10 December 2010
EMA/CVMP/509583/2010
Committee for Medicinal Products for Veterinary Use

Post-authorisation summary of opinion*

ZOLVIX

International non-proprietary name (INN): Monepantel

On 8 December 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product ZOLVIX. The marketing authorisation holder for this veterinary medicinal product is Novartis Healthcare A/S.

The change agreed by the CVMP concerns a change to the therapeutic indications to extend the indications to the inhibited larvae of the following parasites: *Haemonchus contortus, Teladorsagia circumcincta, Teladorsagia trifurcata, Teladorsagia davtiani and Trichostrongylus axei*, as well as a change to sections 4.8 and 12 of the SPC concerning interactions with other veterinary medicinal products.

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 to the marketing authorisation has been granted by the European Commission.

* 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union