ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PCV suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 2 ml contains:

Active substance:	
Inactivated recombinant Porcine Circovirus type 1 expressing the Porcine Circovirus type 2 ORF2 protein	1.6 ≤ RP* ≤ 5.3
Adjuvants:	
Sulfolipo-cyclodextrin (SLCD)	4 mg
Squalane	64 mg
Excipients:	
Thiomersal	0.1 mg

* Relative Potency unit determined by ELISA antigen quantification (*in vitro* potency test) compared to a reference vaccine.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection
A milky white to pink opaque liquid, free from visible particles

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (piglets) from 3 weeks of age.

4.2 Indications for use, specifying the target species

Active immunisation of pigs over the age of 3 weeks against Porcine Circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues, and the lesions in lymphoid tissues associated with PCV2 infection, as well as to reduce clinical signs - including loss of daily weight gain, and mortality associated with Post-Weaning Multisystemic Wasting Syndrome (PMWS).

Onset of immunity: from 3 weeks post-vaccination.
Duration of immunity: 19 weeks post-vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
Do not use in breeding boars.

The benefit of the vaccination of pigs with very high levels of maternally-derived antibodies, e.g. due to vaccination of their mothers, has not been demonstrated.

4.5 Special precautions for use

Special precautions for use in animals

Avoid stress in the animals before and after the time of vaccination.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A transient increase in body temperature (up to 1.7 °C) is very common during the first 24 hours after vaccination. This resolves spontaneously within 48 hours without treatment.
Local tissue reactions in the form of swelling at the injection site are very common and may last for up to 26 days. The area of local tissue reactions is in general below 5 cm in diameter, but in some cases a larger swelling may occur. In clinical studies, a post-mortem examination of the injection site, performed 8 weeks after the administration of a single dose of the vaccine, revealed a mild to moderate granulomatous inflammation of the muscular fibres at the injection site.
Immediate mild hypersensitivity-like reactions may occur commonly after vaccination, resulting in transient clinical signs such as vomiting. These clinical signs normally resolve without treatment.
Exceptionally, a large proportion of animals may react in some specific herds after vaccination. Severe anaphylactic reactions are uncommon but may be lethal. In case of such reactions, appropriate treatment is recommended.

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 and lactation:
Do not use during pregnancy and lactation.

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

Intramuscular use.

Shake well before administration and intermittently during the process of vaccination.
The use of a multi-dosing syringe is recommended. Use vaccination devices according to the manufacturer's instructions.
The vaccine is to be administered aseptically.

Administer one dose of 2 ml to piglets in the neck behind the ear.

Vaccination schedule:
One injection from 21 days of age.

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

No adverse reactions except those mentioned in section 4.6 were observed after the administration of a double dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for suidae, inactivated viral vaccine.
ATC Vet Code: QI09AA07

The vaccine strain is an inactivated recombinant Porcine Circovirus type 1 expressing the Porcine Circovirus type 2 ORF2 protein. It is intended to stimulate active immunity against PCV2 in piglets.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Minimum Essential Medium without phenol red
Sodium bicarbonate
Hepes acid
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as package for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box containing polyethylene bottles with a chlorobutyl elastomer closure and sealed with an aluminium cap.

Cardboard box of 1 bottle of 10 doses (20 ml), 50 doses (100 ml) or 125 doses (250 ml).
Cardboard box of 10 bottles of 10 doses (20 ml), 50 doses (100 ml) or 125 doses (250 ml).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

8. MARKETING AUTHORISATION NUMBERS

EU/2/09/099/001-006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24/07/2009
Date of last renewal: 06/06/2014

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance(s)

Zoetis Inc.
2000 Rockford Road, Charles City
IA 50616
USA

Name and address of the manufacturer responsible for batch release

Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) The administration of the veterinary medicinal product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) The disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Specific pharmacovigilance requirements:
Due to new field strains (PCV genotype), lack of expected efficacy (LEE) events should be submitted electronically on a yearly basis.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Boxes of 10 bottles of 10, 50 or 125 doses
Boxes of 1 bottle of 10, 50 or 125 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PCV suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:

Active substance:	
Inactivated recombinant Porcine Circovirus type 1 expressing the Porcine Circovirus type 2 ORF2 protein	$1.6 \leq RP \leq 5.3$
Adjuvants:	
Sulfolipo-cyclodextrin (SLCD)	4 mg
Squalane	64 mg
Excipients:	
Thiomersal	0.1 mg

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

Box of 1 bottle of 10 doses
Box of 1 bottle of 50 doses
Box of 1 bottle of 125 doses

Box of 10 bottles of 10 doses
Box of 10 bottles of 50 doses
Box of 10 bottles of 125 doses

5. TARGET SPECIES

Pigs (piglets)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Single intramuscular injection of one dose (2 ml).

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

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 the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

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

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/099/001-006

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle label 50 and 125 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PCV suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:

Active substance:	
Inactivated recombinant Porcine Circovirus type 1 expressing the Porcine Circovirus type 2 ORF2 protein	$1.6 \leq RP \leq 5.3$
Adjuvants:	
Sulfolipo-cyclodextrin (SLCD)	4 mg
Squalane	64 mg
Excipients:	
Thiomersal	0.1 mg

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 doses
125 doses

5. TARGET SPECIES

Pigs (piglets)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

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

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle label 10 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PCV suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCES

Inactivated recombinant Porcine Circovirus type 1 expressing the Porcine Circovirus type 2 ORF2 protein $1.6 \leq RP \leq 5.3$

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

10 doses (20 ml)

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6 BATCH NUMBER

Lot {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

PACKAGE LEAFLET:
Suvaxyn PCV suspension for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PCV suspension for injection for pigs

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

One dose of 2 ml contains:

Active substance:	
Inactivated recombinant Porcine Circovirus type 1 expressing the Porcine Circovirus type 2 ORF2 protein	$1.6 \leq RP^* \leq 5.3$
Adjuvants:	
Sulfolipo-cyclodextrin (SLCD)	4 mg
Squalane	64 mg
Excipients:	
Thiomersal	0.1 mg

* Relative Potency unit determined by ELISA antigen quantification (*in vitro* potency test) compared to a reference vaccine.

A milky white to pink opaque liquid, free from visible particles

4. INDICATION(S)

Active immunisation of pigs over the age of 3 weeks against Porcine Circovirus Type 2 (PCV2) to reduce viral load in blood and lymphoid tissues, and the lesions in lymphoid tissues associated with PCV2 infection, as well as to reduce clinical signs - including loss of daily weight gain, and mortality associated with Post-Weaning Multisystemic Wasting Syndrome (PMWS).

Onset of immunity: from 3 weeks post-vaccination.
Duration of immunity: 19 weeks post-vaccination

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A transient increase in body temperature (up to 1.7 °C) is very common during the first 24 hours after vaccination. This resolves spontaneously within 48 hours without treatment.
Local tissue reactions in the form of swelling at the injection site are very common and may last for up to 26 days. The area of local tissue reactions is in general below 5 cm in diameter, but in some cases a larger swelling may occur. In clinical studies, a post-mortem examination of the injection site, performed 8 weeks after the administration of a single dose of the vaccine, revealed a mild to moderate granulomatous inflammation of the muscular fibres at the injection site.
Immediate mild hypersensitivity-like reactions may occur commonly after vaccination, resulting in transient clinical signs such as vomiting. These clinical signs normally resolve without treatment.
Exceptionally, a large proportion of animals may react in some specific herds after vaccination.Severe anaphylactic reactions are uncommon but may be lethal. In case of such reactions, appropriate treatment is recommended.

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).

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 (piglets) from 3 weeks of age.

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

Single intramuscular injection in the neck behind the ear of one dose (2 ml) to pigs from 21 days of age.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before administration and intermittently during the process of vaccination.
The vaccine is to be administered aseptically.
The use of a multi-dosing syringe is recommended. Use vaccination devices according to the manufacturer's instructions.

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 carton and the bottle.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate only healthy animals.
Do not use in breeding boars.
The benefit of the vaccination of pigs with very high levels of maternally-derived antibodies, e.g. due to vaccination of their mothers, has not been demonstrated.

Special precautions for use in animals:
Avoid stress in the animals before and after the time of vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Do not use during pregnancy and lactation.

Interactions 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.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions except those mentioned in section 6 were observed after the administration of a double dose of vaccine.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Medicines should not be disposed of via wastewater or household waste. 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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

The vaccine strain is an inactivated recombinant Porcine Circovirus type 1 expressing the Porcine Circovirus type 2 ORF2 protein. It is intended to stimulate active immunity against PCV2 in piglets.

Cardboard box of 1 bottle of 10 doses (20 ml), 50 doses (100 ml) or 125 doses (250 ml).
Cardboard box of 10 bottles of 10 doses (20 ml), 50 doses (100 ml) or 125 doses (250 ml).

Not all pack sizes may be marketed.