Agencia Española de Medicamentos y Productos Sanitarios

Parque Empresarial Las Mercedes
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28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

[DRAFT] PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Hymatil 300 mg/ml solution for injection for cattle

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0141/001/DC
Name, strength and pharmaceutical form	Hymatil 300 mg/ml solution for injection for cattle
Applicant	Industrial Veterinaria S.A. Esmeralda 19 – 08950 Esplugues de Llobregat (Barcelona) - Spain
Active substance(s)	Tilmicosin
ATC Vet code	QJ01FA91
Target species	Cattle
Indication for use	Cattle: For the treatment of pneumonia associated with Mannheimia haemolytica, Pasteurella multocida, and other organisms sensitive to tilmicosin.

"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."

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MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	
Date product first authorised in the Reference Member State (MRP only)	26/06/2009
Concerned Member States for original procedure	Belgium, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Lithuania, Latvia, Poland, Portugal and Slovakia.

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, 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 Tilmicosin 300 mg/ml.

The container/closure system consist in a coloured glass (type II) vials closed with a grey bromobutyl stopper and sealed with an aluminium capsule.
The particulars of the containers and controls performed are provided and conform to the regulation.

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 Tilmicoisn, 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.

An updated edition of DMF has been included.

Specifications and control methods for each excipient have been provided.

Certificates of analysis have been included for each excipient.

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

No 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 claim of a 28 days stability after first opening is based on the demonstration of stability for 2 batches broached and stored 25 ºC ± 2 ºC and 60 % RH ± 5 %.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL) *(for pharmaceuticals only)*

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

Ecotoxicity

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

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.

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.