FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
14 rue Claude Bourgelat
Parc d'activités de la Grande Marche - Javené
BP 90203
35302 Fougères Cedex
France

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

CEVAC ERY K suspension pour injection pour porcs, moutons et dindes.

PRODUCT SUMMARY

EU Procedure number	16126 NAT
Name and pharmaceutical form	CEVAC ERY K. Suspension for injection
Applicant	FILAVIE
Active substance(s) and strength	Erysipelothrix rhusiopathiae, serotype 2, inactivated at least 1 ELISA unit
ATC Vetcode	QI09AB03 QI04AB08 QI01CB02
Target species	Pig, Sheep, Turkey
Indication for use	For active immunisation against erysipelas

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this immunological veterinary medicinal product (IVMP) are available in the Union Product Database (UPD).

PUBLIC ASSESSMENT REPORT

Legal basis of original application	National application
Date of completion of the original procedure	26/11/2025

1. 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 reactions that may be 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.

2. QUALITY ASPECTS

2.A. Product description

The vaccine contains inactivated Erysipelothrix rhusiopathiae, serotype 2 at the relative potency ≥ 1 (determined by ELISA method according to European Pharmacopeia requirements). The vaccine is adjuvanted with aluminium hydroxide and contains excipients (thiomersal, saline solution containing sodium chloride and water for injections).

The container/closure system is made of glass vials or plastic bottles (LDPE) sealed with rubber stoppers and aluminium caps. The particulars of the containers and controls performed are provided and conform to the regulation.

The choices of the adjuvant, vaccine strains, formulation, inactivating agent and presence of preservative are 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.

2.B. Description of the manufacturing method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site and in accordance with the European Pharmacopoeia and relevant European guidelines.

2.C. Production and control of starting materials

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

Biological starting materials used are in compliance with the relevant Ph. Eur. monographs and European guidelines and are appropriately screened for the absence of extraneous agents according to the Ph. Eur. and other European 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.

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.

2.D. Control tests during manufacturing process

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

2.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:
- general characteristics of the finished product (appearance, volume filled, pH)
- identification of active substance and potency in mice
- determination of aluminium hydroxide content and thiomersal content
- sterility

2.F. Batch-to-batch consistency

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.

2.G. Stability tests

Stability of the antigens is shown. The shelf life of 2 years of the product is supported by data. The vaccine should be used immediately after broaching.

3. SAFETY DOCUMENTATION (safety and residues tests)

This application is based on bibliographic data according to Article 22.

Therefore, the applicant shall not be required to provide the documentation on safety and efficacy if that applicant demonstrates that the active substances of the veterinary medicinal product have been in well-established veterinary use within the Union for at least 10 years, that their efficacy is documented and that they provide an acceptable level of safety.

The applicant confirms that the biological veterinary medicinal product is identical to the vaccine RUVAX (French Marketing authorisation AMM N° FR/V/23900091/1985) that was authorised in France for more than 30 years. The raw materials used and the manufacturing processes are the same. Therefore, no additional data have been provided on the safety of the product.

Warnings and precautions as listed on the product literature are the same as those of the vaccine Ruvax and are adequate to ensure the safety of the product to users / the environment / consumers.

User safety

In case of accidental self-injection, the user should seek medical advice immediately.

Withdrawal Periods

A withdrawal period of zero days for in pig, sheep and turkey is justified.

4. EFFICACY DOCUMENTATION

This application is based on bibliographic data according to Article 22.

Therefore, the applicant shall not be required to provide the documentation on safety and efficacy if that applicant demonstrates that the active substances of the veterinary medicinal product have been in well-established veterinary use within the Union for at least 10 years, that their efficacy is documented and that they provide an acceptable level of safety.

Due to the legal base of the application, the applicant is not required to submit pre-clinical or clinical data. The applicant has not submitted these data on the basis that the vaccine is the same as the vaccine RUVAX that was authorised in France for more than 30 years.

The applicant confirms that the veterinary medicinal product is identical to the vaccine RUVAX (French Marketing authorisation AMM N° FR/V/23900091/1985). The raw materials used and the manufacturing processes are the same. Therefore, no additional data shall be provided on the efficacy of the product

5. 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 are acceptable.

POST-AUTHORISATION PROCEDURES

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/labelling/package leaflet is/are available in the Union Product Database (UPD).

This section contains information on significant changes agreed after the original procedure, which are important for the quality, safety or efficacy of the product.

Significant variations: None.

Summary of change (Application number)	**Approval date**