Annex

Scientific conclusions and grounds for the suspension of the marketing authorisations

Background information

Further to the 2009 Sampling and Testing Programme, out of specification (OOS) results for assay, dissolution and uniformity of dose of Flexicam 1.5 mg/ml Oral Suspension for dogs were obtained.

These findings were assessed by the Rapporteur and the CVMP asked the European Commission to refer officially the matter to the CVMP for its opinion on the measures necessary to ensure the safe use of Flexicam 1.5 mg/ml Oral Suspension for dogs in accordance with the procedure laid down in Article 45 of Regulation (EC) No 726/2004.

The European Commission consequently initiated an Article 45 procedure which started on 13 July 2010. On 14 July 2010 the CVMP recommended the suspension of the Marketing Authorisation for Flexicam 1.5 mg/ml oral suspension for dogs.

It was subsequently confirmed that the marketing authorisation for Acticam 1.5 mg/ml oral suspension for dogs shares the same finished product manufacturer, same product specifications, production processes and methods as for Flexicam 1.5 mg/ml oral suspension for dogs, as well as the same quantitative and qualitative composition.

Therefore on 19 August 2010 the European Commission similarly initiated an Article 45 procedure for Acticam 1.5 mg/ml oral suspension for dogs.

Scientific Conclusions

OOS results for assay, dissolution and uniformity of dose of Flexicam 1.5 mg/ml Oral Suspension for dogs were obtained.

These findings were assessed by the Rapporteur and a list of questions was transmitted to the marketing authorisation holder. The answers provided by the marketing authorisation holder were assessed by the Rapporteur however it was considered that the root cause of the OOS results had not been adequately explained. The OOS results obtained gave rise to concerns relating to accuracy of dosing and, consequently, safety and efficacy in treated animals. Furthermore, a concern has been raised relating to preparation time (shaking before use) required to achieve a homogenous suspension prior to administration. It was noted that, if required, a prolonged preparation time may be impractical for this product.

Whilst the Marketing Authorisation Holder is different, it was subsequently confirmed that the marketing authorisation for Acticam 1.5 mg/ml oral suspension for dogs shares the same finished product manufacturer and has the same specifications, production processes and methods as the marketing authorisation Flexicam 1.5. mg/ml oral suspension.

No sampling and testing results for Acticam 1.5 mg/ml oral suspension for dogs are available as the product is not currently marketed, however similar concerns are applicable considering that the marketing authorisation for Acticam has the same manufacturer and has the same specifications, production processes and methods as Flexicam 1.5 mg/ml oral suspension, as well as the same quantitative and qualitative composition.

The CVMP considers that, in accordance with Article 83 (1.a) of Directive 2001/82/EC, the benefit-risk assessment is negative as, by analogy to Flexicam, there is a fundamental issue affecting the quality of the product and the accuracy of dosing, and therefore the marketing authorisation for the Acticam 1.5 mg/ml oral suspension should be suspended.

The marketing authorisation holder of Acticam 1.5 mg/ml oral suspension for dogs has committed not to place the product on the market until all issues relating to this dossier are resolved.

Grounds for suspension

Results obtained for Flexicam 1.5 mg.ml oral suspension gave rise to concerns relating to accuracy of dosing and, consequently, safety and efficacy in treated animals and a concern has been raised relating to preparation time (shaking before use) required to achieve a homogenous suspension prior to administration. It was noted that, if required, a prolonged preparation time may be impractical for this product.

Whilst the Marketing Authorisation Holder is different, it was subsequently confirmed that the marketing authorisation for Acticam 1.5 mg/ml oral suspension for dogs shares the same finished product manufacturer and has the same specifications, production processes and methods as Flexicam 1.5 mg/ml oral suspension, as well as the same quantitative and qualitative composition.

By analogy with Flexicam 1.5 mg/ml oral suspension for dogs, the CVMP considers that there is a fundamental issue with the quality of Acticam 1.5 mg/ml oral suspension for dogs which will adversely affect accurate dosing of the product and therefore the benefit risk assessment for Acticam 1.5. mg/ml oral suspension is negative.

In the light of the above the CVMP concludes that, in accordance with Article 83 (1.a) of Directive 2001/82/EC, the benefit-risk assessment is unfavourable under the authorised conditions of use.

Given that there are alternative products available it is recommended that the authorisation be suspended until all outstanding issues are satisfactorily resolved and therefore until these issues have been satisfactorily addressed by the submission of data (via appropriate variation applications).