European Medicines Agency
Veterinary Medicines and Inspections

London, 16 October 2009
EMEA/CVMP/632577/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*

AIVLOSIN
42.5 MG/G ORAL POWDER FOR PIGS

International Non-proprietary Name (INN):
Tylvalosin

On 14 October 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.

The extension concerns the addition of a new pharmaceutical form, oral powder at a strength of 42.5 mg/g.

The product will be available in bags of 500 g. Scoops of 1 ml and 5 ml are attached to aid dosing. The product is to be used in individual pigs on farms where only a small number of pigs are to be treated. The indications are treatment and prevention of Swine Enzootic Pneumonia (2.125 mg tylvalosin per kg bodyweight per day for 7) and treatment of Porcine Proliferative Enteropathy (ileitis) and treatment and prevention of Swine Dysentery (4.25 mg tylvalosin per kg bodyweight per day for 10 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 2 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 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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