19 January 2017
EMA/CVMP/757903/2016
Committee for Medicinal Products for Veterinary Use

Question and answer on the information contained within section 5.1 of the SPC on pharmacodynamic properties for pharmaceutical products

This question and answer was developed to aid the writing or update of section 5.1 of the summary of product characteristics (SPC). These principles were agreed by the Committee for Medicinal Products for Veterinary Use (CVMP) and the Veterinary Coordination Group for MRP/DCP (CMDv) at their respective meetings in January 2017 (this document is also published on the CMDv website).

1. What information should be present in SPC section 5.1

According to the SPC guideline for pharmaceuticals contained in Volume 6C of the Notice to Applicants, the following information should be given in SPC section 5.1:

“The pharmacodynamic activity of the active substance(s) should be specified, together with the mechanism of the action, on the basis of the information contained in the application dossier. Also, information on resistance should be included in this section, if appropriate.”

For antimicrobial products, further specific information required on pharmacodynamic properties is elaborated in the CVMP’s ‘Revised Guideline on the SPC for antimicrobial products’.

However, any data mentioned in SPC section 5.1 is to be considered as additional information aiming to provide further details on the scientific basis of the indication(s), as presented in section 4.2, for the target species as presented in section 4.1. Information in section 5.1 should not constitute a new indication or a widening or restriction of an approved indication.

It may be appropriate to provide limited information, relevant to the prescriber, such as the main results (statistically compelling and clinically relevant) regarding pre-specified endpoints or clinical outcomes in the major trials, and giving the main characteristics of the study animal population. Such information on (clinical) studies should be concise, clear, relevant and balanced, and should summarise evidence from relevant studies supporting the indication. The magnitude of effects should be described using absolute figures (including for relative risks or odds ratio). In the exceptional cases when clinically relevant information from subgroup or post-hoc analyses is presented, it should be identified as such in a balanced manner reflecting the limited robustness of both positive and negative secondary observations.

Where results from new studies provide further clarification or information on an authorised indication, such information, relevant to the prescriber, provided it does not itself constitute a new indication, may be considered for inclusion in section 5.1.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

References

- European Commission (2006) Summary of the Product Characteristics – Pharmaceuticals (link)
- European Commission (2009) A guideline on summary of product characteristics (SmPC) September 2009, Volume 2C Notice to Applicants (link)
- CVMP 'Revised Guideline on the SPC for antimicrobial products' EMEA/CVMP/SAGAM/383441/2005
- CVMP 'Guideline for the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats' EMEA/CVMP/EWP/005/2000-Rev.3 (link)