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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

CEFTIOCYL Flow 50 mg/ml, suspension for injection for pigs and cattle

DATE : 2017.10.02.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0304/001/DC
Name, strength and pharmaceutical form	CEFTIOCYL Flow 50 mg/ml, suspension for injection for pigs and cattle
Applicant	VETOQUINOL MAGNY VERNOIS 70200 LURE FRANCE
Active substance(s)	Ceftiofur (as hydrochloride)
ATC Vetcode	QJ01DD90
Target species	Cattle, pigs
Indication for use	Infections associated with bacteria sensitive to ceftiofur

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	2017.07.26.
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	EE, UK, DK, LT, IT, SE, DE, AT, BG, LV, PL, MT, HU, PT, LU, HR, CZ, IE, BE, RO, ES, NL, EL, NO, CY, SK, SI, FI

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, 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.

II. QUALITY ASPECTS

A. Composition

The product contains 50 mg of ceftiofur (as hydrochloride) and the following excipients: water for injections, polysorbate 80 and medium-chain triglycerides.
The packaging of the finished product is as described on the SPC. The particulars of the containers and controls performed are provided and conform to the regulation.
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.
The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is ceftiofur hydrochloride, 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.

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.
An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

See IV.A

Toxicological Studies

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

The toxicological aspects of this product are identical to the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that no additional risks are expected as compared to the reference product.
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 initial predicted environmental concentrations in soil are less than 100 µg/kg.

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

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Residue Studies

No residue depletion studies were conducted according to the waiver from bioequivalence study requirements for immediate release formulations.

The withdrawal periods agreed for the reference product can be applied to the generic product.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, 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 two bioequivalence studies between CEFTIOCYL FLOW and EXCENEL FLOW (reference product) in cattle and pigs following a single subcutaneous administration and a single intramuscular administration, respectively.
Based on the Guideline on the conduct of bioequivalence studies (CVMP/016/00/Rev.2) both reference and generic products can be considered bioequivalent.

Tolerance in the Target Species of Animals

The applicant has not provided a tolerance study which is acceptable because the tested product and the reference product are bioequivalent, and the safety of the excipients of the tested formulation is acknowledged.

Resistance

An update of the resistance data on ceftiofur has been submitted based on published literature.
Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

No clinical studies with the product were submitted by the applicant.

As generic status is confirmed (see preclinical part) the indications and posology as

authorized for the reference product (Excenel Flow, 50 mg/ml, suspension for injection for pigs and cattle) can be applied to CEFTIOCYL Flow 50 mg/ml, suspension for injection for pigs and cattle.

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

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.HEVRA.org).

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.