EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2013
EMA/CVMP/585227/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Aivlosin

International non-proprietary name (INN): Tylvalosin

On 10 October 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Aivlosin. The marketing authorisation holder for this veterinary medicinal product is Eco Animal Health Ltd

The change agreed by the CVMP concerns the extension to add turkeys as a new target species to Aivlosin 625 mg/g granules for use in drinking water in aluminium foil laminated sachets containing 40 g or 400 g, respectively, for treatment of respiratory disease associated with tylvalosin sensitive strains of *Ornithobacterium rhinotracheale* in turkeys.

The withdrawal period for turkeys is 2 days for meat and offal, and the product is not authorised for use in birds producing eggs for human consumption. Aivlosin should not be used within 21 days of the onset of laying eggs for human consumption.

The Minimum Inhibitory Concentration (MIC) of tylvalosin for *Ornithobacterium rhinotracheale* ranges from 0.016 to 32 µg/ml. The efficacy of tylvalosin against *Ornithobacterium rhinotracheale* in turkeys was demonstrated in a challenge model using co-infection with avian metapneumovirus and a single strain of *Ornithobacterium rhinotracheale* under strictly controlled conditions. These studies demonstrated a modest but statistically significant reduction in the incidence of lower respiratory lesions (lung and air sac) and clinical signs in turkeys treated with tylvalosin compared with negative controls. Efficacy studies under field conditions have not been conducted.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SPC) which will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the extension 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.

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