EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2018
EMA/CVMP/686486/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

LONGRANGE

International non-proprietary name (INN): eprinomectin

On 11 October 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion recommending the refusal of the granting of a marketing authorisation for the veterinary medicinal product LONGRANGE, 50 mg/ml, prolonged-release solution for injection.

The applicant MERIAL applied for the following indication:

Treatment of the following parasites:

- Gastrointestinal roundworms (Adult and L4): *Ostertagia ostertagi/lyrata, Cooperia oncophora/surnabada, Cooperia punctata, Haemonchus contortus, Trichostrongylus axei, Trichostrongylus colubriformis, Bunostomum phlebotomum, Nematodirus helvetianus, Oesophagostomum radiatum.*
- Lungworm (Adults and L4): *Dictyocaulus viviparous*
- Ectoparasites: Warbles (parasitic stages: *Hypoderma bovis, Hypoderma lineatum), m*ange mites (*Sarcoptes scabiei* var. *bovis*); lice (*Linognathus vituli, Haematopinus eurysternus, Solenoptes capillatus)* and horn flies (*Haematobia irritans).*

Prevention of reinfections with the following parasites:

- Gastrointestinal roundworms: *Ostertagia ostertagi/lyrata, Trichostrongylus colubriformis, Haemonchus contortus*, *Bunostomum phlebotomum, Oesophagostomum radiatum, Cooperia oncophora/surnabada, Cooperia punctate, Trichostrongylus axei.*
- Lungworms: *Dictyocaulus viviparous*

The active substance of LONGRANGE is eprinomectin, an antiparasitic of the macrocyclic lactone family of endectocides.

The grounds for the negative opinion relate to environmental risk.

The CVMP, on the basis of the quality, safety and efficacy data submitted, considers that the benefit to risk balance for LONGRANGE was not demonstrated to be favourable and therefore cannot recommend

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the opinion.

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the granting of a marketing authorisation.