

12 May 2014
EMA/CVMP/233183/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

DRAXXIN - Extension

International non-proprietary name (INN): tulathromycin

On 8 May 2014, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product DRAXXIN. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

DRAXXIN 100 mg/ml solution for injection is currently authorised for use in cattle and pigs. The route of administration is subcutaneous for cattle and intramuscular for pigs. This extension application concerns the addition of a new strength DRAXXIN 25 mg/ml solution for injection, for intramuscular use in pigs.

The approved indication is for treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and *Mycoplasma hyopneumoniae* sensitive to tulathromycin.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for DRAXXIN and therefore recommends the granting of the marketing authorisation.

¹ Summaries of opinion are published without prejudice to the Commission Decision.

² Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.