EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 June 2013
EMA/CVMP/323249/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Econor

International non-proprietary name (INN): valnemulin

On 13 June 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the marketing authorisation for the veterinary medicinal product Econor. The marketing authorisation holder for this veterinary medicinal product is Novartis Animal Health GmbH.

Econor is currently authorised for pigs (premix for medicated feed, oral powder). The extension concerns the addition of a new target species, rabbits, to the Econor 10% premix for medicated feed presentations.

The new indication for rabbits is the reduction of mortality during an outbreak of epizootic rabbit enteropathy. Treatment should be started early in the outbreak, when the first rabbit has been diagnosed with the disease clinically.

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.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union