European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*

AIVLOSIN
625 MG/G GRANULES FOR USE IN DRINKING WATER FOR PIGS

International Non-proprietary Name (INN):
Tylvalosin

On 11 March 2009, 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 and as granules for use in drinking water for chicken.

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

The product will be available in individual sachets of 40 g and 160 g and is to be administered in drinking water for the "treatment and prevention of porcine proliferative enteropathy (ileitis, PPE) caused by *Lawsonia intracellularis* in pigs. The presence of the disease in the herd should be established before preventive treatment". The dose is 5 mg tylvalosin per kg bodyweight per day in drinking water for 5 consecutive days.

Due to its skin sensitising potential, the product literature includes a number of precautionary user warnings. The withdrawal period for meat and offal is 1 days.

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.

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* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** 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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