United Kingdom
Veterinary Medicines Directorate
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MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

ZincoTec Zinc Oxide 1000 mg/g Premix for Medicated Feeding Stuff

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0488/001/MR
Name, strength and pharmaceutical form	ZincoTec Zinc Oxide 1000 mg/g Premix for Medicated Feeding Stuff
Applicant	SCA NuTec (Provimi Ltd)
Active substance(s)	Zinc Oxide
ATC Vetcode	QA07XA91
Target species	Pigs
Indication for use	For the treatment and control of diarrhoea in young pigs.

MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Mutual Recognition application in accordance with Article 12 of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	13th December 2012.
Date product first authorised in the Reference Member State (MRP only)	9th July 1990.
Concerned Member States for original procedure	Ireland.

I. SCIENTIFIC OVERVIEW

The product is intended to treat diarrhoea in young pigs. It is administered at 2900 – 3100 mg/kg ZincoTec, providing 2320 – 2489 mg/kg elemental zinc, enabling the amount of zinc naturally occurring in the feed to give a total amount of 2500 mg/kg elemental zinc.

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 benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains zinc oxide and no excipients.

The container/closure system consists of 25 kg multi-ply paper sacks, filled via a side valve, which is tucked in to form a closure and glued. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and absence of preservative are justified.

[1] SPC – Summary of product Characteristics.

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.

C. Control of Starting Materials

The active substance is zinc oxide. 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

Scientific data in compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products were provided.

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.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

The shelf-life of the product as packaged for sale is two years. The shelf-life of the product after incorporation into meal or pelleted feed is three months. Special storage precautions are as follows:-

- Store in a cool, dry place.
- Do not store above 25°C.
- Store in tightly closed original container.
- Store away from, food, drink and animal feeding stuffs.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Suitable tests were performed in order to establish the safety of the product.

User Safety

The applicant provided a user safety assessment in compliance with the relevant guideline. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product:-

- Wear either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143 when mixing or handling the feed.
- Avoid contact with the eyes by wearing protective goggles or safety glasses. In case of accidental eye contact, irrigate thoroughly with large quantities of water.
- Avoid contact with the skin by wearing protective clothing including impermeable gloves. In case of accidental skin contact wash the exposed skin with soap and water.
- Contaminated clothing should be removed and washed before being reused.
- In case of accidental ingestion, drink plenty of water and seek medical attention.
- Wash hands after use.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline. 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

The applicant provided residue depletion studies, or provided bibliographical data in line with appropriate guidelines.

Withdrawal Periods

Based on the data provided above, a withdrawal period of twenty-eight days was established. Animals must not be slaughtered for human consumption during treatment.

IV CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

Pharmacodynamics

The precise action of zinc oxide in the treatment and control of diarrhoea in pigs has not been determined. A favourable effect has been noted in gut microflora, with zinc oxide seen to prevent a reduction in the diversity of gut microflora that may occur in pigs following the second week of weaning.

Pharmacokinetics

An essential trace element for livestock, zinc oxide is relatively poorly absorbed. When given to pigs four weeks after weaning, therapeutic levels of zinc increased in the liver and kidney by factors of five and two respectively. Most zinc is thought to be excreted unchanged in the faeces as zinc is essential for daily metabolism and therapeutic levels are poorly absorbed. A small proportion of zinc is excreted in the urine. No biotransformation occurs and zinc may enter the environment via slurry or manure. The burden on the environment is not thought to be large when the product is used as directed.

Tolerance in the Target Species of Animals

Appropriate tolerance studies or bibliographical data were provided.

IV.B Clinical Studies

The applicant conducted appropriate studies to ensure the safety of the 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 benefit/risk 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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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