



EUROPEAN MEDICINES AGENCY
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Refusal of the marketing authorisation for Longrange (eprinomectin)

On 21 June 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Longrange, intended for the treatment and prevention of parasitic infections in cattle.

The company that applied for authorisation is Merial. The company requested a re-examination of the initial opinion. After considering the grounds for this request, the CVMP re-examined the opinion and confirmed the refusal of the marketing authorisation on 11 October 2018.

What is Longrange?

Longrange is a veterinary medicine that contains the active substance eprinomectin. It was to be available as a prolonged-release solution for injection under the skin in cattle. Prolonged-release means that the solution releases eprinomectin slowly over an extended time period - four months in the case of Longrange.

What was Longrange expected to be used for?

Longrange was expected to be used to treat infections with the following parasites: gut roundworms, lungworm, warbles, mange mites, lice and horn flies. It was also expected to prevent reinfections with gut roundworms and lungworm for 100 to 120 days.

How does Longrange work?

The active substance in Longrange, eprinomectin, is a well-known antiparasitic substance that works by attaching to tiny pores on the surface of parasitic nerve or muscle cells called glutamate-gated chloride ion channels. This leads to an increase in the amount of chloride ions that enter the cells, resulting in paralysis and death of the parasite.



What did the company present to support its application?

The company presented data from a main field study of 156 young cattle with natural roundworm and/or lungworm infections that were treated with Longrange. The animals were monitored for 4 months and the main measure of effectiveness was the percentage of animals that were cured of worms over 4 months.

The company also presented data on the effectiveness of Longrange against ectoparasites – those parasites such as lice and warble flies that live on the outside of the animal's body.

What were the CVMP's main concerns that led to the refusal?

The CVMP was concerned mainly about the possible effects of Longrange on the environment, specifically its effects on organisms in cattle dung. Although the company proposed measures to reduce the environmental risk, the CVMP did not consider them to be sufficient.

Therefore, the CVMP was of the opinion that the benefits of Longrange did not outweigh its risks and recommended that it be refused marketing authorisation.