Agencia Española de Medicamentos y Productos Sanitarios

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

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Cadorex 300 mg/ml solution for injection for cattle, sheep and pigs

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0246/001/DC
Name, strength and pharmaceutical form	Cadorex 300 mg/ml solution for injection for cattle, sheep and pigs
Applicant	LIVISTO Int'l, S.L. Av. Universitat Autònoma, 29 08290 Cerdanyola del Vallès Barcelona (Spain)
Active substance(s)	Florfenicol
ATC Vet code	QJ01BA90
Target species	Cattle, sheep and pigs
Indication for use	Cattle: Diseases caused by florfenicol susceptible bacteria: Treatment of respiratory tract infections in cattle due to *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni.* Sheep: Treatment of ovine respiratory tract infections due to *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to florfenicol. Pigs: Treatment of acute outbreaks of swine respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.

MODULE 2

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

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	25/01/2017
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, BG, EL, FR, HU, IE, IT, PL, PT, RO, SI, UK

I. SCIENTIFIC OVERVIEW

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, the consumer of foodstuffs from treated animals 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.

A. Composition

The product contains 300 mg/ml of florfenicol as active substance and the excipients NMethylpyrrolidone, propylene glycol and macrogol 300.

The container/closure system is a polypropylene vial (100 and 250 ml) closed with a bromobutyl rubber stopper and an aluminium capsule. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of a preservative are justified.

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 florfenicol, an established active substance. 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.

The quality of the active substance is documented by means of an ASMF.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

Not applicable.

F. 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.

G. 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.

The in-use shelf-life of 28 days after broaching is supported by the data provided.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is a generic application according to Article 13.1 of the Directive 2001/82/EC as amended, and bioequivalence with a reference product has been demonstrated, results of safety and residue tests are not required.

The safety and residue aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are similar to those of the reference product and are adequate to ensure safety of the product to users / the environment / consumers.

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, the results of pharmacological studies are not required.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, the results of toxicological studies are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline (EMA/CVMP/543/03-Rev 1).
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that further assessment (Phase II studies) was required. The assessment concluded that the environmental impact of the product when used as recommended can be considered as negligible.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

Residue Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, no residue depletion studies are required.

MRLs

Florfenicol is listed in Annex I of Commission Regulation Nº 37/2010. The marker substance is the sum of florfenicol and its metabolites measured as florfenicol-amine.

MRLs are listed below:

Porcine	Muscle	300
	Liver	2000
	Kidney	500
	Skin & fat	500

Bovine, ovine, and caprine	Muscle Liver Kidney	200 3000 300

Withdrawal Periods

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, the same withdrawal periods are justified:

Cattle:
- Meat and offal: by IM route: 30 days
  by SC route: 44 days

- Milk: Not permitted for use in lactating animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption

Sheep:
- Meat and offal: by IM route 39 days

- Milk: Not permitted for use in lactating animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

Pigs:
- Meat and offal: by IM route 18 days

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13.1 of the Directive 2001/82/EC as amended, 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.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the veterinary Heads of Agencies website (www.hma.eu).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

None