11 September 2015
EMA/CVMP/478463/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Simparica

International non-proprietary name (INN): sarolaner

On 10 April 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Simparica chewable tablets for dogs (5 mg, 10 mg, 20 mg, 40 mg, 80 mg, 120 mg) intended for treatment of tick, flea and mange mite infestations. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

The active substance of Simparica is sarolaner (ATCvet code QP53BX06), a new ectoparasiticide belonging to the isoxazoline group, which is systemically active against ticks, fleas and mange mites.

The benefits of Simparica are its efficacy in the treatment of extoparasite infestations in dogs as follows: tick infestations (*Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus* and *Rhipicephalus sanguineus*), flea infestations (*Ctenocephalides felis* and *Ctenocephalides canis*), and sarcoptic mange (*Sarcoptes scabiei*). The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Simparica is generally well tolerated at the recommended dose, adverse reactions (transient neurological signs) are only seen at overdoses.

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 Simparica and therefore recommends the granting of the marketing authorisation.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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