



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 October 2010
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Committee for Medicinal Products for Veterinary Use

Post-authorisation summary of opinion*

Econor – oral powder for pigs (EMA/V/C/042/X/033)

International non-proprietary name (INN): Valnemulin

On 13 October 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the extension of the marketing authorisation for the veterinary medicinal product Econor. The Applicant for this veterinary medicinal product is Novartis Animal Health GmbH, Austria.

Econor is currently authorised as premix for medicated feedingstuff for pigs. The new extension concerns a new pharmaceutical form (oral powder).

The new presentation will be available as 1 kg bags, and is to be used in individual pigs on farms where only a small number of pigs are to receive the veterinary medicinal product. Larger groups should be treated with medicated feeding stuff containing the premix.

The approved indication of the oral powder is for the treatment of swine dysentery, swine enzootic pneumonia and clinical signs of porcine proliferative enteropathy (ileitis).

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after 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 Econor and therefore recommends the granting of the extension of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision.

** 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.

