EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper on revision of the current guideline on the summary of product characteristics for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005)

Agreed by Antimicrobials Working Party	May 2016
Adopted by CVMP for release for consultation	14 July 2016
Start of public consultation	25 July 2016
End of consultation (deadline for comments)	31 October 2016

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Keywords	veterinary medicine, summary of product characteristics, antimicrobial resistance

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1. Introduction

The current guideline on the summary of product characteristics (SPC) for antimicrobial products was developed during 2001-2002 by the EWP and came into effect on 11 June 2003. The guideline was revised by SAGAM (now AWP) during 2006 and 2007 and the revised guideline came into effect on 1 May 2008 (EMEA/CVMP/SAGAM/383441/2005)(1). Since then there have been further significant developments in principles of antimicrobial therapy and antimicrobial resistance and various initiatives have been taken by CVMP. For example:

- The guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/627/2001-Rev.1)(2) has been revised and is coming into effect in August 2016.
- A Q&A document on the CVMP guideline on the SPC for antimicrobial products (EMA/CVMP/414812/2011-Rev.2)(3) was published in February 2016 pertaining to “treatment and prevention” and “suitable pack sizes”.
- The EMA provided ‘Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals’ (EMA/381884/2014)(4).
- In 2012 a Commission implementing decision was published concerning the marketing authorisations for veterinary medicinal products which contain the active substances "Cefquinome and Ceftiofur” (C(2012)182 final)(5).

According to these documents and recommendations from other CVMP reflection papers and referrals, some areas of the guideline would benefit from further explanation. Next to that, more guidance can be provided in the SPC based on experience gained from Marketing Authorisation procedures, with the aim to address the optimal use of antimicrobials and to minimise antimicrobial resistance. This should also improve consistency of SPCs in the EU Member States.

2. Problem statement

The text of the present guideline on the summary of product characteristics for pharmaceutical veterinary medicinal products included in Volume 6C of the Rules Governing Medicinal Products in the European Union (6) should be updated. In some areas it does not cover all necessary points, in particular in sections 4.2 ‘Indications for use, specifying the target species’, 4.3 ‘Contraindications’, 4.4 ‘Special warnings for each target species’, 4.5 i) ‘Special precautions for use in animals’, 4.8 ‘Interaction with other medicinal products and other forms of interaction’, 4.9 ‘Amount(s) to be administered and administration route’, 5.1 ‘Pharmacodynamic properties’ and 6.5 ‘Nature and composition of immediate packaging’. Consistency of the presentation of SPCs 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 related guidelines have been updated and other relevant documents were published by the European Commission and EMA.

Recommendations for prudent use should be stratified and supplemented, if necessary, dependent on the antimicrobial category, the target animal species (food-producing or companion animals), the pharmaceutical form and the type of use (individual or group treatment).

Pack sizes should be consistent with the local husbandry systems, approved posology and treatment duration. Warnings should be included on how to proceed with potential leftovers.

The need for inclusion of special warnings on specific study conditions or findings e.g. for metaphylactic treatment, should be discussed.

The need to include an update of susceptibility data for bacterial target species relevant to the indications should be discussed.

There may be a need to include warnings on cascade use.

4. Recommendation

The AWP/CVMP recommends a revision of the existing guideline and to consider the above mentioned issues.

5. Proposed timetable

Jul – Oct 2016	Concept paper consultation period
Dec 2016	CVMP to decide on further development on guideline
Jan – Sep 2017	First draft guideline to be discussed in WPs
Q4 2017	Proposed date for release of draft guideline for consultation
Q2 2018	Deadline for comments
Q4 2018	Expected date for adoption by CVMP

6. Resource requirements for preparation

It is proposed that the AWP by involving EWP develops a new version of the guideline for further consideration of the CVMP.

7. Impact assessment (anticipated)

For industry and other interested parties, the revision of the current guideline would contribute to the better clarity, transparency and consistency 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 concerned with the use of antimicrobials and with antimicrobial resistance from the use of antimicrobials in veterinary medicine.

9. References to literature, guidelines, etc.

1. Revised guideline on the SPC for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005).

2. Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/627/2001-Rev.1).

3. Question and answer on the CVMP guideline on the SPC for antimicrobial products (EMA/CVMP/414812/2011-Rev.2).

4. Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals (EMA/381884/2014).

5. Commission implementing decision of 13.1.2012 concerning, in the framework of Article 35 of Directive 2001/82/EC of the European Parliament and of the Council, the marketing authorisations for veterinary medicinal products which contain the active substances "Cefquinome and Ceftiofur C(2012)182 final) (http://ec.europa.eu/health/documents/community-register/2012/20120113113370/dec_113370_en.pdf).

6. Guideline on the summary of product characteristics for pharmaceutical veterinary medicinal products included in Volume 6C of the Rules Governing Medicinal Products in the European Union (http://ec.europa.eu/health/files/eudralex/vol-6/c/spcpharmaceuticals_10-07-2006_en.pdf).