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 Rota Coli, emulsion for injection for pigs

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0270/001
Name, strength and pharmaceutical form	FIXR Rota Coli, emulsion for injection for pigs
Applicant	Kernfarm B.V. De Corridor 14D 3621 ZB Breukelen The Netherlands
Active substance(s)	*Rotavirus suis* inact. OSU 6 *Escherichia coli* inact. O101:K99 (F5) *Escherichia coli* inact. O147:K88 (F4) *Escherichia coli* inact. O149:K88 (F4) *Escherichia coli* inact. K85:987P (F6) *Escherichia coli* inact. O101:K99:F41 (F5, F41)
ATC Vetcode	QI 09AL02
Target species	Pigs (pregnant sows and gilts)
Indication for use	For active immunization of pregnant sows and gilts, to induce maternal immunity in suckling piglets against rotavirus and E. coli strains expressing fimbrial adhesion factors F4, F5, F6 and F41.

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).

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	3th of July 2019
Date product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	BE

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 slight reactions observed are indicated in the SPC.
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 Rota Coli is authorized by means of a Similar Biological Application. The reference product for this application is Rokovac Neo, emulsion for injection for pigs, marketing authorisation number 97/044/05-C, registered in Czech Republic by Bioveta, a.s.. FIXR Rota coli is identical to the reference product.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains inactivated antigens of: Rotavirus suis strain OSU 6, Escherichia coli O101:K99 (F5), E.coli O147:K88 (F4), E.coli O149:K88 (F4), E.coli K85:987P (F6) and E.coli O101:K99:F41 (F5, F41) all at a quantity sufficient to achieve a relative potency of ≥1 and the excipients: Oleic adjuvant, formaldehyde and thiomersal.

The container/closure system consists of 10 ml hydrolytic type I glass vials, 50 or 100 ml hydrolytic type II glass vials or 60, 120 or 250 ml plastic bottles. All vials are closed with a rubber stopper and sealed with an aluminium cap.

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.

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 five E.coli strains and a rotavirus strain, E.coli is an established substance described in the European Veterinary Pharmacopoeia. Porcine rotavirus is a novel active substance. 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 Ph. Eur..

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, filling volume, sterility, inactivation control, potency and identity, bacterial endotoxins, formaldehyde content, thiomersal content, closure, pH and viscosity.
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.

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Kernfarm B.V.	DCP
	Publicly available assessment report

G. Other Information

None.

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.

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.

Summary of change (Application number)	**Section updated**	**Approval date**
A.2b) Change in the (invented) name of the medicinal product for Nationally Authorised Products NL/V/0270/001/IB/001	N/A	14th of August 2019