

11 December 2015
EMA/CVMP/750172/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

Bravecto

International non-proprietary name (INN): Fluralaner

On 9 December 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion², recommending the refusal of an extension to the marketing authorisation for the veterinary medicinal product Bravecto. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

The scope of the extension applied for was to add a new pharmaceutical form (spot-on) for dogs and to add a new target species (cats) for this spot-on formulation. Bravecto spot-on solution was intended for the treatment of tick and flea infestations in both dogs and cats.

The grounds for the negative opinion relate to user safety.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that the benefit-risk balance for Bravecto spot-on solution for dogs and cats was not demonstrated to be favourable and therefore cannot recommend the granting of the extension of the marketing authorisation for the above mentioned veterinary medicinal product.

¹ Summaries of opinion are published without prejudice to the Commission Decision.

² 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.