United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

GALLIVAC IBD S706 NEO

Date Created: January 2020

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	GALLIVAC IBD S706 NEO, Effervescent tablet
Applicant	Merial, 29, avenue Tony Garnier, 69007, Lyon, France
Active substance(s)	Each dose of vaccine contains: Active substance: Infectious Bursal Disease virus, attenuated strain S706, $10^{4.0}$ to $10^{5.3}$ $CCID_{50}$* * $CCID_{50}$: Cell Culture Infective Dose 50%
ATC Vetcode	QI01AD09
Target species	Chickens
Indication for use	Active immunisation of chickens to protect against mortality and to reduce lesions associated with Infectious Bursal (Gumboro) Disease. Immunity has been demonstrated 2 weeks after the first administration and has been shown under field conditions to persist throughout the rearing period.

MODULE 2

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

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Full Extension application in accordance with Article 12 (3) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	15th December 2020

I. SCIENTIFIC OVERVIEW

This was a full extension application, submitted in accordance with Article 12 (3) of Directive 2001/82/EC, as amended. The product is GALLIVAC IBD S706 NEO, a vaccine presented in effervescent tablet form against Infectious Bursal Disease virus. The specific strain is attenuated S706, $10^{4.0}$ to $10^{5.3}$ $CCID_{50}$, (cell culture infective dose 50%). The target species is chickens, (broilers, future layers and broiler breeders). GALLIVAC IBD S706 NEO has been developed as an effervescent tablet formulation, which incorporates the same active ingredient as already used in the original freeze-dried GALLIVAC IBD S706 vaccine.

For the proposed product, the active ingredient is freeze-dried, blended with tableting excipients and this dry mixture is directly compressed to form tablets which are packaged in airtight polyamide-aluminium-PVC/aluminium blisters. Appearance and pH differ slightly between the two products, but there is no difference in vaccine titre in suspensions of either pharmaceutical formulation. The difference in excipients between the two products poses no additional risk. Both products are delivered via the same route and to the same species.

The specific indication is active immunisation of chickens to protect against mortality and to reduce lesions associated with Infectious Bursal (Gumboro) Disease. Onset of immunity: 2 weeks after the first administration. Duration of immunity: immunity has been shown under field conditions to persist throughout the rearing period. Only healthy animals should be vaccinated.

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.

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

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains attenuated Infectious Bursal Disease virus, strain S706, 104.0 to $10^{5.3}$ CCID50, (Cell Culture Infective Dose 50%). The excipients are saccharose, lactalbumin hydrolysate, sodium glutamate. water for injections, anhydrous citric acid, sodium bicarbonate. magnesium stearate, sunset yellow FCF (E 110), and purified water.

The container/closure system consists of a polyamide - aluminium – PVC/ aluminium blister, inside a cardboard box. 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 a novel pharmaceutical form, and its development is adequately described in accordance with the relevant European guidelines.

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.

The proposed product is prepared as follows: vaccine component is blended and filtered with the excipients during several stages, prior to being freeze-dried. The product is then prepared by further blending with excipients, before being compressed and packaged.

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 an established active substance described in the European Pharmacopoeia (Ph. Eur). 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 regulations.

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.

The master and working seeds have been produced according to the Seed Lot System as described in the relevant guideline.
The packaging materials comply with Ph. Eur monographs.

II.C.4. Substances of Biological Origin

Transmissible Spongiform Encephalopathy (TSE)

All elements of animal origin are the same as those used in the current production of freeze-dried GALLIVAC IBD. A Certificate of suitability issued by the EDQM has been provided for bovine calf serum, 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. The risk of TSE transmission is reckoned to be negligible.

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

The tests performed during production are described and the results of any relevant tests were provided and deemed acceptable.

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 a suitable number of results, produced according to the method described in the dossier.

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.

G. Other Information

Shelf life after opening the blister: use immediately.
Shelf life after reconstitution according to directions: 2 hours.
Store and transport refrigerated (2ºC-8ºC).
Do not keep unused tablets removed from the blister.
Keep the blisters in the outer carton.

III. SAFETY ASSESSMENT

The safety and efficacy of the GALLIVAC IBD NEO tablet vaccine is ensured by the definition of the same specifications as GALLIVAC IBD freeze-dried vaccine for the minimum guaranteed infective titre in one dose and maximum titre.

Laboratory trials

The applicant provided one confirmatory study, (showing the effect of a single dose and overdose (x10) of the vaccine), to show that the safety and efficacy of the live infectious bursal disease S706 strain is not changed in an effervescent tablet formulation (GALLIVAC IBD NEO), when compared to the GALLIVAC IBD lyophilized vaccine formulation. This was accepted on analysis of the results.

Field studies

Field studies were not required, as the proposed product was established as being of the same efficacy as the already established freeze-dried product.

User safety

The product should be used as directed in the SPC and product literature:

Ecotoxicity

An assessment of the potential risk to the environment from use of GALLIVAC IBD NEO was carried out in line with the CVMP note for guidance (EMEA/CVMP/074/95). The environmental and user risks posed by GALLIVAC IBD have previously been evaluated. Since GALLIVAC IBD NEO is the same vaccine presented as effervescent tablets in tightly sealed aluminium blisters the hazards posed by this new dosage form and container-closure system are mostly unchanged compared to the vaccine currently on the market.

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 and duration of immunity of the product has been demonstrated in a laboratory study in accordance with the relevant requirements. The study was carried out in young birds, which were challenged with Bursal disease virulent challenge at 14 or 49 days post-vaccination. A proportion of birds were unvaccinated. Results confirmed that the proposed product was efficacious and had acceptable duration of immunity, as shown in the SPC and product literature.

Field Trials

Field trials were not required, given that the proposed product had comparable efficacy to GALLIVAC IBD.

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.

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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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