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CHAPTER 3

Union Referral Procedures

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CHAPTER 3 Union Referral Procedures

Table of Contents

Legal Basis and Purpose	3
REFERRALS UNDER ARTICLES 33, 34, 35, 78 OF DIRECTIVE 2001/82/EC, 45 OF REGULATION (EC) No 726/2004 AND 13 OF COMMISSION REGULATION (EC) No 1234/2008	4
1. Introduction	4
2. Article 33(4) of Directive 2001/82/EC ('Mutual Recognition and Decentralised referral')	4
3. Article 34 of Directive 2001/82/EC ('Harmonisation referral')	7
4. Article 35 of Directive 2001/82/EC ('Union interest referral')	8
5. Article 78 of Directive 2001/82/EC ('Urgent Union procedure')	10
6. Article 45 of Regulation (EC) No 726/2004 ('Procedure for centrally authorised products')	11
7. Article 13 of Commission Regulation (EC) No 1234/2008 ('Referral when there is disagreement between Member States on a type II variation procedure')	12
8. Temporary Measures	13
9. General procedural elements	14
10. Regulatory decision at EU level	20
11. Consequences of a referral	20
ANNEX: Notification forms	23

Legal Basis and Purpose

Union pharmaceutical legislation has created a binding EU mechanism which may be invoked on the basis of the following articles:

1. Article 33(4) of Directive 2001/82/EC ('Mutual Recognition and Decentralised referral')
2. Article 34 of Directive 2001/82/EC ('Harmonisation referral')
3. Article 35 of Directive 2001/82/EC ('Union interest referral')
4. Article 78 of Directive 2001/82/EC ('Urgent Union procedure')
5. Article 45 of Regulation (EC) No 726/2004 ('Procedure for centrally authorised products only')
6. Article 13 of Commission Regulation (EC) No 1234/2008 ('Referral when there is disagreement between Member States on a type II variation procedure')

Whenever this binding mechanism is invoked, a scientific evaluation of the matter is undertaken by the Committee for Medicinal Products for Veterinary Use (CVMP) of the European Medicines Agency (EMA). These referrals lead to a Commission decision to be implemented by all Member States and/or applicant(s)/marketing authorisation holder(s). This leads to a harmonised outcome at EU level.

This chapter sets out the details for the above procedures.

REFERRALS UNDER ARTICLES 33, 34, 35, 78 OF DIRECTIVE 2001/82/EC, 45 OF REGULATION (EC) No 726/2004 AND 13 OF COMMISSION REGULATION (EC) No 1234/2008

1. Introduction

The specific conditions under which a referral procedure may be started and those entitled to initiate such referral differ in each of the cases and are specified in detail in sections 2 to 7.

Under certain, well-defined circumstances (where urgent action to protect human or animal health or the environment is necessary) Member States and the Commission may adopt temporary measures whilst waiting for the outcome of a Union referral. These cases are illustrated in section 8.

The procedural elements of the referral procedures to the CVMP are described in section 9.

Except if stated otherwise, reference to national marketing authorisations, by opposition to central marketing authorisations, covers marketing authorisations which have been granted following a mutual recognition or decentralised procedure and “purely” national marketing authorisation, i.e. granted in only one Member State or granted before the mutual recognition procedure and the decentralised procedure (MRP/DCP) were mandatory.

2. Article 33(4) of Directive 2001/82/EC ('Mutual Recognition and Decentralised referral')

2.1 Basic principles

This referral procedure refers to cases where the Member States involved in a mutual recognition or decentralised procedure fail to reach an agreement within the 60-day period in the procedure of the veterinary coordination group for mutual recognition and decentralised procedure (CMDv) under Article 33(1) to (3) of Directive 2001/82/EC.¹

The referral must be initiated by the Reference Member State, on the grounds of potential serious risk to human or animal health or to the environment, where no agreement was reached during the CMDv procedure on the assessment report, the summary of product characteristics (SPC), or the labelling and the package leaflet, prepared by that Reference Member State.

For a description of the CMDv procedure, see CMDv website (www.hma.eu/veterinarymedicines.html).

For the definition of potential serious risk to human or animal health or to the environment, the Commission has adopted a guideline and annex of examples, available at http://ec.europa.eu/health/documents/eudralex/vol-6/index_en.htm

2.2 Can the application be withdrawn or the referral be stopped?

It is in the public interest and in the interest of the Union that questions raised on potential serious risks to human or animal health or to the environment are answered, and that all veterinary medicinal products authorised in the EU fulfil the requirements of quality, safety and efficacy.

An application for mutual recognition of a marketing authorisation or an application in the decentralised procedure may be withdrawn by the applicant(s)/marketing authorisation holder(s) at any time in any Member State.

¹ Homeopathic veterinary medicinal products subject to the special simplified registration procedure foreseen in Article 17 of Directive 2001/82/EC may not be referred to the CVMP. If agreement within the veterinary coordination group procedure is not reached, national authorities are competent to decide on the registration.

In case an applicant withdraws an application during a marketing authorisation procedure in one or more CMSs due to a disagreement based on potential serious risk to human or animal health or to the environment, the withdrawal of the application will not stop the matter from being discussed within the CMDv and this/these CMS(s) may trigger a CVMP referral procedure after the marketing authorisation procedure has been finalised.

After a potential serious risk to human or animal health or to the environment has been raised in accordance with Article 33(1) of Directive 2001/82/EC by a Concerned Member State, a withdrawal of the application in some of the Member States will not stop the referral procedure and, eventually, from a CVMP referral procedure being initiated.

Once a referral according to Article 33(4) of Directive 2001/82/EC has been initiated the referral can only be stopped if the applicant(s)/marketing authorisation holder(s) withdraw the application/marketing authorisation in all EEA Member States

2.3 Procedural steps leading to an Article 33(4) referral

If the Member States do not reach agreement in the CMDv procedure, the Reference Member State will refer the matter to the EMA for the application of the procedure laid down in Articles 36, 37 and 38 of Directive 2001/82/EC.

Only a positive assessment by the Reference Member State can lead a Concerned Member State to raise a potential serious risk concern. It is only if the concerned veterinary medicinal product would be authorised that it might present a “potential serious risk to human or animal health or to the environment”. Consequently, a negative assessment by the Reference Member State cannot be followed up by a referral under Article 33(1) to (4) of Directive 2001/82/EC.

In the referral, the Reference Member State shall provide the EMA with a detailed statement of the matter(s) on which the Member States concerned have been unable to reach agreement and the reasons for their disagreement. The matter(s) referred to the EMA must be based on potential serious risk to human or animal health or to the environment and should be precise. A notification form for this referral is provided in the Annex to this Chapter. The applicant/marketing authorisation holder is provided with a copy of this information. This detailed statement should focus on the following essential elements:

- i. description of the product: the latest available SPC, labelling and package leaflet as achieved during the CMDv procedure;
- ii. description of the remaining areas of disagreement, giving a clear statement of the issues at referral, including in particular the reasons for disagreement and question(s) to be addressed by the CVMP.

In addition, the Reference Member State should provide to the EMA a consolidated report addressing the following:

- i. description of the scientific discussion during the various stages of the mutual recognition/decentralised procedure between the Reference Member State and Concerned Member State(s), including a brief summary of the resolution of other major issues between day 0 and day 60 of the CMDv procedure and a summary of the discussions and outcomes of the CMDv procedure;
- ii. initial assessment report of the Reference Member State and an updated assessment report following the CMDv procedure.

This report will be forwarded to the applicant/marketing authorisation holder at the start of the procedure. As soon as the applicant/marketing authorisation holder is informed that the matter has been referred to

the EMA, in accordance with Article 33(5) of Directive 2001/82/EC the applicant/marketing authorisation holder must forward to the EMA a copy of the application submitted to the competent authorities of the Member States concerned, containing the information and documents referred to in Articles 12, 13, 13a, 13b, 13c or 13d and 14 of Directive 2001/82/EC.

2.4 Scope of the referral

The CVMP is called upon to issue an opinion on the concerns that, in accordance with the assessment report and product information proposed by the Reference Member State, the authorisation of the veterinary medicinal product concerned might present a “potential serious risk to human or animal health or to the environment”.

The term ‘risk’ related to the use of veterinary medicinal products is defined in Directive 2001/82/EC, Article 1(19), as ‘any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health’ and ‘any risk of undesirable effects on the environment’. In addition, on the basis of Article 33(2) of Directive 2001/82/EC, the Commission has adopted a guideline to define a potential serious risk to human or animal health or to the environment, with an annex of examples, available at http://ec.europa.eu/health/documents/eudralex/vol-6/index_en.htm.

If the CVMP is asked about “potential serious risk to human or animal health or to the environment” concerns, it may consider aspects subsequently arising during the assessment, necessary to draft the SPC, labelling and package leaflet which will be annexed to the opinion of the CVMP and to the decision of the Commission as provided in Articles 36, 37 and 38 of Directive 2001/82/EC.

In the case of a positive outcome of the referral the product information (SPC, labelling and package leaflet) will be annexed to the CVMP opinion.

However, in cases where the assessment of the CVMP is restricted to limited parts of the SPC, labelling and package leaflet it will be possible to have in the annex of the opinion only those parts which were subject to amendment during the referral, together with a statement that, for the remaining parts, the SPC, labelling and package leaflet are the final versions achieved during the CMDv procedure. It is also possible that the assessment of the CVMP concludes that no modifications of the SPC, labelling and package leaflet are needed. In such case, the annex of the opinion shall reflect that conclusion.

However, in situations where the matters referred impact important number of sections of the SPC a full product information (SPC, labelling and package leaflet) will be annexed to the CVMP opinion. Certain differences may, however, remain, such as the names of the veterinary medicinal products, the names of the marketing authorisation holders and the legal supply status which may be different between Member States concerned.

2.5 Marketing authorisations before completion of the referral procedure

According to Article 33(6) of Directive 2001/82/EC, when there is a failure to reach an agreement within the CMDv procedure, “*Member States that have approved the assessment report, the summary of product characteristics, labelling and package leaflet of the Reference Member State may, on request by the applicant, grant a marketing authorisation for the veterinary medicinal product without waiting for the outcome of the procedure laid down in Article 36. In that case, the authorisation granted shall be without prejudice to the outcome of that procedure.*”

The SPC, the labelling and the package leaflet to be covered by those marketing authorisations shall be the ones proposed by the Reference Member State or, when these have been subject to amendments agreed within the CMDv procedure, the last version agreed therein.

3. Article 34 of Directive 2001/82/EC ('Harmonisation referral')

3.1 Basic principles

Any Member State, the Commission or the marketing authorisation holder of a particular veterinary medicinal product may initiate a referral if divergent decisions on the authorisation, suspension or revocation of a particular veterinary medicinal product have been taken by two or more Member States. The divergences are to be identified, in the notification form, in a sufficiently precise manner.

Article 34 of Directive 2001/82/EC applies to all national marketing authorisations in order to promote harmonisation of these authorisations throughout the Union.

Article 34(1) may be initiated in the following cases:

- Where a particular veterinary medicinal product has been nationally authorised in two or more Member States and the authorisations diverge;
- Where a particular veterinary medicinal product, with a national marketing authorisation in some or all the Member States, is suspended or revoked for quality, safety or efficacy reasons in some, but not all, Member States;
- Where a particular veterinary medicinal product is nationally authorised in some or all Member States and one of the authorisations is subsequently varied, introducing a divergence versus the other national authorisations.

3.2 Can the referral be stopped?

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

3.3 Procedural steps leading to an Article 34 referral

The referrer (the Commission, a Member State or marketing authorisation holder) sends the question to the CVMP for consideration, together with a detailed explanation of the issue(s) raised. A notification form for this referral is provided in the Annex to this Chapter.

A non-exhaustive list of divergences has to be presented and described to support the notification of the referral.

If the referrer is a Member State or the Commission, the marketing authorisation holder must be informed of the referral.

If the referrer is a marketing authorisation holder, in advance of initiating a referral under Article 34 of Directive 2001/82/EC, he is recommended to have a pre-referral discussion and meeting with the EMA.

Following notification of the referral, the marketing authorisation holder(s) and the Member States concerned forward to the EMA any information relevant to the referral. In particular, the marketing authorisation holder is requested to provide the following information:

- to provide an exhaustive list of differences between the SPCs of the product authorised throughout the Union;
- to advise (giving reasons) if any previous application or marketing authorisation of the product, relating to use in any target species or indication, has been withdrawn, refused, revoked or suspended in any Member State;

- to review all sections of the SPCs and to suggest appropriate changes in the text where divergences exist;
- to propose a fully harmonised SPC, labelling and package leaflet, taking into account the latest guidance (e.g. QRD reference documents and CVMP scientific guidelines);
- to provide all relevant data that is available, in order to substantiate the proposed harmonised SPC, labelling and package leaflet in relation to the divergences identified.

3.4 Scope of the referral

The CVMP is called upon to issue an opinion on the area(s) of divergence amongst the national decisions, on the basis of the question(s) referred to it relating to a particular veterinary medicinal product.

The scope of the referral is to resolve the divergences between the national decisions, and therefore the referral leads to a full harmonisation of the SPC, labelling and package leaflet.

In order to achieve a full harmonisation of the product information, the CVMP may consider other publicly available data.

Certain differences may, however, remain, such as names of the veterinary medicinal products, names of the marketing authorisation holders, legal supply status and certain pharmaceutical particulars (e.g. shelf life and storage conditions).

4. Article 35 of Directive 2001/82/EC ('Union interest referral')

4.1 Basic principles

Article 35 provides that Member States, the Commission or the applicant(s)/marketing authorisation holder(s) of the concerned veterinary medicinal product must initiate a referral whenever the interests of the Union are involved, and 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 variation to the terms of a marketing authorisation which appears necessary in particular to take into account pharmacovigilance information.

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 in the light of quality, safety and efficacy data and to the free movement of products within the Union.

This procedure may, like the Urgent Union procedure, be initiated on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities. However when there is a need for urgent action, the Urgent Union procedure must be initiated, see section 5.

An Article 35 referral may concern:

- a specific veterinary medicinal product,
- a range of veterinary medicinal products, e.g. all containing the same active substance, which is present in several different veterinary medicinal products with different names and different marketing authorisation holders;
- a range of veterinary medicinal products, containing different active substances, belonging to different therapeutic classes, but concerned by the matter referred;
- or a therapeutic class of veterinary medicinal products (different active substances and veterinary medicinal products belonging to the same therapeutic class).

When the referral concerns a range of veterinary medicinal products or a therapeutic class the EMA may limit the procedure to certain specific parts of the authorisation.

In case the matter referred concerns also centrally authorised veterinary medicinal products, then a parallel procedure will be initiated by the European Commission in accordance with Article 45 of Regulation (EC) No 726/2004 (see section 6).

4.2 Can the referral be stopped?

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

The adoption of temporary measures by Member States/Commission will not stop the procedure.

4.3 Procedural steps leading to an Article 35 referral

While the Member States, the Commission or the applicant/marketing authorisation holder must, where the interests of the Union are involved, refer the matter to the CVMP; it is only the Member State concerned or the Commission which must clearly identify the question(s) to the CVMP. Thus, if the referrer is an applicant/marketing authorisation holder, in advance of initiating a referral under this Article, he/she must contact a Member State or the Commission with a request to assess and confirm the Union interest before the matter is referred to the CVMP. The applicant/marketing authorisation holder can include in the scope of the referral only its own product, with justification of potential extension to others. A pre-referral meeting with the EMA is recommended.

The referrer (Member State concerned or the Commission) clearly identifies the question which is referred for consideration to the CVMP together with a detailed explanation on how the Union interests are involved. The applicant(s)/marketing authorisation holder(s) is then informed of the issues arising in the referral.

Pre-referral discussion and meeting, as necessary, between the applicant/marketing authorisation holder and the EMA are also possible in cases where the referrer is a Member State or the Commission.

Following the start of the referral procedure, the Member States and the applicant(s)/marketing authorisation holder(s) must forward to the CVMP all relevant information relating to the veterinary medicinal product(s).

A notification form for this referral is provided in the Annex to this Chapter.

4.4 Scope of the referral

4.4.1 Referral relating to a specific veterinary medicinal product

The CVMP is called upon to issue an opinion on a matter involving Union interest, on the basis of the question(s) referred to it.

However, the CVMP may consider aspects other than those explicitly mentioned in the referral which are necessary to evaluate the veterinary medicinal product under consideration and to harmonise the SPC, labelling and package leaflet to be annexed to the opinion, as applicable.

Certain differences may, however, remain, such as names of the veterinary medicinal products, names of the marketing authorisation holders, legal supply status and certain pharmaceutical particulars (e.g shelf life and storage conditions).

4.4.2 'Class' referral

Where the referral concerns a range of veterinary medicinal products or a therapeutic class, the EMA may limit the procedure to certain specific parts of the authorisation. If the EMA decides to limit the

procedure in this way, only specific sections, or parts of them, of the SPC will be harmonised with the corresponding changes to the relevant package leaflet section and labelling.

A class referral covers all veterinary medicinal products concerned by the matter.

5. Article 78 of Directive 2001/82/EC ('Urgent Union procedure')

5.1 Basic principles

This procedure should be initiated when there is a need to take urgent action regarding concerns resulting from the evaluation of pharmacovigilance data for non-centrally authorised veterinary medicinal products. This procedure must be initiated when a Member State:

- considers suspending or withdrawing a marketing authorisation of a veterinary medicinal product;
- considers an amendment of a marketing authorisation to:
 - o restrict the indications or availability of a veterinary medicinal product;
 - o add a contraindication or a new precautionary measure; and/or
 - o amend the posology of a veterinary medicinal product.

The procedure under Article 78 of Directive 2001/82/EC should not be initiated when the veterinary medicinal product concerned is authorised:

- in only one Member State, the safety concern will be addressed by the Concerned Member State at national level without the initiation of an Urgent Union procedure.
- only through the centralised procedure, a referral procedure will be initiated in accordance with Article 45 of Regulation (EC) No 726/2004 (see section 6).

5.2 Can the procedure be stopped?

Once the procedure is initiated and started, it can only be stopped if all marketing authorisation holder(s) withdraw the concerned marketing authorisations in all Member States.

The adoption of temporary measures by Member States/Commission will not stop the procedure.

5.3 Procedural steps leading to an Article 78 procedure

The general procedural elements are given in section 9 of this chapter.

A Member State which took the urgent action or identified the need for regulatory action, must initiate the procedure laid down in Article 78 of Directive 2001/82/EC. The referring Member State must inform the other Member States, the EMA, the Commission and the marketing authorisation holder(s) on the safety concern(s) supporting the urgent regulatory action(s) being considered or taken.

A notification form for this procedure is provided in the Annex to this Chapter which should be circulated, together with the assessment report supporting considerations for regulatory action, using the pharmacovigilance rapid alert system.

In cases when a Member State considers urgent action to be necessary in order to protect human or animal health, the Member State concerned may suspend the marketing authorisation of the veterinary medicinal product(s). Where such action has been taken, the EMA, the Commission and other Member States must be informed on the following working day at the latest.

When the EMA is informed about the matter and/or urgent actions taken, the CVMP shall give its opinion as soon as possible, according to the urgency.

Following the start of the procedure, the marketing authorisation holder(s) forward(s) to the EMA all relevant information relating to the veterinary medicinal product(s).

5.4 Scope of the procedure

The scope of the procedure is as identified by the Member State that triggered it. However, the scope of the procedure will be extended as appropriate, if EMA identifies that:

- the safety concern relates to other veterinary medicinal product(s) in addition to the one covered by the notification,
- the safety concern is common to all products belonging to the same range or therapeutic class;
- the veterinary medicinal product(s) covered by the notification is authorised in more than one Member State.

6. Article 45 of Regulation (EC) No 726/2004 ('Procedure for centrally authorised products')

6.1 Basic principles

This procedure covers any concerns detailed in section 6.3 relating to centrally authorised veterinary medicinal products. It is initiated by the Commission, requesting the opinion of the CVMP/EMA.

6.2 Can the procedure be stopped?

Following the start of the procedure, this procedure can be stopped if the marketing authorisation holder(s) withdraw all the centralised marketing authorisation(s) concerned.

The adoption of temporary measures by Member States/Commission will not stop the procedure.

6.3 Procedural steps leading to an Article 45 procedure

The Commission will initiate the referral in case a Member State or the Commission considers that:

- a manufacturer or an importer established within the Union territory does not fulfil its obligations laid down in Title IV (manufacture and importation) of Directive 2001/82/EC,
- the measures envisaged under Title VII (pharmacovigilance) and VIII (supervision and sanctions) of Directive 2001/82/EC must be applied, or
- the CVMP has delivered an opinion in that effect on the basis of Article 30 of Regulation (EC) No 726/2004.

The Commission, in view of the urgency, determines the time limit within which the Committee must deliver its opinion.

A notification form for this procedure is provided in the Annex to this Chapter.

Following the start of the procedure, the marketing authorisation holder(s) shall be invited to provide oral or written explanations whenever practicable to the CVMP.

6.4 Scope of the procedure

An Article 45 procedure is initiated when the matter referred involves centrally authorised products. It can concern:

- a single centrally authorised veterinary medicinal product,
- a range of centrally authorised veterinary medicinal products, e.g. all containing the same active substance, which is present in several different veterinary medicinal products with different names and different marketing authorisation holders;
- a range of centrally authorised veterinary medicinal products, containing different active substances, belonging to different therapeutic classes, but that are concerned by the same matter referred;

- a therapeutic class of centrally authorised veterinary medicinal products, comprising several veterinary medicinal products containing different active substances and belonging to the same therapeutic class.

7. Article 13 of Commission Regulation (EC) No 1234/2008 ('Referral when there is disagreement between Member States on a type II variation procedure')

7.1 Basic principles

This referral may be initiated by Member States in respect of veterinary medicinal products which have been granted a national marketing authorisation.

If a Member State, on grounds of potential serious risk to human or animal health or to the environment, cannot:

- recognise the decision on a major variation of Type II within 30 days, by reference to Article 10(4) of Commission Regulation (EC) No 1234/2008, or
- approve an opinion on a work-sharing procedure within 30 days, by reference to Article 20(8) of Commission Regulation (EC) No 1234/2008.

It should refer the matter of disagreement to the CMDv, in accordance with Article 13 of Commission Regulation (EC) No 1234/2008 and the procedure under Article 33(3), (4) and (5) of Directive 2001/82/EC applies. Only a positive assessment by the Reference Member State can lead a Concerned Member State to raise a potential serious risk concern. Indeed, it is only if the concerned veterinary medicinal product would be authorised that it might present a "potential serious risk to human or animal health or to the environment".

If the Member States fail to reach an agreement within the 60-day period in the CMDv, a referral by reference to Article 13 of Commission Regulation (EC) No 1234/2008 will be initiated by the Reference Member State on grounds of potential serious risk to human or animal health or to the environment.

The term 'risk' relating to the use of veterinary medicinal products is defined in Directive 2001/82/EC, Article 1(19), as 'any risk relating to the quality, safety and efficacy of the veterinary medicinal product as regards animal or human health; any risk of undesirable effects on the environment'. In addition, on the basis of Article 33(2) of Directive 2001/82/EC, the Commission has adopted a guideline to define a potential serious risk to human or animal health or to the environment, with an annex of examples available at: http://ec.europa.eu/health/documents/eudralex/vol-6/index_en.htm

7.2 Can the variation application be withdrawn or the referral be stopped?

After a potential serious risk to human or animal health or to the environment has been raised in accordance with Article 13 of Commission Regulation (EC) No 1234/2008 by a Concerned Member State, a withdrawal of the variation application in some of the Member States will not stop the matter from being discussed within the CMDv and, eventually, from a referral procedure being started.

The referral can only be stopped if the marketing authorisation holder(s) withdraw the variation applications in all Member States where the veterinary medicinal product(s) are authorised.

7.3 Procedural steps leading to an Article 13 referral

The procedural steps of Article 33 referral apply.

7.4 Scope of the referral

As provided for in Article 13(2) of Commission Regulation (EC) No 1234/2008, the procedure referred to in Article 33 of Directive 2001/82/EC applies where it has not been possible to achieve agreement under

the mutual recognition procedure for a major variation of type II or a work-sharing procedure of marketing authorisation(s).

The CVMP should limit its opinion to the question referred. Within the scope of the referral, the CVMP may nevertheless consider aspects subsequently arising during the assessment, which may affect the SPC, labelling and package leaflet which will be annexed to the opinion of the CVMP and to the decision of the Commission as provided in Articles 36, 37 and 38 of Directive 2001/82/EC.

Only those parts of the SPC, labelling and package leaflet which were subject to the variation and/or amendments during the referral will be annexed to the CVMP opinion and to the decision of the Commission.

However, in situations where the matters referred impact important number of sections of the SPC, for clarity purpose, a full SPC, labelling and package leaflet may be annexed to the CVMP opinion. Certain differences may, however, remain, such as the names of the veterinary medicinal products, the names of the marketing authorisation holder(s), the legal supply status and certain pharmaceutical particulars (e.g. shelf life and storage conditions) may be different between Member States concerned.

8. Temporary Measures

EU pharmaceutical legislation enables the Member States and/or the Commission to take temporary measures, at any stage of the procedure, in exceptional cases, where urgent action is necessary to protect human or animal health or undesirable effects on the environment and until a definitive decision is adopted at EU level through the adequate referral procedure previously described.

8.1 In the context of Articles 35 and 78 procedures of Directive 2001/82/EC (nationally authorised veterinary medicinal products)

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

All Member States, the Commission and the EMA must be informed by the Member State of the reason for their action no later than the following working day.

In addition, in the context of the procedure under Article 78 of Directive 2001/82/EC, the Commission may request Member States in which the veterinary medicinal product is authorised to take temporary measures immediately, while waiting for the adoption of final measures, which shall follow the procedure foreseen in Article 89(3).

8.2 In the context of an Article 45 procedure of Regulation (EC) No 726/2004 (centrally authorised veterinary medicinal products)

When urgent action is essential to protect human or animal health or the environment, a Member State may, on its own initiative or at the Commission's request, suspend the use on its territory of a centrally authorised veterinary medicinal product.

When it does so, on its own initiative, the Member State must inform the Commission and the EMA of the reasons for its action at the latest on the next working day following the suspension. The EMA must inform the other Member States.

The Commission will initiate the Article 45 procedure, if not already ongoing.

When provisional measures are adopted in line with Article 45(3) of Regulation (EC) No 726/2004, a final decision shall be adopted by the Commission within 6 months.

9. General procedural elements

Notwithstanding the legal provisions described above, it is suggested to carry out some preliminary procedural steps in order to streamline the operation of the EU referral procedures.

In advance of initiating a referral, it is strongly encouraged to send to the EMA:

- A draft notification including a clear and concise identification of the concern to be referred to the CVMP, indicating the veterinary medicinal product(s), active substance(s), pharmaceutical form(s) and/or strength(s), route of administration, target species, applicant(s)/ marketing authorisation holder(s) concerned;
- Scientific documentation (scientific information that is available at the time, before the referral is triggered) in support of the referral;
- Where appropriate, request for a meeting with the EMA to discuss regulatory and procedural issues linked to the referral.

When an issue is referred to the CVMP, information is collected before the end of the first CVMP meeting following the notification for the referral. This includes a list of the names of the veterinary medicinal product(s) affected by the referral (including pending applications, if applicable), together with information on the respective applicant(s)/marketing authorisation holder(s), strength(s), pharmaceutical form(s), target species and route(s) of administration.

In the case of Article 33 referrals initiated in the frame of a repeat use mutual recognition procedure, the list of the names of the veterinary medicinal product affected by the referral shall also include those authorised by the previous mutual recognition procedure(s).

In the case of referrals initiated by (an/a) applicant(s)/marketing authorisation holder(s), the referral should be accompanied by expert reports/overviews which have been updated to include data supporting the reasons for referral. In addition the applicant(s)/marketing authorisation holder(s) should ensure that all available information relating to the matter in question is forwarded to the CVMP members, the competent authorities of the Member States and the EMA.

To ensure a smooth implementation of the above-mentioned requirements, the EMA will inform the applicant(s)/marketing authorisation holder(s) for each initiated referral on the documentation needed as well as on the submission requirements for CVMP rapporteur, co-rapporteur and other Committee members according to their dossier requirements, as appropriate.

For Article 34 and Article 35 referrals initiated by the applicant(s)/marketing authorisation holder(s), the EMA will inform the applicant(s)/marketing authorisation holder(s) of the appropriate fee to be paid.

9.1 Organisation of work within the CVMP and EMA secretariat

The CVMP appoints rapporteur and co-rapporteur(s).

Once the appointments have been made, the EMA informs the applicant(s)/marketing authorisation holder(s).

The CVMP may also consult its working parties, ad-hoc expert groups or individual experts to advise it on specific questions. When it does so, the Committee defines their tasks and specifies the time limit for the completion of these tasks.

For referrals initiated by a Member State or by the Commission, at the first CVMP meeting following the initiation of the referral, the CVMP formulates the question(s) to be addressed to the applicant(s)/marketing authorisation holder(s) and discusses the scope of the documentation actually requested or needed.

For referrals initiated by the applicant(s)/marketing authorisation holder(s), at the first CVMP meeting following the initiation of the referral, the Committee starts its assessment of the issues referred. A list of questions may be adopted at day 30 of the procedure.

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.

It should be stressed that all members of the CVMP are equally concerned by the question submitted in the matter referred to the Committee. They take part in the evaluation procedure and the adoption of opinion independently of the Member State which has nominated them as CVMP member, and of the situation of the veterinary medicinal product in the Member States.

9.2 Hearing of the applicant(s)/marketing authorisation holder(s)

Before issuing its opinion, the CVMP provides the applicant(s)/marketing authorisation holder(s) with an opportunity to present written or oral explanations. As a general principle the oral explanation is based on data that was submitted in advance and assessed by the Committee.

9.3 Timetable

The standard timetable for assessment by the CVMP after notification of the referral is 60 days from the date the matter was referred to it.

For Article 34 and Article 35 referrals, the CVMP may extend that period to 150 days, taking into account the views of the applicant(s)/marketing authorisation holder(s).

For all referrals, in case of urgency, on a proposal from its Chairperson, the CVMP may agree on a shorter deadline.

The time points provided within the referral timetable below are provided for guidance purposes only and correspond to the key steps in the referral procedure. They can be altered in order to reflect the particularities of a referral.

The time points refer to active days, i.e. correspond to the time during which the CVMP is assessing the data provided. The CVMP will not exceed the overall timeframe provided in the legislation.

The CVMP may, however, suspend the time limit of 60/150 days (clock-stop) in order to allow the applicant(s)/marketing authorisation holder(s) to prepare the responses to CVMP list of questions, list of outstanding issues or an oral explanation (as appropriate).

For Article 45 procedures, the Commission may request the opinion of the CVMP within a time-limit determined in the light of the urgency of the matter.

For Article 78 procedures the timetable is determined by the CVMP in accordance with the urgency of the matter.

9.3.1 Timetable for referral procedures under Articles 33, 34, 35 of Directive 2001/82/EC, Article 45 of Regulation (EC) No 726/2004 and Article 13 of Commission Regulation (EC) No 1234/2008

Referral initiated by a Member State or the Commission - **Timetable for the procedure**

Day 0	Notification of a referral to the CVMP/EMA Secretariat.
Day 1	First meeting of the CVMP following notification of referral. The CVMP discusses the question(s) referred during the plenary meeting. Rapporteur and co-rapporteur(s) are appointed. Adoption of CVMP list of questions to be addressed in writing by the applicant(s)/marketing authorisation holder(s), and timetable.
Clock stop	For the applicant(s)/marketing authorisation holder(s) to answer to CVMP list of questions.
Clock re-start (day 2)	Following submission of responses (in accordance with published submission dates) (and if applicable including English SPC, labelling and package leaflet).
Day 20	Rapporteur and co-rapporteur(s) circulate assessment report(s) on the written responses from the applicant(s)/marketing authorisation holder(s) in parallel, if applicable, with the draft SPC/labelling/package leaflet to be annexed to the opinion.
Day 25	Comments from CVMP members on the (co-)rapporteur(s) assessment report(s) and draft SPC/labelling/package leaflet (if applicable).
Day 30	Discussion at the CVMP: Adoption of the CVMP opinion, or Adoption of CVMP list of outstanding issues to be addressed by the applicant(s)/marketing authorisation holder(s) in writing and/or at oral explanation, and timetable for the rest of the procedure.
Clock stop	If necessary, for the applicant(s)/marketing authorisation holder(s) for the submission of written responses and/or preparation for an oral explanation.
Clock re-start	If necessary, following the submission of written responses (in accordance with the published submission dates) and/or at the time of oral explanation.
Day 60	Adoption of the CVMP opinion (with annexes as provided in Article 36 of Directive 2001/82/EC) and CVMP assessment report.

Referral initiated by the applicant(s)/marketing authorisation holder(s) - **Timetable for the procedure**

As in principle there is no “list of questions” at day 1 of the procedure, the timetable is as follows:

Day 0	Notification of a referral to the CVMP/EMA Secretariat.
Day 1	CVMP meeting following notification of referral and provided relevant documentation has been submitted by the applicant(s)/marketing authorisation holder(s) in advance of the start of the procedure. The CVMP discusses the question(s) referred during the plenary meeting. Rapporteur and co-rapporteur(s) are appointed. Adoption of the timetable. No adoption of CVMP list of questions.
Day 20	Rapporteur and co-rapporteur(s) circulate assessment report(s) on the data provided from the applicant(s)/marketing authorisation holder(s) and, if applicable, comments on the proposed SPC/labelling/package leaflet.
Day 25	Comments from CVMP members on the (co-)rapporteur(s) assessment reports and draft SPC/labelling/package leaflet (if applicable).
Day 30	Discussion at the CVMP: Adoption of the CVMP opinion, or Adoption of CVMP list of questions to be to be addressed in writing by the applicant(s)/marketing authorisation holder(s) and/or at oral explanation, and timetable for the rest of the procedure.
Clock stop	If necessary, for the applicant(s)/marketing authorisation holder(s) for the submission of written responses and/or preparation for an oral explanation.
Clock re-start	If necessary, following the submission of written responses (in accordance with the published submission dates) and/or at the time of oral explanation.
Day 60	Adoption of the CVMP opinion (with annexes as provided in Article 36 of Directive 2001/82/EC) and CVMP assessment report.

9.4 Opinion

In the event of an opinion in favour of granting, maintaining or varying a marketing authorisation for the veterinary medicinal product(s) concerned, in accordance with Article 36(5) or Article 78 of Directive 2001/82/EC, the following documents are annexed to the opinion:

- **for nationally authorised products:**
 - i. Summary of the product characteristics, labelling and package leaflet or proposed changes to parts of these documents ~~summary of the products characteristics, labelling and package leaflet~~, as appropriate;
 - ii. Any conditions affecting the authorisation considered essential for the safe and effective use of the veterinary medicinal product including pharmacovigilance, if applicable;
 - iii. Details of any recommended conditions or restrictions with regard to the safe and effective use of the veterinary medicinal product, if applicable;

In addition, a list of the veterinary medicinal products and marketing authorisation holders concerned by the procedure and the scientific conclusions justifying the outcome of the referral are attached to the opinion.

- **for centrally authorised products:**
 - i. Draft summary of the product characteristics, labelling and package leaflet;
 - ii. Any conditions affecting the authorisation considered essential for the safe and effective use of the veterinary medicinal product including pharmacovigilance, if applicable;
 - iii. Details of any recommended conditions or restrictions with regard to the safe and effective use of the veterinary medicinal product, if applicable.

In addition, a list of all presentations of veterinary medicinal products concerned by the procedure and the scientific conclusions justifying the outcome of the referral are attached to the opinion.

In the event of a CVMP opinion recommending the refusal, suspension, revocation or non-renewal of the marketing authorisation(s) for the veterinary medicinal product(s) concerned, the scientific conclusions with the grounds and conditions for the lifting of the suspension, as applicable are annexed to the opinion.

Any divergent positions of the CVMP members are attached to the final CVMP opinion.

Within 15 days of the adoption of the final opinion of the CVMP, the EMA forwards it to the Member States, the Commission and the applicant(s)/marketing authorisation holder(s) together with a report describing the assessment of the referral concerning the veterinary medicinal product(s) and stating the reasons for its conclusions.

A summary of the assessment and conclusions is published on the EMA and Commission websites.

9.4.1 Conditions and restrictions with regard to the safe and effective use of the veterinary medicinal product

In the cases foreseen in Article 36(4) (third indent) and (5)(b) and (c) of Directive 2001/82/EC the authorisation should be granted subject to certain conditions, in view of conditions considered essential for the safe and effective use of the veterinary medicinal product including pharmacovigilance or other

recommended conditions or restrictions with regard to the safe and effective use of the veterinary medicinal product.

The opinion/assessment report of the CVMP should thus include justification for the conditions proposed, i.e. timelines to be kept and details of the reports, including the details for the pharmacovigilance reports to be presented to guarantee a sufficient follow-up of the marketing authorisation. The follow-up to the conditions will normally be monitored by the Member States and only in exceptional cases by the CVMP.

9.5 Re-examination

The possibility for re-examination of CVMP opinion for referral procedures under Articles 33(4), 34 and 35 of Directive 2001/82/EC and Article 13 of Commission Regulation (EC) No 1234/2008 is provided by Article 32(4) of Directive 2001/82/EC.

The CVMP opinions adopted under Article 45 of Regulation (EC) No 726/2004 and Article 78 of Directive 2001/82/EC are not subject to re-examination.

Once the opinion of the CVMP is adopted, the EMA informs the applicant(s)/ marketing authorisation holder(s).

Within 15 days of the receipt of the CVMP opinion, the applicant(s)/marketing authorisation holder(s) may notify the EMA in writing of his/their intention to request a re-examination of the opinion. In that case, applicant(s)/marketing authorisation holder(s) forward the detailed grounds for the request to the EMA within 60 days after receipt of the opinion. In case these deadlines are not respected, the request for re-examination is considered inadmissible and the opinion becomes final.

The scope of the re-examination procedure is limited to the points of the opinion initially identified by the applicant in its request for re-examination and may be based only on the scientific data available when the CVMP adopted the initial opinion. Therefore no new data can be submitted and considered within the re-examination procedure.

Within 60 days from receipt of the detailed grounds for the request, the CVMP must re-examine its opinion. In order to do so, it will appoint a new rapporteur and co-rapporteur different from those appointed for the initial opinion. The rapporteur and co-rapporteur are responsible for making an assessment of the detailed grounds for re-examination. A reasoned conclusion on all relevant points raised by the applicant(s)/marketing authorisation holder(s) must be included in the assessment report.

The conclusions of the re-examination are an integral part of the evaluation and are therefore integrated within the final assessment report appended to the final opinion and reflected in scientific conclusions.

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

10. Regulatory decision at EU level

The Commission starts the Union decision-making procedure following receipt of the CVMP final opinion.

For nationally authorised veterinary medicinal products, the Commission decision is addressed to Member States and will be reported, for information, to the applicant(s)/marketing authorisation holder(s). The Member States are required to either grant, maintain, suspend, refuse or withdraw/revoke the marketing authorisation, or vary the terms of the marketing authorisation as necessary to comply with the decision within 30 days of its notification and are required to inform the Commission and the EMA of the measures taken.

For centrally authorised veterinary medicinal products, the Commission decision is addressed to the marketing authorisation holder(s) and implements directly the changes to the product information required. In case of conditions or restrictions as provided in Article 34(4) point c of Regulation (EC) No 726/2004, the Commission may adopt another decision addressed to the Member States for the implementation of those conditions or restrictions.

When the Commission decision provides for granting, varying or maintaining a marketing authorisation, the documents annexed to the decision are: the SPC, the text of the labelling and package leaflet, the scientific conclusions and, as the case may be, any condition affecting the marketing authorisation considered essential for the safe and effective use of the veterinary medicinal product including pharmacovigilance, and any conditions or restrictions with regard to the safe and effective use of the veterinary medicinal product. In addition when the decision concerns nationally authorised veterinary medicinal products, the list of the names, pharmaceutical forms, strengths, target species and routes of administration of these nationally authorised veterinary medicinal product(s) and their applicants/marketing authorisation holders in the Member States are annexed.

When the Commission decision provides for the suspension of the marketing authorisation, the conditions for the lifting of the suspension will also be annexed.

11. Consequences of a referral

Member States national requirements for the implementation of a referral decision, as well as details on the national procedure(s) to be followed after the Commission decision are included in CMDv website.

11.1 Actions to be taken by the Member States after a referral

Commission decisions following a referral procedure are addressed to all Member States.

Commission decision taken following a referral request Member States directly concerned by the referral procedure to comply with the Commission decision within 30 days of its notification and to inform the Commission and the EMA.

The marketing authorisation holder is urged to take appropriate steps necessary to allow the Member States to comply with the Commission decision.

All Member States must consider whether any action is appropriate as regards products authorised by them and should take the decision into account in any future regulatory action.

When the referral procedure concludes on the variation to the terms of the marketing authorisation such as amendments to the product information and/or condition, these amendments and/or conditions are detailed in the Annex to the Commission decision and are the only binding changes and measures to be implemented by the Member States as an outcome of this procedure.

Any other amendments to the product information than those stated in the Annex to the Commission decision or any new application to vary the terms of a marketing authorisation or to grant a marketing

authorisation would require the submission of the appropriate data within the appropriate procedure and would be subject to assessment by the relevant competent authorities.

In the case of a subsequent application for the same veterinary medicinal product, the evaluation must take into account the Commission decision and Member States should grant or refuse the national marketing authorisations according to the terms of the Commission decision unless there are issues which have not been previously considered. Any Member State or the Commission, as appropriate, would refer the new scientific issue to the CVMP in order to start a new referral procedure.

The same applies in case where a marketing authorisation is pending for the veterinary medicinal product, which was the subject of the referral. The Member States must grant or refuse national marketing authorisations in accordance with the Commission decision.

11.2 Independent applications for marketing authorisation submitted during a referral procedure

While a referral procedure is ongoing, independent applications for marketing authorisation concerning veterinary medicinal products with the same active substance(s) can be submitted. For instance, if an Article 34 referral concerns the “originator” veterinary medicinal product, applications for “generic” veterinary medicinal products of this “originator” veterinary medicinal product may be submitted.

However, where independent applications for products with the same active substance are submitted once a referral is ongoing, Member States should consider the outcome of the referral as far as it may be relevant for the assessment of such applications.

The same occurs in the frame of Article 35 “class” referrals, if applications for marketing authorisations of veterinary medicinal products of the same class or range are submitted.

Applications for variations can be submitted and ongoing procedures can be finalised, even if the veterinary medicinal product is involved in a referral. However, when a referral procedure based on Articles 13 of Commission Regulation (EC) No 1234/2008, Articles 33(4) and 34 of Directive 2001/82/EC is ongoing it is recommended that no new variation procedure is started for the veterinary medicinal product concerned, unless it relates to human or animal health or environmental matters.

11.3 Subsequent applications occurring after finalisation of the referral

Where the referral leads to full harmonisation, the harmonisation of the product information must be maintained. This can be achieved by converting the product to MRP status and using mutual recognition procedures or use the worksharing procedure as described in Commission Regulation (EC) No 1234/2008, in order to maintain the achieved harmonisation for veterinary medicinal products authorised on a purely national basis. Further guidance is available from CMDv website.

Where the procedure or its outcome is limited to certain specific parts of the authorisation, the obligation to follow a mutual recognition procedure only applies if the marketing authorisations were granted initially by the decentralised or mutual recognition procedure. In this case, the marketing authorisations granted through “purely” national procedures may stay national. Nevertheless it is the responsibility of the marketing authorisation holder and the Member States to keep the level of harmonisation reached by the referral procedure by utilising the worksharing procedure as described in Commission Regulation (EC) No 1234/2008.

In case of an Article 35 referral, there may be a large number of products. In this case, different Reference Member States can be chosen for different veterinary medicinal products but the harmonisation should be maintained. The relevant Commission decisions are binding unless a new referral is initiated with respect to a new potential serious risk to human or animal health or the environment. In accordance with Articles 12(3)(n) and 22 of Directive 2001/82/EC and Commission Communication C98/229/03, the mutual recognition procedure will also apply if the same company, or a

company from the same group of companies, applies for a separate marketing authorisation for the product, regardless of whether the product has been the subject of full harmonisation.

In case of Article 34 or 35 referrals of “purely” national products where there is no Reference Member State and the product(s) are transferred to mutual recognition procedure, Reference Member State(s) should be appointed.

The allocation of the Reference Member State will take place at the CMDv meeting taking into account the recommendation of the marketing authorisation holder.

11.4 Follow-up of European Commission referral decisions

The follow-up of the conditions on the marketing authorisations imposed with the Commission decision following a referral procedure will be undertaken either at national or centralised level.

Where the follow-up condition is subject to a specific requirement laid down in the legislation, it should be followed.

As a general principle, the follow-up of a Commission decision following a referral procedure involving nationally authorised veterinary medicinal products will be undertaken by the Member States. The adoption of the referral decision concludes the referral procedure. It will normally be for the authorising national competent authorities to implement any conditions imposed on the marketing authorisation and to perform any subsequent assessments that may be necessary. If this eventually leads to divergences amongst Member States, a new referral procedure would have to be initiated.

However, exceptionally, a referral decision may explicitly foresee further action to be taken at EU level.

ANNEX: Notification forms**NOTIFICATION TO THE CVMP/EMA SECRETARIAT OF A REFERRAL UNDER ARTICLE 33(4) OF DIRECTIVE 2001/82/EC**E-mail: vet.applications@ema.europa.eu

This notification is a referral under Article 33(4) of Directive 2001/82/EC for arbitration to the CVMP made by the Reference Member State following the procedure in the veterinary coordination group for mutual recognition and decentralised procedure (CMDv).

Reference Member State (RMS):-----

Concerned Member States (CMS):-----

Member State(s) who raised concerns regarding a potential serious risk to human or animal health or to the environment: -----

THIS NOTIFICATION IS TO BE COPIED BY THE REFERRING PARTY TO APPLICANT/ MARKETING AUTHORISATION HOLDER AND ALL CVMP MEMBERS

Product name <in the RMS>, if appropriate, strength, pharmaceutical form and target species	
Active substance(s)	
Applicant/marketing authorisation holder in the RMS	
Mutual recognition procedure number < Decentralised procedure number >	

<Member State(s) who raised concerns regarding a potential serious risk to human or animal health or to the environment> consider(s) that the authorisation of this veterinary medicinal product may present a potential serious risk to human or animal health or to the environment on the following grounds:

Short description of the product:

Description of the remaining areas of disagreement between the RMS and CMS(s):

Question(s) to be addressed by the CVMP:

(Please provide a summary of background information and clearly define the question that initiates the referral, together with the latest version of the SPC, labelling and package leaflet as achieved during the CMDv procedure)

(If this space is not sufficient, please summarise and add annex):

Signed

Date

NOTIFICATION TO THE CVMP/EMA SECRETARIAT OF A REFERRAL UNDER ARTICLE 34 OF DIRECTIVE 2001/82/EC

E-mail: vet.applications@ema.europa.eu

This notification is a referral under Article 34 of Directive 2001/82/EC to the CVMP made by the <following Member State>, <Applicant(s)>, <Marketing authorisation holder(s)>, <European Commission>

THIS NOTIFICATION IS TO BE COPIED BY THE REFERRING PARTY TO APPLICANT/ MARKETING AUTHORISATION HOLDER AND ALL CVMP MEMBERS

Name(s) of particular veterinary medicinal product <in the referring Member State>*	
<Active substance(s)>	
Pharmaceutical form(s) <in the referring Member State>	
Strength(s) <in the referring Member State>	
Target species <in the referring Member State>	
Route(s) of administration <in the referring Member State>	
Presentations <in the referring Member State>	
Applicant(s)/Marketing authorisation holder(s) <in the referring Member State>	

The veterinary medicinal product {NAME} and its associated names, does not have the same SPC throughout the Union with respect to e.g. <target species>, <indications for use, specifying the target species>, <contraindications>, <posology>, <withdrawal period(s)>, etc.

The following examples constitute a non-exhaustive list.

<4.1 Target species>

[please provide a detailed overview of the divergences]

<4.2 Indications for use, specifying the target species >

[please provide a detailed overview of the divergences]

<4.3 Contraindications>

[please provide a detailed overview of the divergences]

etc

<Discrepancies also exist between Member States regarding sections {other SPC sections with divergences but for which no detailed overview is provided above}>.

Due to the divergent national decisions taken by Member States concerning the authorisation of the above-mentioned product and its associated names, <Member State> <applicant> <marketing authorisation holder> <the European Commission> notifies the EMA of an official referral under Article 34 of Directive 2001/82/EC in order to resolve divergences among the nationally authorised SPCs for the above-mentioned product and its associated names, and thus to harmonise its divergent SPCs across the Union.

Signed

Date

* When initiated by the MAH the whole range of names, pharmaceutical forms, strengths, routes of administration, target species and presentations of the veterinary medicinal product in all EU Member States (Iceland and Norway, if appropriate) should be mentioned

NOTIFICATION TO THE CVMP/EMA SECRETARIAT OF A REFERRAL UNDER ARTICLE 35 OF DIRECTIVE 2001/82/EC

E-mail: vet.applications@ema.europa.eu

This notification is a referral under Article 35 of Directive 2001/82/EC to the CVMP made by the <following Member State>, <Applicant(s)>, <European Commission>:

<p><Product name(s), if appropriate, strength(s), pharmaceutical form(s) and target species></p> <p><A range of veterinary medicinal products, all containing the same active substance></p> <p><A therapeutic class of veterinary medicinal products, (different active substances and veterinary medicinal products belonging to the same therapeutic class)></p>	
<p><Active substance(s)/therapeutic class></p>	
<p><Applicant(s)/marketing authorisation holder(s)> <In the referring Member State></p>	
<p>Detailed explanation of the matter involving Union interest:</p> <p>If applicable, other issues to be considered:</p> <p>Question(s) to be addressed by the CVMP:</p> <p>In view of the elements described above and the necessity to take an action at EU level, <above mentioned Member State>, <the European Commission> considers that it is in the interest of the Union to refer the matter to the CVMP and requests that it gives its opinion under Article 35 of Directive 2001/82/EC as to whether the marketing authorisations for the abovementioned product(s) should be maintained, varied, suspended, or withdrawn.</p> <p>Signed _____ Date _____</p>	

NOTIFICATION TO THE CVMP/EMA SECRETARIAT OF A PROCEDURE UNDER ARTICLE 78 OF DIRECTIVE 2001/82/EC

E-mail: list-v-ra@eudra.org, vet.applications@ema.europa.eu

This notification is a procedure under Article 78 of Directive 2001/82/EC to the CVMP made by <Member State>:

<Product name(s), <in the referring Member State> if appropriate, strength(s), pharmaceutical form(s) and target species> <Active substance(s)/therapeutic class>	
<Applicant(s)/marketing authorisation holder(s)> <in the referring Member State>	

Detailed explanation of the matter:

(Please append an assessment report with this notification presenting the pharmacovigilance (and other relevant) data evaluated as the basis for the [intended] regulatory action (in accordance with Article 78 (1) of Directive 2001/82/EC) as well as any other relevant documentation for subsequent consideration by the CVMP at the start of the procedure)

If applicable, other issues to be considered:

Therefore, following the evaluation of pharmacovigilance data <above mentioned Member State> initiates a procedure under Article 78 of Directive 2001/82/EC, and requests the CVMP to give its opinion as to whether marketing authorisations for the above-mentioned product(s) should be maintained, varied, suspended, or withdrawn.

This notification is circulated by rapid alert to meet the information exchange requirements with the regulatory network under Article 78 of Directive 2001/82/EC.

Signed

Date

NOTIFICATION TO THE CVMP/EMA SECRETARIAT OF A PROCEDURE UNDER ARTICLE 45 OF REGULATION (EC) No 726/2004
E-mail: vet.applications@ema.europa.eu

This notification is a procedure under Article 45 of Regulation (EC) No 726/2004 to the CVMP made by the European Commission:

<Product name(s), if appropriate, strength(s), pharmaceutical form(s) and target species> <Active substance(s)/therapeutic class>	
Marketing authorisation holder(s)	

Detailed explanation of the matter:

If applicable, other issues to be considered:

Therefore, the European Commission initiates a procedure under Article 45 of Regulation (EC) No 726/2004 and requests the CVMP/EMA to assess the above concerns and their impact on the benefit-risk balance for <veterinary medicinal product(s)><range of veterinary medicinal product(s)> <therapeutic class>. The European Commission requests the CVMP/EMA to give its opinion by <date/timeline> on whether the marketing authorisation(s) for that product/these products should be maintained, varied, suspended or withdrawn.

Signed

Date

NOTIFICATION TO THE CVMP/EMA SECRETARIAT OF A REFERRAL UNDER ARTICLE 13 OF COMMISSION REGULATION (EC) No 1234/2008
E-mail: vet.applications@ema.europa.eu

This notification is a referral under Article 13 of Commission Regulation (EC) No 1234/2008 for arbitration to the CVMP made by the Reference Member State following the procedure in the veterinary coordination group for mutual recognition and decentralised procedure (CMDv).

Reference Member State (RMS):-----

Concerned Member States (CMS):-----

Member State(s) who raised concerns regarding a potential serious risk to human or animal health or to the environment: -----

THIS NOTIFICATION IS TO BE COPIED BY THE REFERRING PARTY TO MARKETING AUTHORISATION HOLDER AND ALL CVMP MEMBERS

Product name <in the RMS>, if appropriate, strength, pharmaceutical form and target species	
Active substance(s)	
Marketing authorisation holder(s)	
<Decentralised> <Mutual recognition> variation procedure number	
<p><Member State(s) who raised concerns regarding a potential serious risk to human or animal health or the environment> consider(s) that the variation(s) to terms of marketing authorisation of this veterinary medicinal product may present a potential serious risk to human or animal health or the environment on the following grounds:</p> <p>Short description of the product:</p> <p>Description of the remaining areas of disagreement between the RMS and CMS(s):</p> <p>Question(s) to be addressed by the CVMP:</p> <p>(please provide a summary of background information and clearly define the question that initiates the referral, together with the latest version of the SPC, labelling and package leaflet as achieved during the CMDv procedure) (if this space is not sufficient, please summarise and add annex):</p> <p>Signed _____ Date _____</p>	