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

## FIXR MYC-VAC Emulsion for Injection for Chickens

**Date Created: June 2023**

# MODULE 1

## PRODUCT SUMMARY

| | |
|---|---|
| Name, strength and pharmaceutical form | FIXR MYC-VAC Emulsion for Injection for Chickens, Emulsion for injection |
| Applicant | Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, 3621 ZB, The Netherlands |
| Active substance(s) | Inactivated *Mycoplasma gallisepticum*, strainis MG-NEV40 and MG-NEV45 |
| ATC Vetcode | QI01AB03 |
| Target species | Chickens |
| Indication for use | For active immunisation of chickens to reduce egg production losses caused by *Mycoplasma gallisepticum.* |

# 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 | 5/4/2023 |

## I. SCIENTIFIC OVERVIEW

The vaccine is proposed for use in chickens (future layers and breeders) to reduce clinical signs and lesions of avian mycoplasmosis.
The recommended vaccine schedule is 0.5 ml administered by the subcutaneous route in the dorsal region of the neck at 10 - 12 weeks of age and repeated at 18 - 20 weeks of age, prior to the start of egg production. The proposed onset of immunity is 3 weeks after the primary vaccination schedule and proposed duration of immunity is one year.

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 inactivated cultures of *Mycoplasma gallisepticum* and the excipients liquid paraffin, sorbitan mono-oleate and sodium ethylmercurithiosalicylate.

The container/closure system consists of polypropylene contained closed with elastomeric stoppers and sealed with aluminium caps. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the adjuvant, vaccine strain and preservative are justified.

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

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*

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of growth of *M. gallisepticum*, inactivation, concentration, and mixing.

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 inactivated *Mycoplasma gallisepticum*, an established active substance described in the. 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. except for β-nicotinamide adenine dinucleotide hydrate and β-propiolactone.

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, pH, viscosity, liquid paraffin, thiomersal, potency and identification, sterility, and emulsion stability.
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 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 broached vaccine is supported by the data provided.

### *G. Other Information*

Shelf-life of the medicinal product as packaged for sale: 21 months.
Shelf life after first opening of the immediate packaging: 10 hours (one working day).
Store in a refrigerator (2°C - 8°C).
Do not freeze.

## 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 in a study summary document. The investigation was performed according to the recommendations of Directive 2001/82/EC as amended and the relevant guidelines in Ph. Eur.

Effects on reproductive performance were examined: The product is not recommended for use in birds in lay and within 4 weeks before the start of the laying period.

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.

The vaccine is inactivated and thus the specific tests to be performed for live vaccines are not applicable.

The adjuvant and excipients used are authorised for use in food-producing animals. 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*

In the field safety study, the animals were vaccinated at the age of 10 weeks and 8 weeks later. One hundred birds from each flock in the two study sites did not receive the test vaccine and were wing-banded and allowed to mix freely with vaccinated birds. From the summary information, there was an absence of

abnormal clinical signs in the vaccinated animals and no increase in the percentage of dead animals in the two weeks following vaccination in comparison to the two weeks before vaccination.

### *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 risk is negligible. No warnings 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 laboratory trials have been submitted. The first laboratory study was to evaluate the immunogenicity of the test vaccine following the administration of the proposed two single doses in chicken at 10 and 18 weeks of age. The second laboratory study was aimed at evaluating the efficacy of the test vaccine against a drop in egg production caused by *M. gallisepticum* infection in laying hens following the same administration scheme.

### *Onset of Immunity*

Onset of immunity: 10 weeks after completion of the primary vaccination schedule
Duration of immunity: 42 weeks after completion of the primary vaccination schedule

### *Field Trials*

The study was performed in accordance with the quality standards applicable at the time of study conduct. These were field trials and as the specified time points vaccinated and control animals were taken back to the animal laboratory for an experimental challenge do demonstrate that the vaccine is also efficacious when it is used in normal filed circumstances.

It is concluded that the egg production in the vaccine groups was statistically significantly higher in comparison to the non-vaccinated control groups after challenge at an age of 28 weeks (peak lay) and at 58 respectively 59 weeks (end lay). Moreover, after each challenge, no drop was observed in the vaccine group. It is obvious that both at the peak of egg production and at the end of lay

a clinically relevant and statistically significant level of protection against a drop in egg production was achieved.

## 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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