Irish Medicines Board

Reference Member State

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-On Solution for Cattle

MODULE 1

PRODUCT SUMMARY

EU Procedure number	IE/V/0260/002/DC
Name, strength and pharmaceutical form	Dectomax 5 mg/ml Pour-On Solution for Cattle
Applicant	Pfizer Healthcare Ireland Trading as: Pfizer Animal Health Ringaskiddy Co. Cork Ireland.
Active substance(s)	Doramectin
ATCvet code	QP 54AA03
Target species	Cattle
Indication for use	For treatment of infestations of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornfly in cattle.

MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	A generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	18/04/2012
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	AT, BG, DK, ES, FI, FR, HU, IS, NL, NO, PL, PT, RO, SE, SI.

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 Doramectin 5 mg/ml and excipients cetearyl octanoate, trolamine and isopropyl alcohol.

The product is supplied in 250 ml and 1 L multi-dose high-density polyethylene bottles with screw-top lids and dosing cups and 2.5 L, 3 L and 5 L multi-dose high-density polyethylene bottles with screw-top lids and draw-off adaptor.

The choice of 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 Doramectin, 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.

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.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). It was confirmed that the formulation and manufacturing process for the product is identical to that of the reference product. As a result it was accepted that the product was bioequivalent to the reference product, Zearl 5 mg/ml Pour-On Solution for Cattle (VPA 10019/057/001 transferred to 10047/029/001).

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been accepted, results of pharmacological tests are not required.

The pharmacological aspects of this product reflect those of the reference product.

Toxicological Studies

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been accepted, results of toxicological tests are not provided.

User Safety

The applicant provided a user safety assessment which showed that when used in accordance with label recommendations, the product will not pose any greater risk to the user than the risks associated with use of the reference product, Zearl 5 mg/ml Pour-On Solution for Cattle.
Warnings and precautions as listed on the product literature are similar to those of the reference product and are adequate to ensure safety of the product to users.

Ecotoxicity

The applicant provided a first phase environmental risk assessment (ERA) in compliance with the relevant guideline which showed that further assessment was required.
The applicant provided a targeted Phase II ERA. The outcome of the ERA indicates a potential risk to aquatic organisms (namely daphnids, following direct excretion scenario) and dung fauna. In order to address the identified risks for aquatic organisms and dung fauna the following risk mitigation measures are recommended:

The following text is proposed in section 4.5 of the SPC (special precautions for use):

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments.
The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of doramectin (and products of the same anthelmintic class) in cattle.
The risk to aquatic ecosystems will be reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

The following text should be included in section 5.3 of the SPC (environmental properties):

Like other macrocyclic lactones, doramectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of doramectin may take place over a period of several weeks. Faeces containing doramectin excreted onto pasture by treated animals may reduce

the abundance of dung feeding organisms which may impact on the dung degradation.
Doramectin is very toxic to aquatic organisms and may accumulate in sediments.

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 the product that is the subject of the present application is identical in every respect (composition, manufacturing process) to the reference product. On this basis it was assumed that depletion of residues from target tissues will be identical. Consequently, exemption from the requirement to present confirmatory residue data was justified and the authorised withdrawal period for the reference product can be applied to the generic product.

MRLs

Doramectin is listed in Table 1 of Council Regulation (EU) No. 37/2010 (O.J. 20.1.2010, L 15/28). The marker substance is doramectin.

MRLs are listed below:

	All mammalian food producing species
Muscle	40 µg/kg
Liver	100 µg/kg
Kidney	60 µg/kg
Fat	150 µg/kg

Withdrawal Periods

Based on the data provided above, a withdrawal period of 35 days for meat in cattle is justified. The product is not to be used in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been accepted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

Resistance

Adequate warnings and precautions in relation to the prudent use of anthelmintic products appear on the product literature.

IV.B Clinical Studies

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been claimed, efficacy studies are not provided. 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.

Quality changes

Summary of change **(Application number)**	**Section updated in Module 3**	**Approval date**
A.2.B Change in invented name of the medicinal product IE/V/0260/002/IB/001	N/A	26/07/2012