusions and all annexes of the CVMP opinion will be published on the Agency's procedure page following the adoption of the European Commission Decision (please refer to Question 35).

Reference:

What EMA publishes on medicines and when – Veterinary medicines - Referrals

31. Will I receive the CVMP opinion?

The designated contact person representing the applicant(s)/marketing authorisation holder(s) (MAHs) (please refer to Question 11) of the veterinary medicinal products concerned by the scope of the referral and identified at the start of the procedure, will receive the Committee for Veterinary Medicinal Products (CVMP) opinion and assessment report electronically via Eudralink following their adoption.

The Agency will also forward the opinion of the Committee and the assessment report to the Member States and the European Commission.

32. When and how can I request a re-examination of the CVMP opinion on the Article 82 referral based on Article 129(3)?

A concerned applicant/marketing authorisation holder (MAH) may, within 15 calendar days of receipt of the Committee for Veterinary Medicinal Products (CVMP) opinion, notify the Agency in writing of its intention to request a re-examination of the CVMP opinion. The request must be submitted within the stated timeline via email to the dedicated EMA's procedure coordinator, copying the relevant procedure mailbox.

When such re-examination request is received, the Agency will inform the CVMP accordingly.

The detailed grounds for the re-examination requested must be sent to the Agency within 60 calendar days of receipt of the CVMP opinion. In case the above-mentioned deadlines are not respected, the request for re-examination is considered inadmissible and the CVMP opinion becomes final.

The detailed grounds submitted will determine the scope of the re-examination procedure and may encompass all aspects set out in the initial CVMP opinion or only certain aspects of it. However, no new data can be presented and considered at this stage of the procedure.

The re-examination procedure will only deal with the aspects of the CVMP opinion identified by the applicant/MAH in the detailed grounds for re-examination. The applicant/MAH may request that the CVMP consults a scientific advisory group (SAG) or ad-hoc expert group (AHEG) during the re-examination procedure. In such a case, this request should be made as early as possible, and no later than the submission of the detailed grounds.

For the re-examination procedure, the CVMP will appoint different (co-)rapporteurs from those appointed for the initial referral opinion and, within 60 calendar days of receipt of the detailed grounds for re-examination, the CVMP will conclude its assessment, including a reasoned conclusion on all relevant points raised by the applicant(s)/MAH(s) on the detailed grounds and adopt a final opinion.

The CVMP opinion automatically becomes final either at the time of the initial opinion if no request for re-examination is notified in writing to the EMA by the applicant(s)/MAH(s) within 15 days of receipt of the opinion or, at the time of adoption of the re-examination opinion.

The CVMP final opinion following re-examination will be sent to the European Commission for the initiation of the decision-making process (please refer to Question 34).

Reference:

Procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions

33. Do I have to submit translations?

The applicants/marketing authorisation holders (MAHs) of veterinary medicinal products concerned by the procedure will not need to provide translations for the Article 82 referral procedure based on Article 129(3).

Translations of all annexes to the Committee for Veterinary Medicinal Products (CVMP) opinion in all EU languages (including Icelandic and Norwegian, if applicable[1]) will be provided by the Translation Centre for the Bodies of the European Union (CdT).

If centrally authorised veterinary medicinal products (CAPs) are part of the referral, and the Committee proposes changes to the product information (PI) (summary of product characteristics, labelling and package leaflet), the Agency will share the CdT translations with the applicant(s)/MAH(s) of the concerned CAP(s), who will then need to insert the translated wording into the relevant sections of the PI in all EU languages to ensure consistency. The applicant(s)/MAH(s) of the CAP(s) involved in the procedure must provide the full revised PI in all EU languages.

The Agency will contact the applicant(s)/MAH(s) as early as possible to ensure the smooth running of the process. Information on the translation process of the CVMP opinion will be included in the letter notifying the adoption of the CVMP opinion.

[1]If concerned veterinary medicinal products are authorised in Iceland and Norway.

34. What happens after the final opinion of the CVMP on the Article 82 referral based on Article 129(3)?

Following receipt of the final CVMP opinion and after the translation process has been finalised, the European Commission will start the decision-making process leading to the adoption of a binding decision.

Information on the decision-making process can be found here.

For nationally authorised veterinary medicinal products (including via the mutual recognition or decentralised procedures), the Commission decision is addressed to all Member States and notified to the concerned applicant(s)/MAH(s), so that they take any necessary action to comply with the decision within 30 days of its notification, unless a different period is mentioned in that decision.

For centrally authorised veterinary medicinal products (CAPs), the Commission decision is addressed to the concerned applicant(s)/MAH(s) that will directly implement the required changes to the product information (summary of product characteristics, package leaflet and labelling).

Nationally authorised veterinary medicinal products which have been subject to a referral procedure, shall be transferred to a mutual recognition procedure. However, in cases where the referral procedure was limited to certain specific parts of the authorisation, there is no obligation to transfer the marketing authorisation into a mutual recognition procedure for subsequent applications. The Co-ordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products (CMDv) guidance on this MRP transfer can be found here.

Reference:

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

35. Will there be any publication in relation to the Article 82 referral procedure based on Article 129(3) after the European Commission Decision?

An overview document, summarising the subject and conclusions of the referral procedure, as well as all annexes of the CVMP opinion in all EU languages will be published on the Agency's procedure page around four weeks after the adoption of the European Commission decision. This page will also be updated to reflect the date of the Commission decision.

Reference:

What EMA publishes on medicines and when – Veterinary medicines - Referrals