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Committee for Veterinary Medicinal Products (CVMP)

Questions and answers on the 'Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products' (EMA/CVMP/EWP/170208/2005-Rev.1)

Question 1:

How should the onset of persistent efficacy (defined as the first time-point on which persistent efficacy is established) be mentioned in the SPC of ectoparasiticides with no established immediate efficacy?

Answer:

In general, where a claim for treatment (immediate efficacy) and/or prevention of re-infestation (persistent efficacy) is made for an ectoparasiticide, the duration of efficacy must be demonstrated. Clear information on the duration of persistent efficacy established for each parasite should be included in section 3.2 of the SPC (EMA/CVMP/EWP/170208/2005-Rev.1). The duration of persistent efficacy is defined as the interval between treatment and the last time-point on which efficacy has been appropriately demonstrated. This is of particular importance for various parasites (ticks, fleas, sandflies, mosquitoes etc.) which are at risk of transmitting vector pathogens including zoonotic pathogens.

The time-point for the assessment of immediate efficacy of the treatment after prior infestation with ectoparasites is usually up to 24 or 48 hours post-treatment depending on the parasite and the effect assessed (acaricidal/insecticidal/repellent). In contrast, the first time-point for assessing the efficacy in preventing re-infestation after treatment is usually 7 days. Consequently, when the immediate efficacy is not demonstrated (efficacy below the required threshold) or not investigated as required, the time of onset of the persistent efficacy remains undetermined and in theory could be up to 7 days after treatment. Therefore, the first time-point on which the prevention of re-infestation has been tested and an acceptable level of efficacy has been demonstrated should be stated in the indication (section 3.2 of the SPC), e.g. *from 7 days after treatment*. This information on the effective duration of persistent efficacy is crucial, especially in the critical cases where reduction of the risk of transmission of vector borne pathogens is claimed.

In line with the above, it is recommended to include both the first and last time point of efficacy in the indication. Therefore, section 3.2 of the SPC should read as follows:

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Prevention of re-infestations with <parasite name, parasite species> through a <type of effect> ***from X days to*** *X weeks after treatment.*

or

Persistent <type of effect> activity ***from X days to*** *X weeks after treatment for <parasite name, parasite species>.*

References

- Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products (EMA/CVMP/EWP/170208/2005-Rev.1)
- 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.4)
- Guideline on the demonstration of efficacy of ectoparasiticides (7AE17a).