15 November 2010

EMA/CVMP/EWP/81987/2010

Committee for Medicinal Products for Veterinary use (CVMP)

Concept paper for a guideline on the demonstration of palatability of veterinary medicinal products

<table>
<thead>
<tr>
<th>Agreed by Efficacy Working party (EWP)</th>
<th>October 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adoption by CVMP for release for consultation</td>
<td>9 November 2010</td>
</tr>
<tr>
<td>End of consultation (deadline for comments)</td>
<td>28 February 2011</td>
</tr>
</tbody>
</table>

Comments should be provided using this template. The completed comments form should be sent to vet-guidelines@ema.europa.eu
1. Introduction

In companion animals, oral medicines are often formulated to mask the bitterness of a substance and/or to improve the acceptance of e.g. tablets offered from the bowl/hand or mixed into the food in order to improve owner compliance. In relation to veterinary medicine products, this often results in an applicant submitting an application for a “palatability” claim, which should be demonstrated by appropriate data.

For group treatment with oral medication via food or drinking water, compliance with uptake of the medicated food / water is a prerequisite for an effective treatment and shall ensure that the animals take up the recommended daily dose completely. Unsatisfactory intake may lead to under-dosing and ineffective treatment.

2. Problem statement

Several guidelines (e.g. bioequivalence, canine anthelmintics) mention the need for considering palatability without giving further advice. In addition, regulatory authorities have through the years received many enquiries on demonstration of palatability. For these reasons it would be useful to provide recommendations on how to properly demonstrate compliance for oral formulations.

3. Discussion (on the problem statement)

Acceptance is influenced by the smell and taste of the product, and also by the shape, size, texture and other characteristics. The willingness to ingest a certain product is dependent on how the sensory signals triggered by these different characteristics are interpreted by the animal. In case claims are made for new products, or existing products where changes to the composition (e.g. flavouring system) are proposed, which may have a potential impact on acceptance of the product, this should be supported by results from properly designed studies. The guideline would provide guidance on how to design and evaluate palatability studies for individual treatment in case of a specific palatability claim for a product.

It should be considered that acceptance of the product may differ between animals kept under experimental and field conditions.

For an oral formulation aimed to be used for group treatment and where similarity to another product has been demonstrated by pharmacokinetic data, compliance data may have to be provided before a conclusion on similarity with regard to efficacy and safety can be drawn. Advice on how to design such studies would be included in a palatability guideline.

4. Recommendation

The EWP/CVMP recommends the drafting of a new guideline on the demonstration of palatability (compliance or acceptance) of oral veterinary medicinal products.
5. Proposed timetable

November 2010  Concept paper adopted by CVMP for release for consultation
February 2011  Deadline for comments
Q2 2012  Expected date for adoption of the draft guideline by EWP
Q3 2012  Draft guideline for discussion and adoption by CVMP for release for consultation

6. Resource requirements for preparation

Preparation of the draft guideline would involve one rapporteur assisted by two co-rapporteurs.
Preparation of the draft guideline will require discussions at 3 EWP meetings.

7. Impact assessment (anticipated)

This new guideline is expected to provide clearer guidance to applicants, as well as to regulatory authorities. It is not intended to increase the usual requirements for veterinary dossiers. It will also provide for a more homogeneous assessment of dossiers.

8. Interested parties

Pharmaceutical industry, veterinary, national medicine agency, scientific committee (EAVPT i.e.).

9. References to literature, guidelines, etc.

Gunew M. N. et al: Long-term safety, efficacy and palatability of oral meloxicam at 0.01 - 0.03 mg/kg for treatment of osteoarthritic pain in cats, Journal of Feline Medicine & Surgery, Vol. 10, Issue 3 (2008), 235-241