European Medicines Agency
Veterinary Medicines and Inspections

London, 14 March 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
POST-AUTHORISATION SUMMARY OF OPINION*
AIVLOSIN

International Non-proprietary Name (INN):
Tylvalosin (previously: acetylisovaleryltylosin).

On 12 March 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant 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., UK. Aivlosin is currently authorised as premix for medicated feeding stuff and as an oral powder for pigs.

The new extension concerns a new target species (chicken) and a new pharmaceutical form (granules for oral solution for medicated drinking water).

The product will be available in individual sachets of 40 g and is to be administered in drinking water to treat respiratory disease in chickens. The dosage is 25 mg tylvalosin per kg bodyweight per day in drinking water for 3 consecutive days. No side effects have been reported in chickens during the clinical trials. However, due to its skin sensitising potential, the product literature includes a number of precautionary user warnings. The withdrawal period for meat and offal is 2 days. The product is not authorised for use in laying birds producing eggs for human consumption.

The agreed indication is:
"Treatment and prevention of respiratory disease associated with *Mycoplasma gallisepticum* in chickens. The product can be used as an aid in the prevention strategy to reduce the clinical signs and mortality from respiratory disease in flocks, where infection *in ovum* with *Mycoplasma gallisepticum* is likely because the disease is known to exist in the parent generation. The prevention strategy should include efforts to eliminate the infection from the parent generation."

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 variation/extension to 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 Aivlosin and therefore recommends the granting of the extension to the marketing authorisation

* Summaries of opinion are published without prejudice to the Commission Decision.
** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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