DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

[DRAFT]PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

FRONTAL DELTA/DELTATIC/SERATIC MEDICATED COLLAR FOR VERY SMALL DOGS
FRONTAL DELTA/DELTATIC/SERATIC MEDICATED COLLAR FOR SMALL TO MEDIUM DOGS
FRONTAL DELTA/DELTATIC/SERATIC MEDICATED COLLAR FOR LARGE TO VERY LARGE DOGS

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0360/001-003/DC
Name, strength and pharmaceutical form	FRONTAL DELTA/DELTATIC/SERATIC MEDICATED COLLAR FOR VERY SMALL DOGS FRONTAL DELTA/DELTATIC/SERATIC MEDICATED COLLAR FOR SMALL TO MEDIUM DOGS FRONTAL DELTA/DELTATIC/SERATIC MEDICATED COLLAR FOR LARGE TO VERY LARGE DOGS
Applicant	VETPHARMA ANIMAL HEALTH S.L. Les Corts, 23 08028. Barcelona - España
Active substance(s)	Deltamethrin
ATC Vetcode	QP53AC11
Target species	Dogs
Indication for use	The collar demonstrates: - Repelent effect (anti-feeding) during 5 months for sandflies (*Phlebotomus perniciosus*) - Repelent effect for 6 months for culicides mosquitoes (*Culex pipiens*) The collar prevents from: - Tick infestation for 6 months. - Fleas infestation for 4 months. It has been proved the repellent efficacy (antifeeding) against *Phlebotomus spp*, so it can be considered as part of the program of prevention for Leishmaniasis and the culex mosquitoes of the complex *Culex pipiens*.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	01/04/2020
Concerned Member States for original procedure	IT, PT, EL, CY, RO, BG, SI, BE

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.
The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains deltamethrin (0.636 g, 1.056, 1.304 g) and excipients Polyvinyl chloride, Calcium stearate, Soybean oil, epoxidized, Diisooctyl adipate, Titanium dioxide (E171), Triphenyl phosphate and Calcium zinc stearates

Each collar is packaged in a sealed sachet made polyethylene terephtalate-aluminium-polypropylene.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is deltamethrin, an established active substance described in the British Veterinary Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

III.A Safety Testing

This application has been submitted in accordance with Article 13 (3), so called hybrid application, and the candidate product has been developed to be equivalent to the reference product. Both products are similar in terms of qualitative and quantitative composition of the active substance and qualitative composition of excipients, are intended to be administered through the same administration route and have the same release profile. Therefore, results of pharmacological or toxicological studies are not required because the safety of the product has already been proved for the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that there is a significant risk for a child ingesting or licking part of the collar. In light of the risks identified, adequate risk mitigation measures have been proposed.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

However, deltamethrin is known to be toxic to bees and aquatic organisms, and the environment may be exposed via transfer of the product from the dog's collar to the aquatic environment. Therefore, in order to mitigate a potential risk to bees or the aquatic life adequate risk mitigation measures have been included in the SPC and product literature.

The product is not expected to pose a risk for the environment when used in accordance with the SPC.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a hybrid application according to Article 13(3), and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Pharmacology

The applicant has conducted studies to show that the physico-chemical properties of the generic and reference product are identical

The consistency of Deltamethrin release has been assessed according to an in vitro test enclosed in section 2.a.4 Pharmaceutical Development

Tolerance in the Target Species of Animals

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

Laboratory Trials

An in vivo study was performed to demonstrate by means of a diffusion study, in order to correlate the in vitro properties of release of deltamethrin from the collar to in vivo bioavailability parameters.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

None