



European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

CONCEPT PAPER ON REVISION OF THE CURRENT GUIDELINE ON THE SPC FOR ANTIMICROBIAL PRODUCTS (EMEA/CVMP/612/01-FINAL)
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AGREED BY SCIENTIFIC ADVISORY GROUP ON ANTIMICROBIALS	3 March 2005
AGREED BY EFFICACY WORKING PARTY AND VETERINARY MUTUAL RECOGNITION FACILITATION GROUP	31 May 2005
ADOPTION BY CVMP FOR RELEASE FOR CONSULTATION	15 June 2005
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 August 2005

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1. INTRODUCTION

The current guideline on the SPC for antimicrobial products was developed during 2001-2002 by the EWP and came into effect 11 June 2003. Since then there have been further significant developments in antimicrobial therapy and antimicrobial resistance and various initiatives by different bodies and authorities are ongoing. A concept paper on further guidance on interpretation of the data from VICH GL27 has been released for consultation. On the basis of experience gained from Marketing Authorisation procedures, more guidance can be provided in the SPC with the aim to address the optimal use of antimicrobials and to minimise antimicrobial resistance. This should also improve harmonisation of SPCs in the EU Member States. In addition the revision will take into account the modification of the SPC headings in line with Directive 2001/82/EC, as amended that is due to come into force on 30 October 2005.

2. PROBLEM STATEMENT

The examples of present guideline in some areas do not cover all necessary points, in particular in 4.1. Pharmacodynamic properties, point 5.5. Recommendations to decrease the risk of development of resistance and point 5.8. Posology and method of administration. Harmonisation of the SPC between products is not optimal across the Member States.

3. DISCUSSION

A need to provide further guidance for Marketing Authorisations SPCs of products containing antimicrobial substances has been identified as currently through the EU SPCs for the same substance might provide substantially different recommendations.

The need of different approaches for food-producing animals and for companion animals should be discussed. In addition, more detailed guidance on how to provide information on breakpoints for susceptibility testing is required.

Recommendations to decrease the risk of development of resistance should describe more precisely the different statements that should generally be used for different antimicrobial veterinary medicinal products, taking into account the substance, the type of use and target animal species.

It should be possible also to include recommendations in the SPC to promote prudent use of antimicrobials and thus minimise the risk for antimicrobial resistance developing.

4. RECOMMENDATION

To start revision of the current CVMP guideline on SPC for veterinary medicinal products containing antimicrobial substances.

5. TIMETABLE

Jun – Aug 2005	Concept paper consultation period
Oct 2005	CVMP to decide on further development on guideline
1-2 Q 2006	First draft guideline to be discussed in WPs
2-3 Q 2006	Draft guideline for discussion and adoption to CVMP

6. RESOURCE REQUIREMENTS FOR PREPARATION

It is proposed that the SAGAM develops a new version of the guideline for further consideration of the CVMP.

7. IMPACT ASSESSMENT

For industry and other interested parties, the revision of the current guideline would contribute to the better clarity, transparency and harmonisation of SPCs for antimicrobials. General benefits would be the improvement of prudent use of antimicrobials and thus a decreased risk for antimicrobial resistance.

8. INTERESTED PARTIES

Veterinary pharmaceutical industry, consumers, animal owners as well as other interested parties that might be related to the use of antimicrobials as well as to antimicrobial resistance from the use of antimicrobials in veterinary medicine.

9. REFERENCES TO LITERATURE, GUIDELINES ETC

Guideline on the SPC for antimicrobial products (EMA/CVMP/612/01-FINAL)