14 December 2012
EMA/CVMP/734548/2012
Committee for Medicinal Products for Veterinary Use

**Summary of opinion***

# Semintra

## International non-proprietary name: Telmisartan

On 13 December 2012, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the granting of a marketing authorisation for the veterinary medicinal product Semintra, 4 mg/ml oral solution, intended for the reduction of proteinuria associated with chronic kidney disease (CKD) in cats. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

The active substance of Semintra is telmisartan, an angiotensin II antagonist (ATC vet code C09CA07), which acts on the Renin-Angiotensin-Aldosterone System (RAAS) displacing angiotensin II from its binding site at the AT-1 receptor subtype.

The benefits of Semintra are its effects (i.e. decrease) on the mean arterial blood pressure and proteinuria associated with chronic kidney disease.

(Rare) adverse effects are mild and transient gastrointestinal signs and elevated liver enzymes, reductions in blood pressure and decreases in red blood cell counts.

The approved indication is: “Reduction of proteinuria associated with chronic kidney disease (CKD) in cats”.

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 Semintra and therefore recommends the granting of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
** 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