ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS
1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUVAXYN® Parvo/E

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 2 ml

Active substance(s):

- Inactivated porcine parvovirus, strain S-80: Inducing an HIA* titre of at least 160 (in rabbits).
- Inactivated Erysipelothrix rhusiopathiae, strain B-7 (serotype 2): RP** ≥ 1.8 in accordance with the EP Monograph

* HIA: haemagglutination inhibiting antibody
** Relative Potency compared to a reference serum obtained from a vaccine that has given satisfactory protection in vaccinated pigs.

Adjuvant(s):

- Marcol 52 (Mineral oil) 730.14 mg
- Montanide 888 (Emulsifier) 74.32 mg
- Simulsol 5100 (Emulsifier) 69.95 mg

Excipient(s):

- Thiomersal 0.2 mg
- Formaldehyde ≤0.05%

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection
Appearance: Ivory white oil emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (gilts and sows).

4.2 Indications for use, specifying the target species

For the active immunisation of pigs (gilts and sows) to:
Prevent reproductive disorders caused by porcine parvovirus.
Reduce clinical signs caused by Erysipelothrix rhusiopathiae infections, serotype 2 and serotype 1.
Onset of immunity: 3 weeks after vaccination
Duration of immunity: 6 months

4.3 Contraindications

Do not use less than 3 weeks before mating.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

- Avoid stress in the animals around the time of vaccination.
- Administer only to animals in good health condition

Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

Following first vaccination transient hyperthermia up to 1 °C above normal for up to 24 hours, very commonly occurs after vaccination.
Local tissue reactions in the form of visible swelling (granulomas) at the injection sites may very commonly occur for up to 16 days. The area of reaction can be diffuse and reach 2-5 cm in diameter.

Following second vaccination transient hyperthermia up to 1 °C above normal, very commonly occurs for 24-48 hours after vaccination.
Local tissue reactions in the form of mild diffuse visible swelling (granulomas) at the injection sites may very commonly occur for at least 14 days. The area of reaction can vary from 5 cm to 10 cm in diameter.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy: Do not use in pregnant sows.
Lactation: No special precautions.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

One dose of 2 ml per animal by intramuscular use in the neck. The vaccine is to be administered aseptically. Shake well before administration and intermittently during the process of vaccination.

Vaccination Schedule:

-Primary Vaccination:
Gilts from 5 months of age and sows: Two injections 3-4 weeks apart. The second dose should be given at least 4 weeks before mating.

-Revaccination:
One dose during each lactation period 3 to 4 weeks before mating.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

An overdose of the product can very commonly result in transient hyperthermia of 1-2 °C above normal for 24 hours after vaccination. Local tissue reactions in the form of visible swelling (granulomas) in the majority of vaccinated pigs for at least 28 days. The area of reaction can be diffuse from 5 to 10 cm in diameter.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against porcine parvovirus and *Erysipelothrix rhusiopathiae*, serotype 2 and serotype 1.
ATC vet code QI09AL01.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Thiomersal
Formaldehyde
Gentamicin

6.2 Major incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf life

15 months.
Following broaching of the vial the vaccine should be used immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 ºC – 8 ºC). Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

20 ml Type I hydrolytic glass vials containing 10 doses and 50 ml Type II hydrolytic glass vials containing 25 doses, with butyl elastomer stoppers and aluminium seals.
Package sizes: carton box with 1 glass vial of 20 ml and carton box with two vials of 50 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

To be completed nationally.

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF RENEWAL OF THE AUTHORISATION

30 October 2007

10. DATE OF REVISION OF THE TEXT

June 2013.
ANNEX III

LABELLING AND PACKAGE LEAFLET
A. LABELLING
PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL 50 ml (25 doses) and CARDBOX 2x50 ml (2x25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUVAXYN® Parvo/E

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml

**Active substances:**
- Inactivated porcine parovirus, strain S-80: Inducing an HIA* titre of at least 160 (in rabbits)
- Inactivated *Erysipelothrix rhusiopathiae*, strain B-7 (serotype 2): RP** ≥ 1.8 in accordance with the EP Monograph

  * HIA: haemagglutination inhibiting antibody
  ** Relative Potency compared to a reference serum obtained from a vaccine that has given satisfactory protection in vaccinated pigs

**Adjuvants:**
- Marcol 52: 730.14 mg
- Montanide 888: 74.32 mg
- Simulsol 5100: 69.95 mg

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

25 doses
2x25 doses

5. TARGET SPECIES

Pigs (gilts and sows)

6. INDICATION(S)

For the active immunisation of pigs (gilts and sows) to:
- Prevent reproductive disorders caused by porcine parvovirus.
- Reduce clinical signs caused by *Erysipelothrix rhusiopathiae* infections, serotype 2 and serotype 1.
7. **METHOD AND ROUTE(S) OF ADMINISTRATION**

One dose of 2 ml per animal by intramuscular use in the neck.
Read the package leaflet before use.

8. **WITHDRAWAL PERIOD(S)**

Withdrawal period(s): Zero days.

9. **SPECIAL WARNING(S), IF NECESSARY**

Accidental injection is dangerous.

10. **EXPIRY DATE**

EXP {month/year}
Once broached, use immediately

11. **SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated. Do not freeze. Protect from light.

12. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

13. **THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only. To be supplied only on veterinary prescription.

14. **THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

15. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

To be completed nationally.
16. **MARKETING AUTHORISATION NUMBER(S)**

*To be completed nationally.*

17. **MANUFACTURER'S BATCH NUMBER**

Batch{number}
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial 20 ml (10 doses) and Cardbox 20 ml (10 doses)

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

   SUVAXYN® Parvo/E

2. **QUANTITY OF THE ACTIVE SUBSTANCE(S)**

   Per dose of 2 ml:
   - Inactivated porcine parvovirus, strain S-80: Inducing an HIA* titre of at least 160 (in rabbits)
   - Inactivated *Erysipelothrix rhusiopathiae*, strain B-7 (serotype 2): RP** ≥ 1.8 in accordance with the EP Monograph

   * HIA: haemagglutination inhibiting antibody
   ** Relative Potency compared to a reference serum obtained from a vaccine that has given satisfactory protection in vaccinated pigs

3. **CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

   10 doses

4. **ROUTE(S) OF ADMINISTRATION**

   Intramuscular route

5. **WITHDRAWAL PERIOD(S)**

   Withdrawal period(s): Zero days

6. **BATCH NUMBER**

   Batch {number}

7. **EXPIRY DATE**

   EXP {month/year}
   Once broached, use immediately
8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
B. PACKAGE LEAFLET
1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
To be completed nationally.

Manufacturer for the batch release:
Zoetis Manufacturing & Research Spain, S.L
C/Camprodon s/n “La Riba”
17813 Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUVAxyN® Parvo/E

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Per dose of 2 ml

Active substance(s):
Inactivated porcine parvovirus, strain S-80: Inducing an HIA* titre of at least 160 (in rabbits)
Inactivated *Erysipelothrix rhusiopathiae*, strain B-7 (serotype 2): RP** > 1.8 in accordance with the EP Monograph

* HIA: haemagglutination inhibiting antibody
** Relative Potency compared to a reference serum obtained from a vaccine that has given satisfactory protection in vaccinated pigs

Adjuvant(s):
Marcol 52: 730.14 mg
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4. INDICATION(S)

For the active immunisation of pigs (gilts and sows) to:
Prevent reproductive disorders caused by porcine parvovirus.
Reduce clinical signs caused by *Erysipelothrix rhusiopathiae* infections, serotype 2 and serotype 1.

5. CONTRAINDICATIONS
Do not use less than 3 weeks before mating.

6. ADVERSE REACTIONS

Following first vaccination transient hyperthermia up to 1°C above normal, very commonly occurs for up to 24 hours after vaccination. Local tissue reactions in the form of visible swelling (granulomas) at the injection sites may very commonly occur for up to 16 days. The area of reaction can be diffuse and reach 2-5 cm in diameter.

Following second vaccination transient hyperthermia up to 1°C above normal, very commonly occurs for 24-48 hours after vaccination. Local tissue reactions in the form of mild diffuse visible swelling (granulomas) at the injection sites may very commonly occur for at least 14 days. The area of reaction can vary from 5 cm to 10 cm in diameter.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
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- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (gilts and sows)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

One dose of 2 ml per animal by intramuscular use in the neck.

Vaccination Schedule:

-Primary Vaccination:
Gilts from 5 months of age and sows: Two injections 3-4 weeks apart. The second dose should be given at least 4 weeks before mating.

-Revaccination:
One dose during each lactation period 3 to 4 weeks before mating.

9. ADVICE ON CORRECT ADMINISTRATION

The vaccine is to be administered aseptically. Shake well before administration and intermittently during the process of vaccination.
10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton.

Shelf-life after first opening the container: use immediately.

12. SPECIAL WARNING(S)

Special precautions for use in animals
- Avoid stress in the animals around the time of vaccination.
- Administer only to animals in good health condition

Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused product or waste material should be disposed of in accordance with national requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally.

15. OTHER INFORMATION

Do not use in pregnant sows

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Do not mix with any other vaccine/immunological product.

An overdose of the product can very commonly result in transient hyperthermia of 1-2°C above normal for 24 hours after vaccination. Local tissue reactions in the form of visible swelling (granulomas) in the majority of vaccinated pigs for at least 28 days. The area of reaction can be diffuse from 5 to 10 cm in diameter.

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