The Netherlands
Medicines Evaluation Board
Graadt van Roggenweg 500
3531 AH Utrecht
(Reference Member State)

NL/V/0252/001

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Maximec Horse Oral Paste 18.7 mg/g

CMS: BE, LU, UK

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0252/001
Name, strength and pharmaceutical form	Maximec Horse Oral Paste 18.7 mg/g
Applicant	Bimeda Animal Health Limited Unit 2/3/4 Airton Close Tallaght, Dublin 24 Ireland
Active substance(s)	Ivermectin
ATC Vetcode	QP54AA01
Target species	Horses
Indication for use	Treatment of parasitic infestations in horses due to large strongyles, small strongyles, lungworms, pinworms, ascarids, hairworms, large-mouth stomach worms, neck threadworms, intestinal threadworms and stomach bots.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary 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.a (iii) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	23rd February 2007
Date product first authorised in the Reference Member State (MRP only)	23rd September 2005
Concerned Member States for original procedure (after RMS change)	BE, LU, UK

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[1].
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. Qualitative and quantitative particulars

The product contains ivermectin 18.7 mg/g and the excipients maize oil, polysorbate 80, apple flavour and silica colloidal anhydrous.

The container/closure system is a multi-dose oral syringe comprising a high density polyethylene (HDPE) syringe barrel and a low density polyethylene (LDPE) cap. The plunger and multi-dose sliding ring are formed from HDPE and the plunger seal is formed from LDPE. 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.

[1] SPC = Summary of product characteristics

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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 ivermectin 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.

The applicant refers to a certificate of suitability (CEP) for ivermectin.

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

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.

H. enetically Modified Organisms

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Not applicable.

J. Other Information

Shelf life: 2 years.
Storage condition: Protect from light

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

Since the application is made in accordance with Article 13.1 (a) (iii) of Directive 2001/82/EC as amended on the basis of essential similarity, data on pharmacodynamics and pharmacokinetics are not required. This type of product is exempt from the requirements to provide bioequivalence studies.

Toxicological Studies

Since the application is made in accordance with Article 13.1 (a) (iii) of Directive 2001/82/EC as amended on the basis of essential similarity this information is not required.

User Safety

The risk management measures that the applicant proposes for this product are the same as for the reference product (Eqvalan Paste). The same warnings are in the relevant section of the SPC for this product as for the reference product and are adequate to ensure safety to users of the product. The SPC presented confirms this.

Do not smoke, drink or eat while handling the product. Wash hands after use.

Ecotoxicity

Since the application is made in accordance with Article 13.1 (a) (iii) of Directive 2001/82/EC as amended, on the basis of essential similarity, data on ecotoxicity are not required. This product is considered to be bioequivalent to the reference product (Eqvalan Paste) and environmental safety is considered to be satisfactory.

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

Since the application is made in accordance with Article 13.1 (a) (iii) of Directive 2001/82/EC as amended on the basis of essential similarity this information is not required.

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MRLs

Ivermectin is listed in Annex I of Council Regulation 2377/90. The marker substance is 22,23-dihydroavermectin $B1_a$

MRLs are listed below:

	Cattle	Pig	Sheep
Liver	100 µg/kg	15 µg/kg	15 µg/kg
Fat	40 µg/kg	20 µg/kg	20 µg/kg

Withdrawal Periods

Based on the data provided above, a withdrawal period of 21 days for meat and offal in horses is justified. Animals must not be slaughtered for human consumption during treatment. The product is not permitted for use in lactating mares producing milk for human consumption.

It is considered that essential similarity has been demonstrated and therefore the proposed withdrawal period is considered satisfactory.

IV CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

Since the application is made in accordance with Article 13.1 (a) (iii) of Directive 2001/82/EC as amended on the basis of essential similarity this information is not required as it has already been presented for the reference product (Eqvalan Paste).

Tolerance in the Target Species of Animals

Since the application is made in accordance with Article 13.1 (a) (iii) of Directive 2001/82/EC as amended on the basis of essential similarity this information is not required as it has already been presented for the reference product.

IV.B Clinical Studies

Laboratory Trials

Since the application is made in accordance with Article 13.1 (a) (iii) of Directive 2001/82/EC as amended on the basis of essential similarity, this information is not required as it has already been presented for the reference product.

Field Trials

Since the application is made in accordance with Article 13.1 (a) (iii) of Directive 2001/82/EC as amended on the basis of essential similarity, this information is not required as it has already been presented for the reference product.

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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 Variations

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 Product Information Database of the Medicines Evaluation Board website.

https://www.diergeneesmiddeleninformatiebank.nl/nl/

Post Authorisation Variations

Maximec Horse Oral Paste, 18.7 mg/g

NL/V/0252/001/IB/011	2 October 2020	Change in the (invented) name of the medicinal product (Belgium only)
National	20 November 2018	Marketing Authorisation Holder change
NL/V/0252/001	15 March 2018	Change in RMS from UK to NL.
UK/V/xxxx/IA/089/G	12 January 2016	Submission of an updated certificate of suitability.
UK/V/xxxx/1A/034/G	18 October 2012	Submission of a new European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
UK/V/0230/1A/020/G	29 March 2012	Grouped variation concerning the submission of two European Pharmacopoeia Certificates of Suitability.
UK/V/0230/001/IB/006	11 November 2011	Variation to change the QRD test and as a result the mock-ups for the finished product in Belgium.
UK/V/230/001/IA/004	31 March 2011	Variation to update a TSE Ph. Eur. Certificate of Suitability for an excipient.
	03 December 2010	Renewal (UK as RMS).
UK/V/0230/001/II/001	14 October 2009	Addition of a safety warning in the SPC and Product Literature.
UK/V/0230/001/1A/002	08 October 2008	Submission of an updated European Pharmacopoeia Certificate of Suitability for the active substance.
	23 February 2007	MRP (UK as RMS).