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

FLOXYME 50 mg/ml SOLUTION FOR USE IN DRINKING WATER

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0182/001/DC
Name, strength and pharmaceutical form	FLOXYME 50 mg/ml SOLUTION FOR USE IN DRINKING WATER
Applicant	ANDERSEN. S.A Avda. De la Llana 123 Polígono Industrial “La Llana” 08191 Rubí (Spain)
Active substance(s)	Florfenicol
ATC Vet code	QJ01BA90
Target species	Pigs
Indication for use	Treatment and prevention at the group level where clinical signs are present of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol. The presence of the disease should be established in the herd before initiating preventive treatment.

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 (3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	29/05/2013
Date product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	BE, CY, DE, FR, HU, IT, NL, PL, PT

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/ml florfenicol as active substance and Macrogol 300 as excipient.

The container/closure system consists of one litre bottle made of opaque high density polyethylene (HDPE), with HDPE screw cap, a disk and security seal. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation is 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 neither described in the European Pharmacopoeia nor in the British Veterinary Pharmacopoeia. Data on the active substance is presented following an ASMF procedure.

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 excipient is described in the European Pharmacopoeia.

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. Tests comprised those for in-use stability.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening of the immediate packaging: 28 days.
Shelf-life after dilution or reconstitution according to directions (in-use): 24 hours
Do not use the veterinary medicinal product for more than 5 hours with proportioners, if galvanised piping is used.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

This is a hybrid application according to Article 13(3) of Directive 2001/82/EC and amendments.
The only difference compared to the reference veterinary medicinal product is a change in strength (quantitative change to the active substance). Taking into account that the amount of active substance to be administered is the same in both products, safety studies are not required because all these data are in the documentation that supports the marketing authorisation of the reference product.

III.A Safety Testing

Pharmacological Studies

As this is a hybrid application according to Article 13(3), results of pharmacological test are not provided because evidences were already proved for the reference product.

Toxicological Studies

As this is a hybrid application according to Article 13(3), results of toxicological test are not provided because evidences were already proved for the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the use of the product poses an acceptable risk.
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 was required. The assessment concluded that the product does not pose an inacceptable risk for the environment when used under the labelled conditions of use.
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

No residue depletion studies were conducted because this is a hybrid application according to Article 13(3) and the equivalence to the reference product is proved.

MRLs

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

MRL are listed below:

	Porcine
Muscle	300 µg/kg
Liver	2000 µg/kg
Kidney	500 µg/kg
Skin and fat	500 µg/kg

Withdrawal Periods

Based on the data provided above, a withdrawal period of 20 days for meat in pigs is justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

This is a hybrid application according to Article 13(3) of Directive 2001/82/EC and amendments.
The only difference compared to the reference veterinary medicinal product is a change in strength (quantitative change to the active substance). Taking into account that the amount of active substance to be administered is the same in both products, safety studies are not required because all these data are in the documentation that supports the marketing authorisation 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.

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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

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