United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

AviPro AE Suspension for Use in Drinking Water for Chicken

Date Created: **September 2023**

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	AviPro AE Suspension for Use in Drinking Water for Chicken, Suspension for use in drinking water
Applicant	Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA
Active substance(s)	Avian encephalomyelitis virus, live strain 143 Calnek
ATC Vetcode	QI01AD02
Target species	Chickens
Indication for use	For active immunization of future layers and breeding chickens from 14 weeks of age against Avian Encephalomyelitis Virus and to induce passive immunity in young chickens against infection with Avian Encephalomyelitis.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Full application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	21/06/2023

I. SCIENTIFIC OVERVIEW

This is a full application in accordance with Article 12(3).

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, any 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 [2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains live avian encephalomyelitis virus, strain 1143 Calnek and the excipients: disodium hydrogen phosphate, lactose monohydrate, potassium dihydrogen phosphate, skim milk powder and water.

The container/closure system consists of a glass vial closed with a rubber stopper, sealed with an aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the vaccine strain and the absence of preservative are justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

II.B. Method of Preparation of the Product

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of: preparation, incubation and harvest of eggs, homogenisation and formulation.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

II.C. Control of Starting Materials

The active substance is live avian encephalomyelitis virus, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

Starting materials of non-biological origin used in production comply with Ph. Eur.

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 Ph. Eur.

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

II.C.4. Substances of Biological Origin

Scientific data and/or 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.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

II.E. 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 are appearance, identification of active substance, potency, sterility, and purity.

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.

II.F. 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.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 1 year
Shelf life after dilution according to directions: 2 hours

Store and transport refrigerated (2 °C-8 °C).
Protect from frost.
Protect from direct sunlight.

Shelf life after dilution according to directions:
Protect finished vaccine suspension against direct sunlight and temperature above 25°C as well as frost

III. SAFETY ASSESSMENT

Laboratory trials

The safety of the administration of one dose, an overdose in the target animal is demonstrated. The investigation was performed according to the recommendations of Directive 2001/82/EC as amended and the relevant guidelines.

Effects on reproductive performance were examined: Do not use in birds in lay and within 4 weeks before the start of the laying period.

There is 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.

For each live strain included in the vaccine:
Specific studies or scientific assessments were carried out to describe the spread, dissemination, reversion to virulence, biological properties, recombination or genetic reassortment of the vaccine strain.

The excipients used do not pose a significant risk to the consumer. Based on this information, no withdrawal period is proposed.

No specific assessment of the interaction of this product with other medicinal product was made. Therefore, an appropriate warning in the SPC is included.

Field studies

Several field studies were conducted between 1983 and 1997 to investigate the safety of the vaccine. These studies supported the safety under field conditions.

Ecotoxicity

The applicant provided a Phase 1 environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

The assessment concluded that the overall risk to the environment is estimated as effectively zero. No warnings regarding are therefore 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 laboratory studies in accordance with the relevant requirements.

Two studies were performed to evaluate the proposed onset of immunity and a further two studies were provided to test the challenge virus strain and to evaluate the potency.

An additional four studies were done with challenges to assess passive immunity.

Field Trials

The field trials provided show that vaccinated animals seroconvert in a variable period and efficacy of the product has been demonstrated in field trials in accordance with the relevant requirements.

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 of the product is favourable.

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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