Veterinary Medicines Directorate

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Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Innovax-ILT-IBD Concentrate and Solvent for Suspension for Injection for Chickens

Date Created: June 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Innovax-ILT-IBD Concentrate and Solvent for Suspension for Injection for Chickens
Applicant	MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ
Active substance(s)	Live Herpesvirus of turkey strain HVT/IBD/ILT
ATC Vetcode	QI01AD18
Target species	Chicken (one day old chicks and embryonated eggs
Indication for use	For active immunisation of one-day-old chicks or 18-19 day-old embryonated chicken eggs: • to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus and Marek's disease (MD) virus. • to prevent mortality and to reduce clinical signs and lesions caused by infectious bursal disease (IBD) virus. Onset of immunity: IBD: 3 weeks of age, ILT: 4 weeks of age, MD: 5 days of age. Duration of immunity: IBD: 100 weeks, ILT: 100 weeks, MD: entire risk period.

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 8 of VMRs 2013 (Schedule 1, Article 1) as amended.
Date of conclusion of the procedure	26/03/2024

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, 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 Herpesvirus of turkey strain HVT/IBD/ILT and the excipients bovine serum, veggie medium, dimethyl sulfoxide, sodium chloride, disodium hydrogen phosphate dihydrate, phenolsulfonphthalein (Phenol red), potassium dihydrogen phosphate and water for injections.

The container/closure system consists of Type 1 glass ampoule. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the vaccine strain and 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.

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

II.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.

II.C. Control of Starting Materials

The active substance is live Herpesvirus of turkey strain HVT/IBD/ILT, an established active substance described in the European Pharmacopoeia. 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. or in-house specifications.

Biological starting materials used are in compliance with the relevant Ph. Eur. Monographs or in-house specifications and guidelines and are appropriately screened for the absence of extraneous agents according to the relevant guidelines; 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.

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 demonstration of the batch to batch consistency is based on the results of three 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 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.

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

G. Other Information

Shelf life of the concentrate as packaged for sale: 3 years.
Shelf life of the solvent (multilayer plastic bags) as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 2 hours.

Concentrate:
Store and transport frozen in liquid nitrogen (below -140 °C).

Solvent:
Store below 30 °C.

Container:
Store liquid nitrogen container securely in upright position in a clean, dry and well-ventilated room separated from the hatching/chicken room in the hatchery.

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 is demonstrated.

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

Specific studies were carried out to describe the spread, dissemination, reversion to virulence, biological properties, recombination or genetic reassortment of the vaccine strain.

The excipients used are permitted substances where no MRLs are required or out of the scope of MRL evaluation. 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

Two field studies were conducted, one using the *in-ovo* route and the other using subcutaneous route of administration. These studies demonstrated that the vaccine is safe when administered under the field conditions following the recommended routes.

Ecotoxicity

The applicant provided a Phase 1 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 laboratory studies in accordance with the relevant requirements.

Onset and Duration of Immunity

Several studies were conducted to determine the protection of the vaccine. Studies were conducted for IBD, ILT and MD routes of administration. The data supports that the vaccine prevents mortality and reduces clinical signs.
The onset and duration of immunity are as follows:
Onset:
IBD: 3 weeks of age
ILT: 4 weeks of age
MD: 5 days of age
Duration:
IBD: 100 weeks
ILT: 100 weeks
MD: entire risk period

Field Trials

Efficacy was investigated as part of the two field studies as described in Part III. The efficacy of the vaccine can be considered supported by these trials as the birds were shown to be protected at various levels.

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 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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