College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

FIXR MS-VAC Emulsion for injection for chickens

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0302/001
Name, strength and pharmaceutical form	FIXR MS-VAC Emulsion for injection for chickens
Applicant	Kernfarm B.V. De Corridor 14D 3621 ZB Breukelen The Netherlands
Active substance(s)	inactivated culture of *Mycoplasma synoviae*, strains MS-NEV1 and MS-NEV2
ATC Vetcode	QI01AB03
Target species	Chicken
Indication for use	For active immunization of chickens to prevent mortality and reduce clinical signs (arthritis, joint swelling, lameness) and infections due to *Mycoplasma synoviae*. Onset of immunity: 3 weeks after basic vaccination Duration of immunity: 42 weeks

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MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(4) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	4th of March 2020
Date product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	BE, UK

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.

FIXR MS-Vac is authorized by means of a Similar Biological Application. The reference product for this application is MS-VAC, inactivated vaccine in injectable emulsion for chickens, marketing authorisation number 100122011, 100122023, 100122035 and 100122047, registered in Italy by FATRO S.p.A. FIXR MS-Vac is identical to the reference product.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains inactivated *Mycoplasma synoviae* strains MS-NEV1 and MS-NEV2 1 x 10^{10} CFU before inactivation and capable to induce not less than 70% protection in chickens and the excipients light liquid paraffin, thiomersal, sorbitan monooleate, sodium chloride and water for injections.

The container/closure system consists of (250 ml) polypropylene bottles with elastomer stoppers and aluminium caps.

The choice of the vaccine strains is justified.

The inactivation process and the detection limit of the control of inactivation are correctly validated.

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

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B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

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

C. Control of Starting Materials

The active substances are inactivated antigens of two *Mycoplasma synoviae* strains, these are novel active substances. The active substances are manufactured in accordance with the principles of good manufacturing practice.

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.

Starting materials of non-biological origin used in production comply with pharmacopoeia monographs or 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 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.

D. Control tests during production

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

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 include in particular Appearance, pH, viscosity, liquid paraffin, thiomersal, sterility, potency and identity and free formaldehyde.
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.

F. Stability

Stability data on the active substances 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

None.

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III. SAFETY ASSESSMENT

The product is authorized in accordance with Article 13(4) of Directive 2001/82/EC as amended. The applicant confirmed that the biological veterinary medicinal product is identical to the reference biological veterinary medicinal product. The safety claims for this product
are equivalent to those of the reference product.

Warning statements and precautions as listed in the product literature are based on those of the reference product and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users, consumers and the environment

Environmental Risk Assessment

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

The assessment concluded that the vaccine has no undesirable effect on the environment and no special limitations are necessary to reduce the risk to the environment. No warnings are therefore required.

IV. CLINICAL ASSESSMENT (EFFICACY)

The product is authorized in accordance with Article 13(4) of Directive 2001/82/EC as amended. The applicant confirmed that the biological veterinary medicinal product is identical to the reference biological veterinary medicinal product. The efficacy claims for this product are equivalent to those of the reference product.

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.

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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 Heads of Veterinary Medicines Agencies website (www.HMA.eu).

This section 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.

None

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