



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 January 2014  
EMA/CVMP/735220/2013  
Committee for Medicinal Products for Veterinary Use

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

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### Panacur AquaSol

International non-proprietary name (INN): Fenbendazole

On 15 January 2014, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted an opinion<sup>2</sup>, recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Panacur AquaSol. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

The already authorised product, Panacur AquaSol indicated for the treatment and control of gastro-intestinal nematodes in pigs, was authorised for use in the European Union on 9 December 2011.

This extension application concerns addition of a food-producing target animal species to extend the use of Panacur AquaSol to include chickens.

The approved indication for chickens is:

- Treatment of gastro-intestinal nematodes in chicken infected with *Ascaridia galli* (L5 and adult stages) and *Heterakis gallinarum* (L5 and adult stages).

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 Panacur AquaSol and therefore recommends the granting of the extension of the marketing authorisation.

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

<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.

