EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2019
EMA/CVMP/465180/2019
Committee for Medicinal Products for Veterinary Use

**Summary of opinion[1] (post-authorisation)**

# Bravecto

International non-proprietary name (INN): fluralaner

On 12 September 2019, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Bravecto. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Bravecto is currently authorised as chewable tablets in dogs and spot-on solution in dogs and cats for the treatment of tick and flea infestations; also, the product can be used as part of a treatment strategy for the control of flea allergy dermatitis. The variation concerns the addition of new therapeutic indications: for the treatment of demodicosis caused by *Demodex canis* in dogs, for the treatment of sarcoptic mange (*Sarcoptes scabiei* var. *canis*) infestation in dogs and for the treatment of infestations with ear mites (*Otodectes cynotis*) in cats.

Detailed conditions for the use of this product are described in the updated 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.

[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.

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