Agencia Española de Medicamentos y Productos Sanitarios

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España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Cemay, 50 mg/ml, suspension for injection for pigs

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0164/001/DC
Name, strength and pharmaceutical form	Cemay, 50 mg/ml, suspension for injection for pigs
Applicant	Laboratorios Maymó, S.A. Via Augusta, 302 08017, Barcelona (Spain).
Active substance(s)	Ceftiofur (as ceftiofur hydrochloride)
ATC Vet code	QJ01DD90
Target species	Pigs
Indication for use	For the treatment of bacterial respiratory disease associated with Pasteurella multocida, Actinobacillus pleuropneumoniae and Streptococcus suis.

MODULE 2

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

"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."

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	28/06/2011
Date product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	DE, EL, FR, IT, PT.

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 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. Composition

The veterinary medicinal product contains 50 mg/ml of ceftiofur (as ceftiofur hydrochloride) and excipients (hydrogenated soya lecithin, sorbitan monoleate and cotton seed oil).

The container/closure system are polypropylene bottles of 100 and 250 ml with bromobutyl rubber stoppers and an aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation is justified.

It 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 veterinary medicinal product is manufactured and sterilised fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

The manufacturing process is a non-standard one. Process validation on industrial batches will be performed post-authorisation

C. Control of Starting Materials

The active substance is ceftiofur hydrochloride, an established active substance. The manufacturing authorisation holder certifies that the active substance is manufactured in compliance 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 its specification have been provided.

A copy of the ASMF has been included.

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 veterinary medicinal product.

E. Control on intermediate products

Controls performed after primary packaging before terminal sterilization are described.

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 analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification. Analytical data of production scale batches will be provided post-authorisation.

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 when stored under the approved conditions.

The claim of 28 days stability after broaching is based on the demonstration of stability on two batches. Data on an aged batch generate at the final point of the ongoing stability study will be provided post-authorisation.

H. Genetically Modified Organisms

None of the starting materials used in the manufacture of the product contains genetically modified organisms.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT

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

Residue depletion studies in injection sites using the final formulation have also been conducted in pigs. Samples of muscle at injection site were taken from animals at several time points. The analytical method was fully validated.

MRLs

Ceftiofur is included in the Regulation 470/2009 as a pharmacological active substance with the following MRLs:

Active substance	Marker residue	Animal specie	MRL (µg/kg)	Target tissue
Ceftiofur	Sum of all residue retaining the betalactam structure expressed as Desfuroylceftiofur	All mammalian food producing species	1000 2000 2000 6000 100	Muscle Fat Liver Kidney milk

Withdrawal Periods

Based on the data provided above, a withdrawal period of 5 for meat in pigs is justified.

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

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

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.

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.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>