DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Syvac Ery Parvo emulsion for injection for pigs

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0394/001/DC
Name, strength and pharmaceutical form	Syvac Ery Parvo emulsion for injection for pigs
Applicant	LABORATORIOS SYVA, S.A. C/ Marqués de la Ensenada, 16 28004 MADRID SPAIN
Active substance(s)	Inactivated *Erysipelothrix rhusiopathiae*, serotype 2, strain SE-9 Inactivated Porcine parvovirus, strain PVP-7
ATC Vetcode	QI09AL01
Target species	Pigs
Indication for use	For the active immunisation of gilts, sows and boars to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 2, as shown under experimental challenge conditions in seronegative pigs. For the active immunisation of gilts and sows for the reduction of transplacental infection in progeny caused by porcine parvovirus. Onset of immunity: *E. rhusiopathiae*: 3 weeks after completion of the primary vaccination scheme. Porcine parvovirus: from the beginning of the gestation period after completion of the primary vaccination scheme. Duration of immunity: *E. rhusiopathiae*: 5 months Porcine parvovirus: for the duration of gestation.

MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	Day 210: 27/07/2022
Date product first authorised in the ReferenceMemberState (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, BG, CZ, DE, DK, EL, FI, FR, HR, HU, IE, IT, NL, PT, PL, RO, SE, SK, UK(NI)

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.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains two active substances:
- Inactivated *Erysipelotrhix rhusiopathiae* serotype 2, strain SE-9
- Inactivated Porcine parvovirus, strain PVP-7

The vaccine is presented as an emulsion for injection and includes Montanide ISA 201 VG as adjuvant and thiomersal as preservative.

The container/closure system is based on polypropylene colourless vials containing 50 ml (25 doses) or 100 ml (50 doses), with a type I bromobutyl rubber stopper, sealed with an aluminium closure. The vaccine is marketed in cardboard boxes containing 1 vial of 25 doses or 50 doses.

The choice of the adjuvant, vaccine strains for both active substances, formulation, inactivating agent and the 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.

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 product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substances are inactivated *Erysipelotrhix rhusiopathiae* serotype 2, strain SE-9 and inactivated Porcine parvovirus, strain PVP-7, established active substances described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The specifications of the active substances are considered adequate to control the quality of the materials. Batch analytical data demonstrating compliance with this specification have been provided.

Starting materials of non-biological origin used in production comply with relevant European Pharmacopoeia monographs with the exception of Monosodium glutamate which complies with USP monograph. Starting materials of non-biological origin not included in a pharmacopoeia comply with internal specifications and Certificate of Analysis of the suppliers are provided for them.

Biological starting materials used are in compliance with the relevant Ph. Eur. Monographs and guidelines, when relevant. They are appropriately assessed for the absence of extraneous agents according to the Ph. Eur. General Chapter 5.2.5; 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 4 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, identification of both active substance, sterility, potency of both active substances, viscosity, density, stability of the emulsion, content of thiomersal, residual formaldehyde, pH, filling volume and secondary package. The tests carried out comply with the requirements of the specific Ph. Eur. monographs (Swine erysipelas vaccine inactivated – 0064 and Porcine parvovirosis vaccine inactivated – 0965).

The demonstration of the batch to batch consistency is based on the results of 5 batches produced according to the method described in the dossier. Other supportive data provided confirm the consistency of the production process.

F. Stability

The stability of the antigens of the active substances has been demonstrated with 3 consecutive antigen batches. The satisfactory results support a 12 months stability period for both antigens at refrigerated temperature (5±3°C).

The stability of the finished product has been demonstrated with the satisfactory results on four different consecutive batches manufactured with four different antigen batches. It was shown that the vaccine Syvac Ery Parvo can be stored up to 2 years in the recommended conditions of storage (protected from light at 5 ± 3 ºC).

The in-use shelf-life of the broached vaccine is supported by the data provided and has been established in 10 hours.

G. Other Information

Not applicable.

III. SAFETY ASSESSMENT

Potential adverse effects derived from administration of the vaccine on target species have been determined through three safety laboratory studies, two efficacy laboratory studies, in which the safety was additionally determined, and two field studies.

The three safety laboratory studies and the safety field study were done with batches of Syvac Ery Parvo at the maximum potency. One efficacy laboratory study evaluating in addition safety parameters was done with different batches prepared at maximum, standard, minimum and subpotent potency. The other efficacy laboratory study which evaluated additionally safety parameters was done with a batch at minimum potency. The clinical trials were done with a maximum potency and a standard batch of the vaccine, respectively.

Laboratory trials

The safety of the administration of one dose and the repeated administration of one dose in the target animal is demonstrated in the laboratory studies cited above and summarized below.
As explained before data from some efficacy laboratory studies are included in the table since safety parameters were also assessed when they were carried out.

Study title	Study type	Study objective	Study design	Vaccine	Administration regimen	Studied animals (sex/category/number)	Endpoints
Safety study of the vaccine against porcine parvovirus and *Erysipelothrix rhusiopathiae* in pigs	Laboratory	To demonstrate the safety of the administration of one dose and a repeated dose in animals of the minimum recommended age under laboratory conditions	Two groups: G1: Control group. Placebo (saline) G2: Vaccinated group.	Ery-Parvo vaccine. Maximum potency batch Placebo (saline)	3 doses 14 days apart	Males and females/minimum recommended age (12 weeks) 20 pigs (2 groups of 10 animals)	Temperature Local reactions General reactions
Efficacy of the vaccine against porcine parvovirus in sows	Laboratory	To assess the efficacy of the vaccine against porcine parvovirus after primary vaccination under laboratory conditions	Five groups: Groups A to D: Vaccinated groups. Four groups of 12 animals Grupo E: control. One group of 10 animals	Ery-Parvo vaccine. Group A: Maximum potency batch Group B: Standard batch Group C: Minimum potency batch Group D: Sub potent batch	2 doses 4 weeks apart (primovaccination)	Non pregnant gilts of 5-6 months old 58 gilts (4 groups of 12 animals and 1 group of 10 animals)	Local reactions Temperature General reactions

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Study title	Study type	Study objective	Study design	Vaccine	Administration regimen	Studied animals (sex/category/number)	Endpoints
				Grupo E: placebo (saline)			
Efficacy of the vaccine against porcine parvovirus in sows. Efficacy of revaccination.	Laboratory	To assess the efficacy of the vaccine against porcine parvovirus after revaccination	Two groups: Groups A: Vaccinated group. Grupo B: control	Ery-Parvo vaccine: Minimum potency batch Placebo (saline)	3 doses at day 0, day 28 and day 169.	Non pregnant gilts at the minimum recommended age (20 weeks) 27 gilts: one group of 16 animals and one group of 11 animals	Local reactions Temperature General reactions
Safety of the vaccine administered to gestating sows at first trimester of gestation (~38 days of gestation)	Laboratory	To demonstrate the safety of the vaccine after repeated vaccination of gilts in the first half of gestation (at the end of the first third of gestation and 2 weeks later(2nd third)	Controled study. Two groups: G1: Vaccinated group. G2: Control group. Placebo (saline)	Ery-Parvo vaccine. Maximum potency batch Placebo (saline)	2 doses 14 days apart	Pregnant gilts 10 months age 14 gilts at ≈38 days of pregnancy (2 groups: 1 group of 10 animals and 1 group of 4 animals)	Temperature Local reactions General reactions Reproductive performance Abortions Adverse events
Safety of the vaccine administered to gestating gilts at third trimester of gestation (~90 and ~104	Laboratory	To demonstrate the safety of the vaccine after repeated vaccination of gilts at last half of gestation	Controled study. Two groups:	Ery-Parvo vaccine. Maximum	3 doses about 90 and 104 days of pregnancy and at day 14 of lactation	Pregnant and lactating gilts Females	Temperature Local reactions

Study title	Study type	Study objective	Study design	Vaccine	Administration regimen	Studied animals (sex/category/number)	Endpoints
days of gestation) and during lactation (~14 days after farrowing)		and during lactation	G1: Vaccinated group. G2: Control group. Placebo (saline)	potency batch Placebo (saline)		11 months age 15 gilts at ≈90 days of pregnancy (2 groups: 1 group of 10 animals and 1 group of 4 animals)	General reactions Reproductive performance Abortions Adverse events

These studies were performed according to the recommendations of Directive 2001/82/EC as amended and the relevant guidelines. The corresponding Ph.Eur. monographs were followed (0064 and 0965).

Effects on reproductive performance were examined in two studies and the conclusions adequately reflected on the SPC.

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 Montanide (no MRL required), thiomersal (MRL not applicable), silicone antifoam and PBS. Based on the provided 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

Two field studies were carried out to support safety results derived from laboratory trials.

One field study was performed in breeding sows/gilts to demonstrate the safety and efficacy of the intramuscular administration of the vaccine in animals at the minimum age (details in Efficacy part), and the other study was done in gestating gilts/sows previously vaccinated.

The results supported the safety use of the vaccine in all the studied categories.

Environmental 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 risk of using the vaccine is null because:

- It is an inactivated vaccine and does not contain infectious particles.
- It does not contain compounds with possible environmental implications.
- Vaccination is carried out by intramuscular administration, which avoids direct or indirect contact of the vaccine to the environment.
- The SPC/PL includes warning related to safety elimination and free of risks for the environment:
  6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products.

"*Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements*."

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)

IV.B Clinical Studies

Laboratory Trials

The applicant has conducted six laboratory trials, two of them to establish the challenge model for the two components of the vaccine, and one field study to demonstrate the efficacy of the candidate vaccine.

These studies were in accordance with the relevant requirements, which show that the vaccine produces an active immunisation in gilts, sows and boars to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 2. Additionally, the vaccine produces an active immunisation of gilts and sows for the reduction of transplacental infection in progeny caused by porcine parvovirus.

Laboratory studies testing the vaccine against swine erysipelas

As an initial step to investigate the efficacy of the vaccine, the challenge model proposed by Paul-Erlich-Institute (Johannes *et al*., 1998; Cussler *et al*. 2001) and described in the *Ph. Eur. 0064* was evaluated.

Once the challenge model was established, two laboratory studies involving vaccination and challenge were conducted to demonstrate evidence of the efficacy of the product with the proposed vaccination schedule:

- One of the study was designed to study the onset of immunity after completion of the primary vaccination schedule. This study also investigated the effective dose by using four different formulations of the vaccine with different antigenic payloads.
- A second study was focused on the duration of immunity, showed to be 5-months after primovaccination. Subsequently, efficacy of revaccination with a single dose was demonstrated by challenge the animals 5 months later (phase two of this second study).

Laboratory studies testing the vaccine against porcine parvovirus (PPV)

The first laboratory study performed was focused on validating the challenge. The objective was to reproduce a standard PPV infection model to be used in the efficacy/immunogenicity test for PPV. The inoculum P2MPK was assessed in a challenge study according to *Ph. Eur. 0965*.

Once the challenge model was validated, the following studies were performed to assess the efficacy of the vaccine against PPV with the proposed vaccination schedule:

- The first one assessed the efficacy of the vaccine and the effective dose, using four different formulations of the vaccine with different antigenic payloads.

- The second study assessed the efficacy of the revaccination of a single dose administered after the completion of the primary vaccination schedule.

Efficacy of the vaccine against swine erysipelas

Efficacy of vaccination was demonstrated in controlled laboratory challenge studies by intradermally administration of *E. rhusiopathiae*, serotype 2, strain NF4. At challenge, 21 days after vaccination, 7 of 7 (100%) of unvaccinated control animals were confirmed as diseased. Vaccinated animals (with the standard potency batch) showed no signs of the disease (skin lesions) (12 of 12 animals (100%)).

The duration of protection was tested in a second study and established in 5 months. In this study, twelve vaccinated pigs and 7 control pigs were submitted to challenge five months after primovaccination or saline solution administration, for vaccinated and control groups, respectively. The challenge was done by intradermally administration of *E. rhusiopathiae*, serotype 2, strain NF4. In pigs from the control group, generalized skin lesions were observed in all animals (7 of 7 animals (100%). In the vaccinated group, one out of 12 animals (8.33%) showed skin lesions of moderate size.

The duration of revaccination was also assessed. Twelve animals primovaccinated were treated with a third dose of the vaccine five months after primovaccination. As a control group, 7 animals were administered three dose of saline solution following the same scheme of vaccination than in treated animals. These subgroups were challenged 5 months after the third dose administration. . In the control group, the 7 pigs developed typical skin lesions from day 1 or day 2 post-challenge. Lesions generalized in all animals at day 5 post-challenge. In the vaccinated group, 1 out of 12 animals (8.33 %) developed diamond-shaped skin lesions that appeared at day 4 post-challenge.

Summary table of the efficacy studies of the vaccine against swine erysipelas

Animals Groups Number Age	**Antibody status**	**Vaccine: route of administration**	**Challenge: Day post-vaccination**	**Follow up: Duration Endpoints***	**Results: Cases/total (%) (for standard antigen content batch)**		**% Efficacy (95% CI)****
Study 1					Vaccinates	Controls	
Onset of immunity: Pigs 12 weeks old Vaccinates: 12 pigs per group Controls: 7 pigs	Negative	Group 1: vaccine at 4 times the standard antigen content. Group 2: standard antigen content. Group 3: substandard potency vaccine. Group 4: highly substandard potency vaccine. Control group: placebo (saline)	21 days	Endpoint 1: Clinical signs of the disease caused by Erysipelas Endpoint 2: Antibodies against Erysipelas Endpoint 3: Rectal temperature Endpoint 4: General signs	Endpoint 1: Clinical signs of the disease caused by Erysipelas 0/12 (0%)	Endpoint 1: Clinical signs of the disease caused by Erysipelas 7/7 (100%)	Endpoint 1: Clinical signs of the disease caused by Erysipelas 100%
Study 2					Vaccinates	Controls	
Duration of immunity (DOI):	Negative	Standard antigen	Subgroup 1 (DOI	Endpoint 1: Clinical signs of	Subgroup 1 (DOI after	Subgroup 1 (DOI after	Subgroup 1 (DOI after

Animals Groups Number Age	**Antibody status**	**Vaccine: route of administration**	**Challenge: Day post-vaccination**	**Follow up: Duration Endpoints***	**Results: Cases/total (%) (for standard antigen content batch)**		**% Efficacy (95% CI)****
<u>Subgroup 1 (DOI after primovaccination):</u> Pigs 12 weeks old Vaccinates:12 Controls: 7 <u>Subgroup 2 (DOI after revaccination administered 5 months after primovaccination):</u> Pigs 12 weeks old Vaccinates:12 Controls: 7		content. Saline solution.	<u>after primovaccination):</u> 152 days (5 months) <u>Subgroup 2 (DOI after revaccination administered 5 months after primoccination):</u> 150 days (5 months)	the disease caused by Erysipelas Endpoint 2: Antibodies against Erysipelas Endpoint 3: Rectal temperature Endpoint 4: General signs	<u>primovaccination):</u> Endpoint 1: Clinical signs of the disease caused by Erysipelas 1/12 (8.33%) <u>Subgroup 2 (DOI after revaccination administered 5 months after revaccination):</u> Endpoint 1: Clinical signs of the disease caused by Erysipelas 1/12 (8.33%)	<u>primovaccination):</u> Endpoint 1: Clinical signs of the disease caused by Erysipelas 7/7 (100%) <u>Subgroup 2 (DOI after revaccination administered 5 months after revaccination):</u> Endpoint 1: Clinical signs of the disease caused by Erysipelas 7/7 (100%)	<u>primovaccination):</u> Endpoint 1: Clinical signs of the disease caused by Erysipelas 91.6% <u>Subgroup 2 (DOI after revaccination administered 5 months after revaccination):</u> Endpoint 1: Clinical signs of the disease caused by Erysipelas 91.6%

*Specified according to efficacy endpoints relating to claims in the indication. Primarily, primary endpoints should be listed but secondary endpoints relevant for the indications can be included.

** Vaccine efficacy = $\frac{\text{cases}_{\text{controls}} / \text{total}_{\text{controls}} - \text{cases}_{\text{vaccinates}} / \text{total}_{\text{vaccinates}}}{\text{cases}_{\text{controls}} / \text{total}_{\text{controls}}} \times 100$

Efficacy of the vaccine against porcine parvovirus

The efficacy of the vaccine against porcine parvovirus was demonstrated in two controlled laboratory challenged studies.
The challenge strain was validated in an additional separate study. The selected strain was PPV strain NADL-8.
The following studies were performed to assess the efficacy of the vaccine against porcine parvovirus:

- The first one was designed to assess the efficacy of the vaccine using four different formulations of the vaccine with different antigenic payloads (high, standard, and two sub-standard antigen payloads). Each group was vaccinated with one of these different batches of the vaccine. In addition, a control group was also included and inoculated with placebo.
The gilts were vaccinated according to the proposed vaccination scheme consisting of two injections of 2 ml each separated by an interval of 4 weeks. The second dose was administered 2-3 weeks before mating.
The artificial insemination occurred on 2 consecutive days on the first oestrus. Pregnancy was confirmed by ultrasounds around 20 days after insemination and non-pregnant gilts were withdrawal from the study.
At 40th day of gestation, gilts were challenged and subsequently euthanized at about 90th day of gestation. The foetuses were examined for infection with PPV. Protection was assessed by confirming absence of PPV.
Safety of the vaccine was also evaluated by monitoring rectal temperature and local and systemic reactions after each vaccination.

-The second study assessed the efficacy of the revaccination of a single dose administered after the completion of the primary vaccination schedule. This study was performed as a controlled and blinded study using 27 sows distributed in two groups.
Animals enrolled in the study were gilts of 5 months of age, free of antibodies against PPV and in good health conditions.
One group was vaccinated with Syvac Ery Parvo vaccine and the other group was inoculated with placebo.
The vaccine used was formulated to obtain a sub-standard potency vaccine.
Gilts were vaccinated according to the proposed primary vaccination scheme consisting of two injections of 2 ml each separated by an interval of 4 weeks. The second dose was administered 2-3 weeks before mating.
After artificial insemination, animals were subjected to a pregnancy diagnosis. The pregnant animals were maintained under observation during the reproductive cycle and revaccinated at lactation, 2-3 weeks before the second mating, approximately 20 weeks after the completion of the primary vaccination, with a single dose of 2 ml.
Pregnancy was confirmed by ultrasounds prior to challenge. At 40th day of the second gestation, sows were challenged and subsequently euthanised at about 90th day of gestation and their foetuses were examined. Infection of the foetuses by PPV was assessed.

Safety of the vaccine was also evaluated by monitoring rectal temperature and local and systemic reactions after each vaccination.

Summary table of the efficacy studies of the vaccine against porcine parvovirus

Animals Groups Number Age	**Antibody status**	**Vaccine: route of administration**	**Challenge: Day post-vaccination**	**Follow up: Duration Endpoints***	**Results: Cases/total (%) (for standard antigen content batch)**		**% Efficacy**
Study 1					Vaccinates	Controls	
Onset of immunity: Gilts (5-6 months of age) Vaccinates:12/group Controls: 9	Negative	Group 1: vaccine at 4 times the standard antigen content Group 2: standard antigen content. Group 3: substandard potency vaccine Group 4: highly substandard potency vaccine Control group: placebo (saline)	40th days of gestation	Endpoint 1: Infection of the foetuses Endpoint 2: Antibodies against PPV in gilts Endpoint 3: Abortion and general clinical signs	Endpoint 1: Infection of the foetuses (standard batch) 4/115 (3.5%)	Endpoint 1: Infection of the foetuses 67/67 (100%)	Endpoint 1: Infection of the foetuses 96.5%
Study 2					Vaccinates	Controls	
Duration of	Negative	Vaccine:	40th days of	Endpoint 1:	Endpoint 1:	Endpoint 1:	Endpoint 1:

Animals Groups Number Age	**Antibody status**	**Vaccine: route of administration**	**Challenge: Day post-vaccination**	**Follow up: Duration Endpoints***	**Results: Cases/total (%) (for standard antigen content batch)**		**% Efficacy**
immunity (DOI): Gilts (5-6 months of age) Vaccinates:16/group Controls: 11		Sub-Standard antigen content. Saline solution	gestation after primovaccination (2 doses) and revaccination (1 dose)	Infection of the foetuses Endpoint 2: Antibodies against PPV in gilts Endpoint 3: Abortion and general clinical signs	Infection of the foetuses (sub standard batch) 4/156 (2.6%)	Infection of the foetuses 87/92 (94.6%)	Infection of the foetuses 97.3%

*Specified according to efficacy endpoints relating to claims in the indication. Primarily, primary endpoints should be listed but secondary endpoints relevant for the indications can be included.

** Vaccine efficacy = $\frac{\text{cases}_{\text{controls}}/\text{total}_{\text{controls}} - \text{cases}_{\text{vaccinates}}/\text{total}_{\text{vaccinates}}}{\text{cases}_{\text{controls}}/\text{total}_{\text{controls}}} \times 100$

Field Trials

The applicant conducted one field study to test the safety and efficacy in breeding sows/gilts under field conditions.

The study was designed as a multisite, positive controlled, randomized, blinded study.

A total of 648 animals were included at the beginning of the study. The animals selected were gilts, primiparous and multiparous sows. The gilts were of 6 months of age. They were cross breed animals from commercial farms with a known history of PPV and erysipelas infections based on vaccination plans and clinical records before the onset of the study.

All animals were monitored during the first reproductive cycle. In addition, a representative number of gilts were subjected to revaccination with a single dose and monitored during the second reproductive cycle.

A routine standard batch was used.

The monitoring consisted of the assessment of reproductive parameters for PPV as well as the presence of clinical signs and mortality associated to erysipelas. In addition, blood collection was carried out monthly to investigate the antibody titres.

The presence of active infections of PPV and/or erysipelas in the farms were monitored during the study. There was evidence of the presence of PPV wild-strains in the farms during the performance of the study. However, there was not evidence of the presence of erysipelas that caused disease in the animals during the study.

After the analysis of the results of the study, the next conclusions were obtained:

• No records of dead or abortion attributable to the vaccine were recorded in this study

• Non-inferiority on the proportion of the mummies at farrowing was observed in Syvac Ery Parvo group compared to the vaccine control group in three farms with active PPV circulation.

• Efficacy of the vaccine against erysipelas has not been proved in this trial due to the lack of evidence of circulation of agent in the farms. However, a seroconversion in unvaccinated gilts and an increase in the antibody titers in vaccinated sows were observed after administration of Syvac Ery Parvo, responses were comparable or higher to the one obtained with the positive control vaccine.

Taking into account the results of all the laboratory studies and field trials carried out with Syvac Ery Parvo, the onset and duration of immunity were established as follows:

Onset of immunity:
E. rhusiopathiae: 3 weeks after completion of the primary vaccination scheme.

Porcine parvovirus: from the beginning of the gestation period after completion of the primary vaccination scheme.

Duration of immunity:
E. rhusiopathiae: 5 months
Porcine parvovirus: for the duration of gestation.

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

None