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Veterinary Medicines Division

Questions & answers on Article 35 referral procedures

This guidance document addresses a number of questions which stakeholders, in particular the applicants or marketing authorisation holders (MAHs), may have on Article 35 referral procedures to the Committee for Medicinal Products for Veterinary Use (CVMP). It provides an overview of the European Medicines Agency's ('the Agency') practical and operational aspects with regards to the handling of Article 35 referral procedures.

This integrated version has been created for printing purposes only. Please refer to the individual questions & answers as published in the referral procedures guidance to access the hyperlinked information.

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 and should be read in conjunction with "The Rules governing Medicinal Products in the European Union, Notice to Applicants", Volume 6A, Chapter 3.

Applicants/MAHs must in all cases comply with the requirement of EU legislation.

[1] Removal of contact details from questions 18 and 30

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Initiation of an Article 35 referral procedure

1. What is the legal basis for an Article 35 referral procedure?

An Article 35 referral procedure follows the provisions of Article 35 of Directive 2001/82/EC.

It applies where the interests of the European Union are involved, before a decision is taken on an application for a marketing authorisation, or on the suspension or revocation of a marketing authorisation, or on any other amendment to the terms of a marketing authorisation that appears necessary, in particular to take pharmacovigilance information into account.

The procedure for an Article 35 referral is laid down in Articles 36, 37 and 38 of Directive 2001/82/EC.

References:

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Notice to Applicants, volume 6A Procedures for marketing authorisation, Chapter 3 Union Referral Procedures

2. In which situations can an Article 35 referral procedure be initiated?

An Article 35 referral procedure should be initiated where the interests of the Union are involved.

The term 'interest of the Union' refers particularly to the interests of human or animal health or of the environment related to veterinary medicinal products in the Union (for example in light of concerns related to the quality, safety and efficacy of a veterinary medicinal product) and to the free movement of products within the Union.

References:

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Notice to Applicants, volume 6A Procedures for marketing authorisation, Chapter 3 Union Referral Procedures

3. Who can initiate an Article 35 referral?

An Article 35 referral procedure can be initiated by Member States, the European Commission or by applicants and/or marketing authorisation holders (MAHs).

The initiator of the referral procedure refers the matter to the Committee for Medicinal Products for Veterinary Use (CVMP) by submitting a notification form to the Agency. The notification form will identify the concern and question(s) referred to the CVMP for consideration, together with a detailed explanation of how the Union interests are involved.

Only Member States or the European Commission can identify the question(s) to the CVMP so such questions should not be included in a notification from an applicant/MAH. Furthermore, if the referrer is an applicant/MAH, it should contact a Member State or the European Commission with a request to assess and confirm the Union interest, in advance of initiating a referral under this Article. The applicant/MAH can only include its own product in the scope of the referral, with justification of potential extension to others.

References:

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Notice to Applicants, volume 6A Procedures for marketing authorisation, Chapter 3 Union Referral Procedures

4. Can a Member State take regulatory action during an Article 35 referral?

A Member State (MS) may, where urgent action is necessary to protect human or animal health or the environment, suspend a marketing authorisation at any stage of the procedure, and prohibit the use of the veterinary medicinal product concerned on its territory until a definitive decision is adopted.

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

References:

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Notice to Applicants, volume 6A Procedures for marketing authorisation, Chapter 3 Union Referral Procedures

5. Which veterinary medicinal products can be involved in an Article 35 referral?

All veterinary medicinal products affected by the concern and with a valid marketing authorisation which has been granted nationally (including via the mutual recognition and decentralised procedures) in the European Economic Area (EEA) will be included in the Article 35 referral. Ongoing applications for marketing authorisations may also be included.

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

Veterinary medicinal products authorised through the centralised procedure cannot be included in referral procedures. However, a procedure under Article 45 of Regulation (EC) No 726/2004, applicable to centrally authorised products, could be initiated by the European Commission and Member States in parallel for products of the same active substance or therapeutic class.

The applicants/marketing authorisation holders (MAHs) cannot choose whether or not to include their veterinary medicinal products in an Article 35 referral. The inclusion of their products depends on the scope of the procedure.

References:

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Notice to Applicants, volume 6A Procedures for marketing authorisation, Chapter 3 Union Referral Procedures

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down the Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency

6. How are the veterinary medicinal products identified to be part of an Article 35 referral?

Before the start of the referral procedure the Agency will request from the national competent authorities of the Member States within the European Economic Area (EEA) to identify the authorised veterinary medicinal products or the applications concerned by the procedure.

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 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, that there are no ongoing application(s) in other Member State(s) and that the interest of the EU is not involved, an Article 35 referral procedure will not be initiated and the issue will be handled unilaterally by the Member State concerned.

8. When and how will an Article 35 referral be announced?

The matter will be discussed at the next upcoming plenary meeting of the Committee for Medicinal Products for Veterinary Use (CVMP) and a brief summary will be included in the respective 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 concern under consideration in general terms.

9. How will the applicants/marketing authorisation holders be informed of the start of the Article 35 referral?

All applicants/marketing authorisation holders (MAHs) of a product(s) concerned by the Article 35 referral will be notified electronically (via e-mail/Eudralink) by the Agency. The letter notifying the applicant/MAH 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 primary contact point during the procedure, as well as the e-mail address of the procedure-shared mailbox, which should always be copied in all correspondence with the Agency;
- the notification triggering the referral procedure;
- the list of the products involved in the referral procedure;
- the timetable and the list of questions (see Question 13 below) adopted by the Committee for Medicinal Products for Veterinary Use (CVMP). *NB List of questions not applicable at this stage if procedure triggered by the MAH.*

10. Should applicants/marketing authorisation holders identify a contact person to communicate with the Agency during the Article 35 referral?

To facilitate the exchange of information during the procedure, the applicants/marketing authorisation holders (MAHs) should inform the Agency of the designated contact person for the Article 35 referral procedure by way of a letter of representation.

All documentation concerning the Article 35 referral procedure will be sent to the contact person only. The contact details of the person should be clearly stated (name, address, phone and fax number and email address) in the 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 procedure coordinator identified in the letter that is sent to the applicants/MAHs when the referral procedure is initiated.

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.

11. 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 Medicinal Products for Veterinary Use (CVMP) during the procedure.

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

Fees are payable only for referrals under Article 35 of the Directive 2001/82/EC, which have been initiated by the applicant or marketing authorisation holder (MAH).

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

13. Who can submit data to be considered during the Article 35 referral procedure?

The applicants/marketing authorisation holders (MAHs) concerned by an Article 35 referral procedure will be requested to submit information relevant for the assessment in response to a list of questions adopted by the Committee for Medicinal Products for Veterinary Use (CVMP) during the procedure.

Applicants/MAHs will be informed of the start of the procedure and during the procedure on how and when to submit data (please refer to Questions 9, 14 and 17).

The submission of data is an opportunity for the applicants/MAHs to present written or oral explanations to the CVMP within the time limit as specified in the procedure timetable, before an opinion is issued by the CVMP.

Regardless of whether or not the applicants/MAHs present written or oral explanations to the CVMP, an opinion will be issued by the CVMP, applicable to all marketing authorisations concerned by the procedure.

14. How will data be gathered during the procedure?

At the start of the procedure the data considered necessary for the assessment will be identified in a list of questions for submission within the specified deadline as indicated in the timetable (please refer to Question 9, 17 and 20).

The Committee for Medicinal Products for Veterinary Use (CVMP) may also collect additional data from the marketing authorisation holder through a list of outstanding issues and/or in an oral explanation in accordance with an extended timetable.

The CVMP 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.

15. Who will perform the assessment?

The assessment of data within the Article 35 referral is the responsibility of the Committee for Medicinal Products for Veterinary Use (CVMP). At the start of the procedure, the CVMP Chairperson appoints a rapporteur and co-rapporteur(s) who will perform the assessment of all data collected within the agreed timelines.

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

16. How are the rapporteur and co-rapporteur appointed?

At the next upcoming CVMP plenary meeting, the Chairperson of the Committee for Medicinal Products for Veterinary Use (CVMP) appoints (co-)rapporteurs for an Article 35 referral procedure from amongst the members or alternates.

If the procedure was triggered by a Member State, the CVMP member of that Member State will be appointed as rapporteur, if not the rapporteurship will be opened up to all members, along with the co-rapporteurship.

In case of an Article 35 referral 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. In such cases the CVMP Chairperson will endeavour to apply the criterion of best available expertise for the appointment of the (co-)rapporteurs.

Reference:

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

During the assessment

17. How shall I present my responses to the CVMP's list of questions/outstanding issues?

Applicants/marketing authorisation holder(s) (MAHs) are requested all available evidence to support the Article 35 referral procedure to submit to the Agency and all members of the Committee for Medicinal Products for Veterinary Use (CVMP).

It is left to the applicants/MAHs' discretion to submit the relevant documentation necessary for the evaluation of the matter referred.

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. All submissions are expected to be submitted in English and electronically only.

Referral procedures triggered by a Member State or the European Commission

The answers should be numbered according to the numbering on the CVMP list of questions or list of outstanding issues. The answers should be presented in two parts as described below:

Section I

Section I should contain an introduction, a written summary answering each question, a conclusion and a proposed summary of product characteristics/labelling/package leaflet (if requested).

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.

Section II

Section II should contain the supportive documentation (e.g. protocols, study reports, literature) organised by quality, safety, residue, pre-clinical and clinical data and post-marketing experience, as applicable.

In response to a specific question, proprietary or published data may be presented.

Referral procedures triggered by an applicant/marketing authorisation holder

In these referrals, the procedure starts with the evaluation of the data submitted by the applicant/MAH.

It is left to the applicant's/MAH's discretion to submit the documentation necessary for the evaluation of the matter under referral. The same principles as described above are recommended to be followed. This should be accompanied by an expert report/overview that reflects the up-to-date regulatory status. In all cases, data submitted should be accompanied by an overall summary of their content. A table of contents listing all studies (pre-clinical, clinical, post-marketing studies, etc.) and literature referred to in the responses is requested.

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

In the situation where applicants/MAHs have formed a group (please refer to Question 11), the cover letter accompanying the single consolidated response and/or request for oral explanation should clearly identify the parties responsible for the submission/request.

18. To whom shall I submit my responses?

Responses from the applicants/marketing authorisation holders (MAHs) should be submitted to the rapporteur, the co-rapporteur, all remaining members of the CVMP (including co-opted members) and to the Agency within the timeline specified in the cover letter to the list of questions or list of outstanding issues.

All submissions for referral procedures should be sent to the Agency via the eSubmission Gateway or eSubmission Web Client. These portals send automated acknowledgement of receipt of submission, or of failed submission if an error occurred. The Agency no longer accepts submissions on CD-ROM or DVD.

For detailed information on submission to CVMP members please refer to the dossier requirements for referral procedures.

For more information please refer to eSubmission website.

There is no need to send any separate paper cover letters for these submissions.

~~Should you have any questions regarding your submission, please contact us via email: vet.applications@ema.europa.eu, for any technical issues contact eSubmission@ema.europa.eu.~~

19. How will my data be assessed?

All information gathered will be assessed within an agreed timeframe (please refer to Question 20). The assessment report(s) prepared by the CVMP (co-)rapporteurs will reflect all data reviewed and considered relevant for the assessment.

The CVMP may in some cases require input from other individual experts to advise it on specific questions in relation to the assessment.

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

20. 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 Medicinal Products for Veterinary Use (CVMP) takes to assess the data provided.

The timetable for the Article 35 referral procedure when triggered by a Member State or the European Commission is as follows:

Article 35 referral procedure initiated by a Member State or the European Commission - *Timetable for the assessment*	Active day
Notification of a referral to the CVMP/Agency Secretariat	Day 0
Discussion at the first meeting of the CVMP following receipt of the notification: • Appointment of the (co-)rapporteur(s)	Day 1

Article 35 referral procedure initiated by a Member State or the European Commission - *Timetable for the assessment*	Active day
• Discussion of the question(s) referred • Adoption of a timetable and CVMP list of questions to be addressed by the applicants/marketing authorisation holders (MAHs)	
Preparation and submission of written explanations by the applicants/MAHs in response to the CVMP list of questions	Clock Stop
Re-start of the procedure following submission of written explanations	Clock re-start Day2
Circulation of the (co-)rapporteur's assessment report(s) on the applicants'/MAHs' written responses 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 reports and proposed SPC/labelling/package leaflet, if applicable	Day 25
Discussion at the CVMP meeting: • Discussion of assessment reports and comments received from CVMP members; • Decision on need for oral explanations; • Adoption of a CVMP list of outstanding issues to be answered in writing and/or in an oral explanation, if needed.	Day 30
Preparation and submission of written and/or of oral explanations by the applicants/MAHs in response to the CVMP list of outstanding issues, if applicable	Clock Stop
Re-start of the procedure following submission of written explanations or at the time of oral explanations	Clock re-start Day 31
Circulation of the (co-)rapporteur's revised assessment report on the applicants'/MAHs' explanations and on the proposed SPC/labelling/package leaflet, if applicable	Day 45
Adoption of a CVMP opinion (with annexes as provided in Article 36 of Directive 2001/82/EC) and CVMP assessment report	Day 60

The timetable for the procedure when triggered by an applicant/MAH is as follows:

Article 35 referral procedure initiated by an applicant/MAH - *Timetable for the assessment*	Day
Notification of a referral to the CVMP/Agency Secretariat Agency to liaise with applicant/MAH to ensure that the relevant documentation is submitted to the CVMP/Agency Secretariat	Day 0
Discussion at the first meeting of the CVMP following receipt of the notification (provided that the relevant documentation has been submitted by the	Day 1

Article 35 referral procedure initiated by an applicant/MAH - *Timetable for the assessment*	Day
applicant/MAH in advance of the start of the procedure): • Appointment of the (co-)rapporteurs • Adoption of the timetable for the assessment of the documentation already submitted to the CVMP/Agency Secretariat (no CVMP list of questions is adopted)	
Circulation of the (co-)rapporteur's assessment report(s) on the applicant's/MAH's submitted documentation and on the proposed 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 reports and comments received from CVMP members; • Decision on need for oral explanations; • Adoption of a CVMP list of questions to be answered in writing and/or in an oral explanation	Day 30
Preparation and submission of written and/or of oral explanations by the applicant/MAH in response to the CVMP list of questions	Clock Stop
Re-start of the procedure following submission of written explanations or at the time of oral explanations	Clock re-start Day 31
Circulation of the (co-)rapporteur's assessment report(s) on the applicant's/MAH's explanations and on the proposed SPC/labelling/package leaflet, if applicable	Day 51
Comments in writing from CVMP members on the (co)-rapporteurs assessment report(s) and proposed SPC/labelling/package leaflet, if applicable	Day 55
Adoption of a CVMP opinion (with annexes as provided in Article 36 of Directive 2001/82/EC) and CVMP assessment report	Day 60

The CVMP may extend the time limit of 60 days up to 150 days (including clock-stops) 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 to support the CVMP's assessment.

The CVMP may, however, suspend the time limit of 60/150 days (clock-stop) in order to allow the MAH to prepare the responses to 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, 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 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.

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

All applicants/marketing authorisation holder(s) (MAHs) of veterinary medicinal products included in the scope of the Article 35 referral procedure will be provided with the Committee for Medicinal Products for Veterinary Use (CVMP) (co-)rapporteur's assessment report(s) electronically via Eudralink.

22. Will I have the possibility to present my views in front of CVMP and how is this organised?

The Committee for Medicinal Products for Veterinary Use (CVMP) may decide whether there are issues that would benefit from being addressed orally by the applicants/marketing authorisation holders (MAHs). The applicants/MAHs will be duly informed in advance of the issues to be addressed during an oral explanation.

Applicants/MAHs may also make a request to the CVMP to present an oral explanation. In such a case, the applicants/MAHs should send a written request 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 should be held.

The oral explanation should take place during the assessment phase and 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.

Applicants/MAHs can provide the oral explanation on their own behalf or on behalf of the group of applicants/MAHs whom they represent.

23. What should I do if my veterinary medicinal product is withdrawn or transferred to another marketing authorisation holder?

If a marketing authorisation is withdrawn in any Member State during the referral procedure, the former marketing authorisation holder (MAH) should inform the procedure coordinator for the referral procedure without delay. The Agency will then liaise with the national competent authority of the Member State concerned. Following confirmation by the national competent authority of the withdrawal of the marketing authorisation, the Agency will inform the former MAH that this specific marketing authorisation will no longer be included in the ongoing referral procedure.

If the marketing authorisation is transferred during the referral procedure, the new MAH should provide a copy of the transfer decision of the relevant competent authority to the procedure coordinator for the referral procedure. It should also provide information on the new contact person for the procedure to the procedure coordinator (please refer to Question 10). Following receipt of the transfer decision, the Agency will inform the former MAH that they are no longer included in the referral procedure, in relation to the marketing authorisation transferred.

24. What should I do if the name of my veterinary medicinal product changes or if the name or address of the applicant/marketing authorisation holder changes?

If the name of a product or the name and/or address of an applicant/marketing authorisation holder (MAH) changes during the referral procedure, the applicant/MAH should inform the EMA's procedure

coordinator. 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.

Committee for Medicinal Products for Veterinary Use (CVMP) opinion

25. When will the CVMP opinion be issued?

The Committee for Medicinal Products for Veterinary Use (CVMP) will issue an opinion on the matter within the agreed timeframe (please refer to Question 20). The CVMP may extend that period up to 150 days, to take into account all available data as well as other issues that need to be addressed before issuing an opinion.

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

26. What could be the opinion of CVMP?

The Committee for Medicinal Products for Veterinary Use (CVMP) opinion on the matter referred under Article 35 may be that:

a) the application does not satisfy the criteria for authorisation;

b) the marketing authorisations should be granted, maintained or varied;

c) the marketing authorisations should be subject to certain conditions or;

d) the marketing authorisations should be suspended or revoked.

Where the opinion stipulates that the marketing authorisations should be varied, including changes/additions to the summary of the product characteristics, labelling or package leaflet, the opinion will include the required wording and location for the changes.

Where the marketing authorisation should be subject to certain conditions, or should be suspended with condition(s) for lifting the suspension, these conditions will be clearly stated in the CVMP opinion. These can include, but are not limited to, requesting the MAH to conduct a post-authorisation study. The assessment of the fulfilment of the condition(s) will be the responsibility of the Member States, unless otherwise stated.

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 will be appended to the opinion.

27. How is the CVMP opinion structured?

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

- a cover page in which the adopted opinion is outlined together with the voting outcome of CVMP;
- a listing of all veterinary medicinal products concerned, including the names of all identified products involved in the procedure and their respective applicants/marketing authorisation holders (MAHs) in each Member State;
- the scientific grounds and explanations for the CVMP opinion;
- the harmonised summary of product characteristics/labelling/package leaflet, if applicable;

- the conditions or restrictions imposed on the marketing authorisation(s), 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.

28. When is the CVMP opinion published?

A brief outcome of the Committee for Medicinal Products for Veterinary Use (CVMP) opinion will be included in the CVMP meeting highlights that are released on the Friday of the CVMP plenary meeting week.

A Questions & Answers document and all annexes of the CVMP opinion will be published on the Agency's website following the adoption of the European Commission Decision (please refer to Question 33).

29. Will I receive the CVMP opinion?

The designated contact person representing the applicant/marketing authorisation holder (MAH) (please refer to Question 10) identified at the start of the procedure, will receive the Committee for Medicinal Products for Veterinary Use (CVMP) opinion and assessment report following their adoption.

30. When and how can I request a re-examination of the CVMP opinion?

The marketing authorisation holder (MAH) may, within 15 calendar days of the receipt of the Committee for Medicinal Products for Veterinary Use (CVMP) opinion, notify the Agency in writing of its intention to request a re-examination of the CVMP opinion. The request must be submitted ~~via email to vet.applications@ema.europa.eu~~ within the stated timeline.

In case this deadline is not respected, the request for re-examination is considered inadmissible and the CVMP opinion becomes final and will be sent to the European Commission for the initiation of the decision-making process.

Re-examination

If, within 15 calendar days of receipt of the CVMP opinion, the applicant/MAH has notified the Agency in writing of its intention to request a re-examination of the CVMP opinion, the Agency will inform the CVMP and new CVMP (co-)rapporteurs will be appointed for the re-examination procedure.

The detailed grounds for the re-examination requested should be sent to the Agency within 60 calendar days of receipt of the CVMP opinion. The detailed grounds for re-examination must be sent within the stated timelines. In case these 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 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 MAH in the detailed grounds for re-examination. The 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 should be no later than the submission date of the detailed grounds.

Within 60 calendar days of receipt of the detailed grounds for re-examination, the CVMP will conclude its assessment of the detailed grounds and adopt a final opinion.

The CVMP final opinion following re-examination will be sent to the European Commission for the initiation of the decision-making process.

31. When do I have to submit translations?

The applicants/marketing authorisation holders (MAHs) might, where applicable, be requested to provide translations in all EU languages (including Icelandic and Norwegian, if applicable[2]) of the following annexes to the Committee for Medicinal Products for Veterinary Use (CVMP) opinion:

- listing of veterinary medicinal products concerned by the procedure;
- wording to be included in the relevant sections of the summary of product characteristics/labelling/package leaflet, if applicable.

The Agency will contact the applicant/MAH as early as possible to ensure the smooth running of the process.

Detailed information on the translation process of the CVMP opinion will be included in the letter notifying the adoption of the CVMP opinion.

32. What happens after the final opinion of the CVMP on the Article 35 referral?

Following receipt of the CVMP opinion and after the translation process has been finalised, the European Commission will then start the decision-making process leading to the adoption of a binding decision addressed to the Member States and notified to the applicants/marketing authorisation holders (MAHs).

Detailed information on the decision-making process can be found here.

The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv) recommendation for implementation of Commission Decisions can be found here.

33. Will there be any publication in relation to the Article 35 referral procedure after the European Commission Decision?

Around four weeks after the adoption of the European Commission Decision, a Questions & Answers document, summarising the subject and outcome of the referral procedure, as well as all annexes of the CVMP opinion in all EU languages will be published on the Agency's website.

[2] If authorised in Iceland and Norway