5 October 2017
EMA/667400/2017
Committee for Medicinal Products for Veterinary use

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CVMP assessment report for MiPet Easecto (EMEA/V/C/004732/0000)

International non-proprietary name: sarolaner

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

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Introduction

On 20 July 2017 the applicant Zoetis Belgium SA submitted an application for a marketing authorisation to the European Medicines Agency (the Agency) for MiPet Easecto.

The eligibility to the centralised procedure was agreed upon by the CVMP on 12 April 2017 under Article 3(2)(a) of Regulation (EC) no 726/2004. This application is a duplicate application of the centrally authorised product Simparica (EU/2/15/191/001-018) as it falls within the scope of Article 82(1) of Regulation (EC) No 726/2004.

The applicant applied for the following indication: treatment of tick infestations, flea infestations, sarcoptic mange, ear mite infestations, and demodicosis.

The active substance of MiPet Easecto is sarolaner, an acaricide and insecticide belonging to the isoxazoline family. Sarolaner blocks GABA- and glutamate-gated chloride channels in the central nervous system of insects and acarines. The target species is dogs and the product is intended for oral administration.

MiPet Easecto chewable tablets contain 5 mg, 10 mg, 20 mg, 40 mg, 80 mg, or 120 mg sarolaner and are presented in blister packs containing 3 tablets.

The rapporteur appointed is Jeremiah Gabriel Beechinor and the co-rapporteur is Peter Hekman.

The legal basis for this application refers to Article 13(c) of Directive 2001/82/EC, relating to informed consent from a marketing authorisation holder for an authorised veterinary medicinal product: Simparica (EU/2/15/191/001-018).

On 5 October 2017, the CVMP adopted an opinion and CVMP assessment report.

On 31 January 2018, the European Commission adopted a Commission Decision granting the marketing authorisation for MiPet Easecto.

Scientific advice

Not applicable.

MUMS/limited market status

Not applicable.

Part 1 - Administrative particulars

Detailed description of the pharmacovigilance system

The applicant has provided a detailed description of the pharmacovigilance system (dated 2 May 2017) which fulfils the requirements of Directive 2001/82/EC. Based on the information provided the applicant has the services of a qualified person responsible for pharmacovigilance and the necessary means for the notification of any adverse reaction occurring either in the Community or in a third country.

Manufacturing authorisations and inspection status

The active substance (sarolaner) is manufactured outside the EEA. A Qualified Person (QP) declaration is provided by the QP at the EU batch release site. The declaration is issued on behalf of all sites involved in the manufacture of the dosage form and was issued following an audit of the active substance manufacturing site in May 2014.

Manufacture of the product involves manufacture of an intermediate product containing the active substance which is then combined with tableting excipients to produce the finished product.

The finished product is manufactured and packaged outside of the EEA. Batch release for the EU will be carried out by Zoetis Belgium SA. The EudraGMP manufacturing authorisation reference for this site is 40740.

Evidence that all sites are appropriately authorised for the operations conducted for such veterinary medicinal products has been included in the dossier.

No concerns have been raised during the assessment that would give rise to any manufacturing site inspection prior to authorisation.

Overall conclusions on administrative particulars

The detailed description of the pharmacovigilance system was considered in line with legal requirements.

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

Part 2 - Quality

This application is an informed consent of Simparica Chewable Tablets for Dogs. The quality data in support of the application for MiPet Easecto are identical to the up-to-date quality data of the Simparica Chewable Tablets for Dogs dossier, which has been assessed and approved (including all post-marketing procedures).

Therefore, no quality data have been submitted. This is considered acceptable.

Part 3 – Safety

This application is an informed consent of Simparica Chewable Tablets for Dogs. The safety data in support of the application for MiPet Easecto are identical to the up-to-date safety data of the Simparica dossier, which has been assessed and approved (including all post-marketing procedures).

Therefore, no safety data have been submitted. This is considered acceptable.

To ensure comprehensive adverse event surveillance and to benefit from the possibility of aligning periodic safety update report (PSUR) submissions for informed consent products as foreseen in the legislation, PSUR submissions should be synchronised for the informed consent product, MiPet Easecto and Simparica, which is currently on a six monthly cycle. The next data lock point (DLP) is expected to be 30 November 2017. In addition, surveillance of the data in EudraVigilance Veterinary (EVVet) will also be synchronised for signal detection of the two products.

Part 4 – Efficacy

This application is an informed consent of Simparica Chewable Tablets for Dogs. The efficacy data in support of the application for MiPet Easecto are identical to the up-to-date efficacy data of the Simparica dossier, which has been assessed and approved (including all post-marketing procedures).

Therefore, no efficacy data have been submitted. This is considered acceptable.

Part 5 – Benefit-risk assessment

This marketing authorisation application for MiPet Easecto has been submitted by Zoetis Belgium SA as an informed consent application in accordance with Article 13c of Directive 2001/82/EC.

The quality, safety and efficacy of MiPet Easecto are identical to the up-to-date quality, safety and efficacy profile of Simparica. The application for MiPet Easecto consists of only Part 1 – Summary of the dossier. Information on the scientific discussion can be found in the European Public Assessment Report (EPAR) for Simparica published on the EMA website.

Consequently, and in line with the assessment undertaken in the framework of the initial marketing authorisation application, as well as in all post-authorisation procedures for Simparica, the CVMP considers that the benefit-risk balance for MiPet Easecto is positive.

To ensure comprehensive adverse event surveillance, signal detection and PSUR submissions will be synchronised with those for the informed consent product, Simparica.

Conclusion

Based on the original data presented on quality, safety and efficacy, the Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the application for MiPet Easecto is approvable since these data satisfy the requirements for an authorisation set out in the legislation (Regulation (EC) No 726/2004 in conjunction with Directive 2001/82/EC).

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