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**COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
(CVMP)**

**CONCEPT PAPER ON THE CLASSIFICATION OF VETERINARY MEDICINAL
PRODUCTS AUTHORISED BY THE COMMUNITY**

AGREED BY CVMP FOR RELEASE FOR CONSULTATION	12 September 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	30 November 2007

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KEYWORDS

Classification, centrally authorised veterinary medicinal products, prescription, change in classification, criteria, guideline

1. INTRODUCTION

The classification of medicinal products for veterinary use is governed by Directive 2001/82/EC as amended by Directive 2004/28/EC. Regulation (EC) No. 726/2004 lays down procedures for the authorisation and supervision of medicinal products for veterinary use which are authorised by the Community (centrally authorised products).

2. PROBLEM STATEMENT

Whilst the legislation and guidance for classification of medicines for human use is well developed, for centrally authorised veterinary medicinal products this is not the case and guidance is needed.

In accordance with Article 67 of Directive 2001/82/EC, as amended, veterinary medicinal products require a veterinary prescription where the product is subject to official restrictions on supply or use, where the product requires special precautions to be taken by the veterinary surgeon, where a precise diagnosis is required, where the product is an officinal formula or where the active substance contained in the product has been authorised for use in a veterinary medicinal product for less than five years. A prescription is also required for food-producing animals unless an exemption has been granted (see [Directive 2006/130/EC](#)).

To date, centrally authorised products, mainly because of their novel nature, have automatically been classified as being of prescription only status. However, Marketing Authorisation Holders choosing to use the centralised procedure should have the opportunity to change to a less restrictive classification where there is adequate assurance that such a change would not lead to safety problems and provided that the requirements of the Directive are met.

There is currently no mechanism for changing the classification of a centrally authorised veterinary medicinal product.

3. DISCUSSION (on the problem statement)

Criteria need to be developed to allow the Marketing Authorisation Holder to apply for a change in classification of a centrally authorised veterinary medicinal product e.g. where an active substance has been on the market for 5 years or longer, where there is no risk for consumer safety, no risk to human or animal health as regards the development of antimicrobial or anthelmintic resistance etc.

Guidance should be provided with regard to the classification of different pharmaceutical forms where a prescription might be required for one form or target species but not another.

In addition to appearing in Annex II of the Community Decision, the legal status appears in the label text which is included in Annex III A of the Community Decision. However, the expression of the legal status in the label text in the Commission Decision is limited to one of the main classifications following the criteria of Article 67 of Directive 2001/82/EC ("veterinary medicinal product subject to prescription") which is common to all EEA countries.

Sub-categories of any classification should remain subject to the national requirements of the Member State where the product is marketed; these sub-categories should continue to be indicated on the packaging of a centrally authorised product in the "blue box" area. One or more of the sub-categories may be used for one veterinary medicinal product. Even if the legislation in a Member State does not provide for certain sub-categories, the marketing authorisation holder is under an obligation to ensure that the medicinal product is marketed, all over the Community, subject to the conditions laid down in the Commission Decision.

4. RECOMMENDATION

It is recommended that a guideline on the classification of centrally authorised veterinary medicinal products is drafted and that a mechanism to change the classification is included in the guidance.

5. PROPOSED TIMETABLE

It is anticipated that the guideline will be adopted by the CVMP for release for consultation in February 2008 with a period of consultation of between 3 – 6 months.

The guideline will also be forwarded to the Notice to Applicants (NTA) Working Group for their consideration and possible inclusion in Volume 6C of the NTA on final adoption.

It is anticipated that any such guideline would come into operation with immediate effect.

6. RESOURCE REQUIREMENTS FOR PREPARATION

The Secretariat will draft the guideline and will consult the CVMP and NTA Working Group during its' development.

7. IMPACT ASSESSMENT (Anticipated)

Marketing Authorisation Holders will have the opportunity to request a change in classification of their products where the agreed criteria are met. The CVMP would be invited to review each request to change on a case-by-case basis.

The resource implications are minor for the EMEA and for industry. Use of a Type II variation application to change the classification of a veterinary medicinal product would be proposed. There is an anticipated benefit for the Marketing Authorisation Holder as the supply route of centrally authorised products is extended.

Article 85 (3) of Directive 2001/82/EC prohibits the advertising to the general public of veterinary medicinal products which are only available on prescription. It is therefore anticipated that centrally authorised products which have changed classification to non-prescription status could be directly advertised to the general public.

8. INTERESTED PARTIES

IFAH Europe, EAGGVP, FVE, COPA/COGECA, BEUC.

9. REFERENCES TO LITERATURE, GUIDELINES ETC

[Regulation \(EC\) No. 726/2004](#) of the European Parliament and of the Council of 31 March 2004.

[Directive 2001/82/EC](#) of the European Parliament and the Council of 6 November 2001 on the Community Code relating to Veterinary Medicinal Products as amended by Directive 2004/28/EC of the European Parliament and the Council of 31 March 2004.

[Commission Directive 2006/130/EC](#) implementing Directive 2001/82/EC as regard the Establishment of Criteria for Exempting Certain Veterinary Medicinal Products for food-producing animals from the Requirement of a Veterinary Prescription.

Guideline on the Packaging Information of Veterinary Medicinal Products Authorised by the Community (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-6/newdoc/blue_box_3_2005.pdf)