8 December 2017
EMA/CVMP/763148/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

ZACTRAN

International non-proprietary name (INN): gamithromycin

On 7 December 2017, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product ZACTRAN. The marketing authorisation holder for this veterinary medicinal product is MERIAL.

ZACTRAN is currently authorised as solution for injection. The variation concerns the addition of a new therapeutic indication: *Bordetella bronchiseptica* - new pathogen for the approved indication: treatment of swine respiratory disease (SRD).

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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact