14 December 2012
EMA/CVMP/741181/2012
Committee for Medicinal Products for Veterinary Use

Post-authorisation summary of opinion*

Profender

International non-proprietary names (INNs): emodepside and praziquantel

On 13 December 2012, 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 Profender modified release tablets for dogs. The marketing authorisation holder for this veterinary medicinal product is Bayer Animal Health GmbH.

The change agreed by the CVMP concerns amendment of the therapeutic indication for the treatment of *Trichuris vulpis* in dogs to add L4 stage larvae (to the already authorised indication covering mature and immature adults of *Trichuris vulpis*), and to change the wording under point 4.7 of the SPC regarding use the product during pregnancy and lactation. In addition the package leaflet has been amended to include the contact details of local representatives.

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.

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