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

TYLMASIN 250 mg/g PREMIX FOR MEDICATED FEEDING STUFF FOR PIGS AND CHICKENS

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0225/001/DC
Name, strength and pharmaceutical form	TYLMASIN 250 mg/g PREMIX FOR MEDICATED FEEDING STUFF FOR PIGS AND CHICKENS
Applicant	Triveritas Limited Bank Barn How Mill Brampton, CA8 9JY , Reino Unido
Active substance(s)	Tylosin Phosphate
ATC Vet code	QJ01FA90
Target species	Pigs, Chickens
Indication for use	Pigs: Treatment and metaphylaxis of enzootic pneumonia caused by *Mycoplasma hyopneumoniae*, atrophic rhinitis, Porcine Proliferative Enteropathy caused by *Lawsonia intracellularis*. Chickens: Treatment and metaphylaxis of Chronic Respiratory Disease (CRD) caused by *Mycoplasma gallisepticum* or *M. synoviae*, necrotic enteritis caused by *Clostridium perfringens*, sensitive to tylosin

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	18/11/2015
Date product first authorised in the Reference Member State (MRP only)	04/12/2015
Concerned Member States for original procedure	IT, 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.

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II. QUALITY ASPECTS

A. Composition

The product contains 250 mg of Tylosin phosphate as active substance and Pregelatinised potato starch, Dipotassium phosphate and Wheat meal as excipients.

The container/closure systemare a three layer paper bags with an internal polyethylene bag with pack sizes of 5 Kg and 20 Kg. Tylmasin 250 mg/g premix is also packed in block-bottom zipped sachets of polyethylene/aluminium/polyethylene terephthalate of 1 Kg pack size.

The choice of the formulation 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 Tylosine Phosphate, 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.

Active substance is supported by an ASMF.

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

Certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

E. Control on intermediate product

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

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.

H. Genetically Modified Organisms

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

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

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

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.

III.A Safety Testing

User Safety

The user safety warnings proposed by the applicant are in line with those approved for other similar products registered in Europe with the same composition and are considered suitable to prevent users from the risks derived from the use 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 tylosin -at the calculated exposure- poses a risk for terrestrial plants that can be eliminated by mixing litter from treated poultry with litter from non treated poultry.
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 generic application according to Article 13, and bioequivalence with a reference product has been demonstrated.

Withdrawal Periods

The same withdrawal period as for the reference product is justified:

Pigs: Meat and offal: Zero days
Chickens: Meat and offal: Zero days
Eggs: Zero days

IV. CLINICAL ASSESSMENT (EFFICACY)

This is a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC. As 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

As this was a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, pre-clinical studies are not required.

IV.B Clinical Studies

As this was a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, clinical studies are not required.

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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).

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