



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 February 2016
EMA/CVMP/65204/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

DRAXXIN

International non-proprietary name (INN): tulathromycin

On 18 February 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of a variation 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.

The change agreed by the CVMP concerns the addition of the following new therapeutic indications in the target species (pigs):

- Treatment of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica*.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

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.

