22 February 2019
EMA/CVMP/64944/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Chanhold

International non-proprietary name (INN): selamectin

On 21 February 2019, 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 Chanhold, spot-on solution, intended for cats and dogs. The applicant for this veterinary medicinal product is Chanelle Pharmaceuticals Manufacturing Ltd. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Chanhold is a medicinal product containing selamectin (ATCvet code QP54AA05) as active substance which paralyses and/or kills a wide range of invertebrate parasites. The product is intended for use in cats and dogs for treatment and/or prevention of different species of fleas, worms, lice and mites.

Chanhold is a generic of Stronghold, which has been authorised in the EU since 25 November 1999. Studies have demonstrated the satisfactory quality of Chanhold, and its bioequivalence to the reference product Stronghold. A question and answer document on generic medicines can be found *here*.

The full indication is:

Cats and dogs:

- Treatment and prevention of flea infestations caused by *Ctenocephalides* spp. for one month following a single administration. This is as a result of the adulticidal, larvicidal and ovicidal properties of the product. The product is ovicidal for 3 weeks after administration. Through a reduction in the flea population, monthly treatment of pregnant and lactating animals will also aid in the prevention of flea infestations in the litter up to seven weeks of age. The product can be used as part of a treatment strategy for flea allergy dermatitis and through its ovicidal and larvicidal action may aid in the control of existing environmental flea infestations in areas to which the animal has access.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 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 5545
Send a question via our website www.ema.europa.eu/contact

- Prevention of heartworm disease caused by *Dirofilaria immitis* with monthly administration. The product may be safely administered to animals infected with adult heartworms, however, it is recommended, in accordance with good veterinary practice, that all animals 6 months of age or more living in countries where a vector exists should be tested for existing adult heartworm infections before beginning medication with the product. It is also recommended that dogs should be tested periodically for adult heartworm infections, as an integral part of a heartworm prevention strategy, even when the product has been administered monthly. This product is not effective against adult *D. immitis.*
- Treatment of ear mites (*Otodectes cynotis*).

Cats:

- Treatment of biting lice infestations *(Felicola subrostratus*)
- Treatment of adult roundworms (*Toxocara cati*)
- Treatment of adult intestinal hookworms (*Ancylostoma tubaeforme).*

Dogs:

- Treatment of biting lice infestations (*Trichodectes canis*)
- Treatment of sarcoptic mange (caused by *Sarcoptes scabiei*)
- Treatment of adult intestinal roundworms (*Toxocara canis*).

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-risk balance for Chanhold and therefore recommends the granting of the marketing authorisation.