13 March 2024
EMA/129995/2024
Veterinary Medicines Division

Committee for Veterinary Medicinal Products (CVMP)

CVMP assessment report for Lotimax (EMEA/V/C/006441/0000)

INN: Lotilaner

Assessment report as adopted by the CVMP with all information of a commercially confidential nature deleted.

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Introduction

The applicant Elanco GmbH submitted on 22 December 2023 an application for a marketing authorisation to the European Medicines Agency (The Agency) for Lotimax, through the centralised procedure under Article 21 of Regulation (EU) 2019/6, i.e. 'informed consent'. The cross-referred medicinal product is Credelio chewable tablets for dogs (EMEA/V/C/004247).

The eligibility to the centralised procedure was agreed upon by the CVMP on 5 October 2023 as an informed consent application.

The dossier has been submitted in line with the requirements for submissions under Article 21 of Regulation (EU) 2019/6, an informed consent application.

The applicant demonstrated permission (letter of access) to use the technical documentation on quality, safety and efficacy submitted by Elanco GmbH in respect of the already authorised veterinary medicinal product Credelio chewable tablets for dogs (EMEA/V/C/004247). The dossier includes data for Part 1A and 1B, as described in Annex I (points 1 to 6.4) of Regulation (EU) 2019/6.

At the time of submission, the applicant applied for the following indications:

- Dogs: For the treatment of flea and tick infestations. The product provides immediate and persistent killing activity for 1 month for fleas (*Ctenocephalides felis* and *C. canis*) and ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *I. hexagonus* and *Dermacentor reticulatus*). The product can be used as part of a treatment strategy for the control of flea allergy dermatitis. For the treatment of demodicosis (caused by *Demodex canis*).

The active substance of Lotimax is lotilaner, a pure enantiomer from the isoxazoline class, which is a potent inhibitor of gamma–aminobutyric acid (GABA)-gated chloride channels, resulting in rapid death of ticks and fleas. The target species is dogs.

Lotimax is presented as chewable tablets for dogs containing 56.25, 112.5, 225, 450 or 900 mg lotilaner, each tablet strength is available in pack sizes of 3 tablets.

The rapporteur appointed is Rory Breathnach and the co-rapporteur is Gábor Kulcsár.

On 13 March 2024, the CVMP adopted an opinion and CVMP assessment report.

On 25 April 2024, the European Commission adopted a Commission Decision granting the marketing authorisation for Lotimax.

Part 1 - Administrative particulars

Summary of the Pharmacovigilance System Master File

The applicant has provided a summary of the pharmacovigilance system master file which fulfils the requirements of Article 23 of Commission Implementing Regulation (EU) 2021/1281. Based on the information provided the applicant has in place a pharmacovigilance system master file (PSMF) and has the services of a qualified person responsible for pharmacovigilance and the necessary means to fulfil the tasks and responsibilities required by Regulation (EU) 2019/6.

Manufacturing authorisations and inspection status

Active substance

Manufacture and quality control testing of the active substance lotilaner and the active substance intermediate takes place outside the EEA. A GMP declaration for the active substance manufacturing sites, and active substance intermediate manufacturing sites was provided from the Qualified Person (QP) at the EU batch release site. The declaration for the active substance manufacturing sites was based on on-site audits by the manufacturing site responsible for batch release.

Finished product

Batch release of the finished product takes place at Elanco France S.A.S., Huningue, FR. GMP certification, which confirms the date of the last inspection and shows that the site is authorised for the activity indicated above, is available on the EudraGMDP database.

Primary packaging and secondary packaging of the finished product takes place outside the EEA. GMP certification of the sites confirming the date of the last inspection and showing that the sites are authorised for the activities indicated above, is available on the EudraGMDP database.

Overall conclusions on administrative particulars

The summary of the pharmacovigilance system master file was considered in line with legal requirements.

The GMP status of the active substance and of the finished product manufacturing sites has been satisfactorily established and are in line with legal requirements.

Part 2 - Quality

This application is an informed consent application of Credelio chewable tablets for dogs (EMEA/V/C/004247).

The quality data in support of this application are identical to the up-to-date quality data of the dossier for Credelio chewable tablets for dogs (EMEA/V/C/004247), which has already been assessed and approved by the CVMP (including any post-authorisation procedures).

Therefore, no quality data have been submitted in support of this application. This is appropriate given the legal basis of this application (informed consent).

Part 3 – Safety

This application is an informed consent application of Credelio chewable tablets for dogs (EMEA/V/C/004247).

The safety data in support of this application are identical to the up-to-date safety data of the dossier for Credelio chewable tablets for dogs (EMEA/V/C/004247), which has already been assessed and approved by the CVMP (including any post-authorisation procedures).

Therefore, no safety data have been submitted in support of this application. This is appropriate given the legal basis of this application (informed consent).

In addition, signal management will be aligned with Credelio chewable tablets for dogs (EMEA/V/C/004247) and annual submissions will follow the same proposed due dates as for Credelio chewable tablets for dogs (EMEA/V/C/004247).

Part 4 – Efficacy

This application is an informed consent application of Credelio chewable tablets for dogs (EMEA/V/C/004247).

The efficacy data in support of this application are identical to the up-to-date efficacy data of the dossier for Credelio chewable tablets for dogs (EMEA/V/C/004247), which has already been assessed and approved by the CVMP (including any post-authorisation procedures).

Therefore, no efficacy data have been submitted in support of this application. This is appropriate given the legal basis of this application (informed consent).

Part 5 – Benefit-risk assessment

Lotimax contains lotilaner as active substance, a pure enantiomer from the isoxazoline class, which is a potent inhibitor of gamma–aminobutyric acid (GABA)-gated chloride channels, resulting in rapid death of ticks and fleas. The veterinary medicinal product is presented as chewable tablets for oral use in dogs at a dose rate of 20 - 43 mg lotilaner/kg bodyweight in dogs. The applicant applied for the following indications:

- Dogs: For the treatment of flea and tick infestations. The product provides immediate and persistent killing activity for 1 month for fleas (*Ctenocephalides felis* and *C. canis*) and ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *I. hexagonus* and *Dermacentor reticulatus*). The product can be used as part of a treatment strategy for the control of flea allergy dermatitis. For the treatment of demodicosis (caused by *Demodex canis*).

This marketing authorisation application has been submitted as an informed consent application in accordance with Article 21 of Regulation (EU) 2019/6. Thus, the quality, safety and efficacy data of Lotimax are identical to that of Credelio chewable tablets for dogs (EMEA/V/C/004247).

Consequentially, and in line with the assessment of data provided in the framework of the initial marketing authorisation application, as well as within all post-authorisation procedures for Credelio, the CVMP considers that the benefit-risk balance for Lotimax is positive. Details on the scientific discussion of Credelio can be found in the European Public Assessment Report (EPAR) published on the EMA website.

In addition, signal management will be aligned with Credelio and annual submissions will follow the

same proposed due dates as for Credelio.

Conclusion

This application for Lotimax is based on an informed consent to use the quality, safety and efficacy contained in the marketing authorisation of Credelio chewable tablets for dogs as complemented by administrative information. The Committee for Veterinary Medicinal Products (CVMP) considers that the application for Lotimax is approvable since the marketing authorisation application satisfies the requirements for an informed consent authorisation set out in the legislation (Regulation (EU) 2019/6).