14 July 2022
EMA/654744/2022
Veterinary Medicines Division

Committee for Veterinary Medicinal Products (CVMP)

CVMP assessment report for Lotilaner Elanco (EMEA/V/C/006030/0000)

INN: lotilaner

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

Introduction **3**

Part 1 - Administrative particulars **4**

Summary of the Pharmacovigilance System Master File 4

Manufacturing authorisations and inspection status 4

Overall conclusions on administrative particulars 4

Part 2 - Quality **4**

Part 3 – Safety documentation (Safety tests) **5**

Part 4 – Efficacy **5**

Part 5 – Benefit-risk assessment **5**

Introduction

The applicant Elanco GmbH submitted on 2 May 2022 an application for a marketing authorisation to the European Medicines Agency (The Agency) for Lotilaner Elanco, 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 and cats (EMEA/V/C/004247).

The eligibility to the centralised procedure was agreed upon by the CVMP on 4 November 2021 as an informed consent application.

In addition to being an informed consent application, the present application is also considered to be a duplicate application of Credelio chewable tablets for dogs and cats (EMEA/V/C/004247).

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 and cats (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*).
- Cats: For the treatment of flea and tick infestations. The product provides immediate and persistent killing activity for 1 month against fleas (*Ctenocephalides felis* and *C. canis*) and ticks (*Ixodes ricinus*). The product can be used as part of a treatment strategy for the control of flea allergy dermatitis.

The active substance of Lotilaner Elanco 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 are cats and dogs.

Lotilaner Elanco is presented as chewable tablets for dogs containing 56.25, 112.5, 225, 450 or 900 mg lotilaner and as chewable tablets for cats containing 12 or 48 mg lotilaner; each tablet strength is available in pack sizes of 1 or 3 tablets.

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

On 14 July 2022, the CVMP adopted an opinion and CVMP assessment report.

On 13 September 2022, the European Commission adopted a Commission Decision granting the marketing authorisation for Lotilaner Elanco.

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) with reference number PSMFELANCO01 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 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 site 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. The declaration for the active substance intermediate site was based on an on-site audit by a third party.

Finished product

Batch release of the finished product takes place at Elanco France, 26 Rue De La Chapelle, Huningue, France. The site has a valid GMP certificate issued by the French competent authority.

Manufacture of the dosage form takes place within the EEA. Primary and secondary packaging of the finished product takes place outside the EEA and both packaging sites are appropriately certified as complying with EU GMP requirements.

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 and cats (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 and cats (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 documentation (Safety tests)

This application is an informed consent application of Credelio chewable tablets for dogs and cats (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 and cats (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 and cats (EMEA/V/C/004247) and annual submissions will follow the same proposed due dates as for Credelio chewable tablets for dogs and cats (EMEA/V/C/004247).

Part 4 – Efficacy

This application is an informed consent application of Credelio chewable tablets for dogs and cats (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 and cats (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

Lotilaner Elanco 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 product is presented as chewable tablets for oral use in dogs and cats at a dose rate of 20 - 43 mg lotilaner/kg bodyweight in dogs and 6 - 24 mg lotilaner/kg bodyweight in cats. 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*).
- Cats: For the treatment of flea and tick infestations. The product provides immediate and persistent killing activity for 1 month against fleas (*Ctenocephalides felis* and *C. canis*) and ticks (*Ixodes ricinus*). The product can be used as part of a treatment strategy for the control of flea allergy dermatitis.

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 Lotilaner Elanco are identical to that of Credelio chewable tablets for dogs and cats

(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 Lotilaner Elanco 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 Lotilaner Elanco is based on an informed consent to use the quality, safety and efficacy contained in the marketing authorisation of Credelio chewable tablets for dogs and cats (EMEA/V/C/004247), as complemented by administrative information. The Committee for Veterinary Medicinal Products (CVMP) considers that the application for Lotilaner Elanco is approvable since the marketing authorisation application satisfies the requirements for an informed consent authorisation set out in the legislation (Regulation (EU) 2019/6).

The CVMP considers that the benefit-risk balance is positive and, therefore, recommends the granting of the marketing authorisation for the above mentioned veterinary medicinal product.