EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 February 2026
EMA/CVMP/757903/2016-Rev.1
Committee for Veterinary Medicinal Products

Question and answer on the information contained within section 4.2 of the SPC on pharmacodynamic properties for pharmaceutical products

1. What information should be provided in SPC section 4.2 'Pharmacodynamics'?

The information included in SPC section 4.2 should outline the pharmacodynamic activity of the active substance(s), including the mechanism of the action, based on the information contained in the application dossier.

For antimicrobial and antiparasitic veterinary medicinal products, specific information on pharmacodynamic properties of such products and resistance should also be included in this SPC section, as appropriate. For antimicrobial veterinary medicinal products, this includes classification and mode of action, antimicrobial spectrum, where applicable MIC distribution data, epidemiological cut-off values, clinical breakpoints, resistance mechanisms and the molecular genetics of acquired resistance, etc. With regard to antiparasitic veterinary medicinal products, information such as the classification and mode of action, type of effect, speed of kill, mechanisms and genetic basis of acquired resistance, etc. should be included. Further information and guidance are available in the CVMP Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/383441/2005) and in the CVMP Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products (EMA/CVMP/EWP/170208/2005).

In this SPC section it may also be appropriate to provide information from pivotal pre-clinical studies/clinical trials which may be relevant for the prescriber. The main results (statistically confirmed and clinically relevant) regarding pre-specified endpoints or clinical outcomes and main characteristics of the study animal population may be described in this SPC section in relation to the indication(s) only. The magnitude of effects should be described using absolute and relative values; for example, for relative risks or odds ratios, the risk in the control group and in the treated group should also be included, to facilitate a complete clinical interpretation. Detailed study methodology and findings should not be presented in the SPC; these are normally published as part of the Public Assessment Report. When included (because of relevance for the prescriber), such information outlining the main results from the pivotal pre-clinical studies/clinical trials should be clear, balanced and concise. However, any data mentioned in SPC section 4.2 is to be considered as additional information aiming to provide further details on the scientific basis of the accepted indication(s), as presented in SPC section 3.2, for the target species as presented in SPC section 3.1. Information in SPC section 4.2 should not constitute a new indication or a widening or restriction of an approved indication and should not be promotional in nature.

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References

- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (link)
- Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/383441/2005) (link)
- Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products (EMA/CVMP/EWP/170208/2005) (link)