Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

MUTUAL RECOGNITION PROCEDURE

FINAL PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

MEGANYL 50 mg/ml
Solution for injection for cattle, pigs and horses

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0249/001/MR
Name, strength and pharmaceutical form	MEGANYL 50 mg/ml solution for injection for cattle, pigs and horses
Applicant	Laboratorios SYVA S.A.U. Avda. Párroco Pablo Díez, 49-57 (24010) León Spain
Active substance(s)	Flunixin (as flunixin meglumine)
ATC Vet code	QM01AG90
Target species	Cattle, pigs and horses.
Indication for use	<u>In Cattle:</u> It is recommended for the control of acute inflammation and because of its antipyretic effect on bovine respiratory disease in cattle <u>In Pigs:</u> It may be used as adjunctive therapy in the treatment of the pain and inflammation associated with metritis-mastitis-agalactia (MMA) syndrome in pigs. <u>In Horses:</u> For the alleviation of inflammation and pain associated with musculo-skeletal disorders in acute and chronic conditions. For the alleviation of visceral pain associated with colic in the horse.

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	Mutual Recognition application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	Day 90: 22/07/2015
Date product first authorised in the Reference Member State (MRP only)	17/07/2007
Concerned Member States for original procedure	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 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 Flunixin (as flunixin meglumine) as active substance and phenol, sodiumformaldehyde sulfoxilate, disodium edetate, diethanolamine, propylene glycol, hydrochloric acid and water for injection as excipients.

The container/closure system are colourless glass vials type II with bromobutyl rubber stopper type I and aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of preservative (phenol) 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 Flunixin meglumine, an established active substance described in the European Pharmacopoeia. 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.

RO-CEP 2013-017-Rev 02.
R1-CEP 2007-108-Rev 00.

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 products

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.

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 safety 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 and consumers.

III.A Safety Testing

Pharmacological Studies

No pharmacological data were required because this is a generic application and the bioequivalence with the reference product has been demonstrated.

Toxicological Studies

No toxicological data were required because this is a generic application and the bioequivalence with the reference product has been demonstrated.

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 for users implementing the indicated protective measures.
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 no further assessment is required. The assessment concluded that the product has an acceptable risk for the environment.
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 and the bioequivalence with the reference product has been demonstrated.

MRLs

The active substance is listed in Table 1 in the Annex of Commission Regulation 37/2010 in accordance with the following MRL:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissue
Flunixin	Flunixin	Bovine	20 µg/kg 30 µg/kg 300 µg/kg 100 µg/kg	Muscle Fat Liver Kidney
	5-hydroxy flunixin	Bovine	40 µg/kg	Milk
	Flunixin	Porcine	50 µg/kg 10 µg/kg 200 µg/kg 30 µg/kg	Muscle Skin+Fat Liver Kidney
	Flunixin	Equidae	10 µg/kg 20 µg/kg 100 µg/kg 200 µg/kg	Muscle Fat Liver Kidney

Withdrawal Periods

Based on the data provided above, the following withdrawal periods are justified:

Cattle: Meat and offal: 4 days.
Milk: 24 hours.

Pigs: Meat and offal: 24 days.

Horse: Meat and offal: 4 days.
Milk: Not authorised for use in mares producing milk for human consumption.

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

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

Tolerance in the Target Species of Animals

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

IV.B Clinical Studies

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

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

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