

18 March 2016 EMA/CVMP/159748/2016 Committee for Medicinal Products for Veterinary Use

Summary of opinion<sup>1</sup> (post-authorisation)

## Profender

International non-proprietary name (INN): praziquantel / emodepside

On 17 March 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion<sup>2</sup>, recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Profender. The marketing authorisation holder for this veterinary medicinal product is Bayer Animal Health GmbH.

Profender is currently authorised as spot-on solution. The variation concerns adding the following therapeutic indications for Profender spot-on solution for cats:

- *Toxocara cati* (L3 larvae) treatment of queens during late pregnancy to prevent lactogenic transmission to the offspring;
- Dipylidium caninum (immature adult);
- Aelurostrongylus abstrusus (adult).

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), for which an updated version reflecting the changes 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.

<sup>&</sup>lt;sup>2</sup> 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.



<sup>&</sup>lt;sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision.