Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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(Reference Member State)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Poulvac AE

PuAR correct as of 18/01/2018 when RMS was transferred to DE. Please contact the RMS for future updates

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0269/001/MR
Name, strength and pharmaceutical form	Poulvac AE
Applicant	Fort Dodge Animal Health Ltd.
Active substance	Avian Encephalomyelitis virus, strain AE-67
ATC Vetcode	QI01AD02
Target species	Chickens
Indication for use	For active immunisation of future layer and breeding chickens to prevent mortality due to infection with avian infectious encephalomyelitis virus.

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(3) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	12 February 2008
Date product first authorised in the Reference Member State (MRP only)	26 October 2005
Concerned Member States for original procedure	Austria Bulgaria Czech Republic Denmark Estonia Germany Italy Latvia Lithuania Poland Portugal Romania Slovakia Slovenia Spain

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 the active substance avian encephalomyelitis virus strain AE-67 and the excipients sucrose, sorbitol, dehydrated non-fat milk, N-Z Amine Type YT, L-glutamic acid monopotassium, potassium phosphate monobasic and potassium phosphate dibasic.

The container/closure system comprises type I glass containers and stoppers are type I bromobutyl rubber. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the vaccine strain 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.

No process validation data on the product have been presented, however this was considered acceptable.

C. Control of Starting Materials

The active substance is avian encephalomyelitis virus strain AE-67 a novel active substance whose manufacture is appropriately controlled.

Starting materials of non-biological origin used in production comply with in-house specifications.

Biological starting materials used are in compliance with the relevant Ph. Eur. Monographs and guidelines and are appropriately screened for the absence of extraneous agents according to the Ph. Eur.; any deviation was adequately justified.

The master and working seeds have been produced according to the Seed Lot System as described in the relevant guideline.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Scientific data have been provided and risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

E. Control tests during production

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 tests performed on the final product conform to the relevant requirements; any deviation from these requirements is justified. The tests include in particular visual inspections, identity, safety, sterility and purity, residual humidity and batch to batch consistency. The demonstration of the batch to batch consistency is based on the results of 3 batches produced according to the method described in the dossier. Other supportive data provided confirm the consistency of the production process.

G. Stability

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 in-use shelf-life of the reconstituted vaccine is supported by the data provided.

H. Genetically Modified Organisms

Not applicable

J. Other Information

Shelf life: 18 months
In-use shelf life: 2 hours

III. SAFETY ASSESSMENT

Laboratory trials

The safety of the administration of one dose, an overdose and the repeated administration of one dose in the target animal has been demonstrated in a single study. The investigation was performed according to the recommendations of Directive 2001/82/EC as amended and the relevant guidelines. No adverse reactions, clinical signs or mortalities were observed after any vaccination. Necropsies of 10x vaccinated and control birds showed all birds to be normal. There was a statistically significant difference between the group mean weights of the Ix dose and 10x dose groups, both before and after vaccination. However, there was no statistically significant difference between those groups and the non-vaccinated control group at any time. The absence of any adverse effects in either of the vaccinated groups and the lack of a significant difference between the weight gains of the vaccinated and control groups support the safety of this vaccine.

No investigation of effect on reproductive performance was conducted because the vaccine is not intended for this category of animals.

There are no data suggesting that this product might adversely affect the immune system of the vaccinated animal or its progeny therefore a specific study was not carried out.

Specific studies were carried out to describe the spread, dissemination, reversion to virulence, biological properties, recombination or genetic reassortment of the vaccine strain. It was concluded that the vaccine virus disseminates widely in vaccinates and spreads easily among birds after vaccination. The SPC contains a warning that "all non-vaccinated birds present on a farm should be vaccinated at the same time."

The interaction of the vaccine with other vaccines was studied. Although no safety concerns were raised by combination of the vaccine with a variety of other vaccines no compatibility is claimed in the SPC and section 4.8 states that "no information is available on the safety and efficacy from the concurrent use of this vaccine with any other" and recommends that "no other vaccines should be administered within 14 days before or after vaccination with the product."

Field studies

An old study report with sparse detail has been provided which provides some evidence from field use that supports the observations made in laboratory studies.

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 adequate to ensure safety to the environment when the product is used as directed.

IV CLINICAL ASSESSMENT (EFFICACY)

Clinical Studies

Laboratory Trials

The efficacy of the product has been demonstrated in two laboratory studies in which the vaccine was administered via drinking water as recommended and a further supportive trial in which wing-stab administration was used. The titre of the vaccine batches used in the laboratory studies was less than the minimum specified for the product, thereby confirming that commercial batches of minimum titre would be efficacious. These studies provide sufficient support for the efficacy of the vaccine as claimed in the SPC.

Field Trials

The applicant has provided a single field study. Significant immunity has been shown in the field to last for the whole of the normal laying period but the duration of immunity in progeny has not been demonstrated beyond the day of hatch; this is reflected in the SPC. There is no information on efficacy of the vaccine in the presence of maternally derived antibodies but since it is intended for use only in chickens at least ten weeks old when maternal antibodies will have waned this is acceptable.

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