ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Circo+MH RTU emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:	
Inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2 ORF2 protein	2.3 – 12.4 RP*
Inactivated *Mycoplasma hyopneumoniae,* strain P-5722-3	1.5 – 3.8 RP*
Adjuvant:	
Squalane	0.4% (v/v)
Poloxamer 401	0.2% (v/v)
Polysorbate 80	0.032% (v/v)
Excipients:	
Thiomersal	0.2 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

Emulsion for injection.
White homogenous emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (for fattening).

4.2 Indications for use, specifying the target species

For active immunisation of pigs from 3 weeks of age against Porcine Circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues and fecal shedding caused by infection with PCV2.
For active immunization of pigs from the age of 3 weeks against *Mycoplasma hyopneumoniae* to reduce lung lesions caused by infection with *M. hyopneumoniae*.

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 23 weeks after vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate only healthy animals.

4.5 Special precautions for use

Special precautions for use in animals
No information is available on the safety of this vaccine in breeding boars. Do not use in breeding boars.

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 (on average 1 °C) was very commonly observed during the first 24 hours after vaccination in laboratory and field trials. In individual pigs the temperature increase compared to pre-treatment may commonly exceed 2 °C. This resolves spontaneously within 48 hours without treatment.
Local tissue reactions in the form of swelling at the injection site, which may be associated with local heat, redness and pain at palpation, are very common and may last for up to 2 days (based on laboratory safety studies). The area of local tissue reactions is in general below 2 cm in diameter. In a laboratory study, a post-mortem examination of the injection site, performed 4 weeks after the administration of a repeated single dose of the vaccine, very commonly revealed a mild inflammatory response, as evidenced by the absence of tissue necrosis and little fibrosis.
Immediate mild hypersensitivity-like reactions were uncommonly observed after vaccination, resulting in transient clinical signs such as vomiting, diarrhea or depression, in field efficacy studies. These clinical signs normally resolve without treatment. Anaphylaxis may occur in very rare cases. 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

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Do not use during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

Intramuscular use.
Administer one dose of 2 ml to pigs in the neck behind the ear.

Vaccination schedule:
One injection from 3 weeks of age.

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. During storage, a slight black deposit may appear and the emulsion may separate into two distinct phases. Upon shaking, the black deposit disappears and the emulsion becomes homogenous again.

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

A transient increase in body temperature (on average 0.8 °C) was observed 4 hours after administration of a 2-fold overdose. This resolved spontaneously within 24 hours without treatment.
Local tissue reaction in the form of swelling (below 2 cm in diameter) at the injection site was commonly observed and resolved within 2 days.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Suidae, inactivated viral and inactivated bacterial vaccines for pigs.
ATCvet code: QI09AL08

The vaccine contains an inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2 ORF2 protein. The vaccine also contains inactivated *Mycoplasma hyopneumoniae.* It is intended to stimulate active immunity against PCV2 and *Mycoplasma hyopneumoniae* in pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Squalane
Poloxamer 401
Polysorbate 80
Monobasic potassium phosphate anhydrous
Sodium chloride
Potassium chloride
Disodium phosphate anhydrous
Sodium phosphate dibasic heptahydrate
Disodium tetraborate decahydrate
EDTA tetrasodium
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.
A slight black deposit may appear and the emulsion may separate into two distinct phases during storage. Upon shaking, the black deposit disappears and the emulsion becomes homogenous again.

6.5 Nature and composition of immediate packaging

High density polyethylene vials of 50 ml, of 100 ml and of 250 ml (25, 50 and 125 doses), with a chlorobutyl elastomer closure and sealed with an aluminium cap.

Pack size:
Cardboard box of 1 vial of 50 ml (25 doses), 100ml (50 doses) or 250 ml (125 doses).
Cardboard box of 10 vials of 50 ml (25 doses) or 100 ml (50 doses).
Cardboard box of 4 vials of 250 ml (125 doses).

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

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/2/15/190/001-006.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 06/11/2015.
Date of last renewal: 16/09/2020.

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

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

Name and address of the manufacturers of the biological active substances

Zoetis WHC 2 LLC
2000 Rockford Road,
Charles City IA 50616
USA

Zoetis LLC
601 W. Cornhusker Highway, Lincoln
Nebraska 68521
USA

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

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.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Circo+MH RTU emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

Inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2 ORF2 protein	2.3-12.4 RP
Inactivated *Mycoplasma hyopneumoniae* strain P-5722-3	1.5-3.8 RP

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

25 doses
50 doses
125 doses

10 x 25 doses
10 x 50 doses
4 x 125 doses

5. TARGET SPECIES

Pigs (for fattening)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before 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

Disposal: read 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/2/15/190/001
EU/2/15/190/002
EU/2/15/190/003
EU/2/15/190/004
EU/2/15/190/005
EU/2/15/190/006

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE VIALS (125 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Circo+MH RTU emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

Inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2 ORF2 protein	2.3-12.4 RP
Inactivated *Mycoplasma hyopneumoniae* strain P-5722-3	1.5-3.8 RP

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

125 doses

5. TARGET SPECIES

Pigs (for fattening)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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 REACH AND SIGHT 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/2/15/190/003

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

HDPE VIALS (25 OR 50 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Circo+MH RTU emulsion for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCES

Inactivated recombinant chimeric PCV type 1 containing the PCV type 2 ORF2 protein	2.3-12.4 RP
Inactivated *Mycoplasma hyopneumoniae* strain P-5722-3	1.5-3.8 RP

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

25 doses
50 doses

4. ROUTE(S) OF ADMINISTRATION

IM

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 Circo+MH RTU emulsion 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 authorization holder and manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Circo+MH RTU emulsion for injection for pigs

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

Each dose (2 ml) contains:

Active substances:	
Inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2 ORF2 protein	2.3 – 12.4 RP*
Inactivated *Mycoplasma hyopneumoniae,* strain P-5722-3	1.5 – 3.8 RP*
Adjuvant:	
Squalane	0.4% (v/v)
Poloxamer 401	0.2% (v/v)
Polysorbate 80	0.032% (v/v)
Excipients:	
Thiomersal	0.2 mg

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

White homogenous emulsion.

4. INDICATION(S)

For active immunisation of pigs from 3 weeks of age against Porcine Circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues and fecal shedding caused by infection with PCV2.
For active immunization of pigs from 3 weeks of age against *Mycoplasma hyopneumoniae* to reduce lung lesions caused by infection with *M. hyopneumoniae*.

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 23 weeks after vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A transient increase in body temperature (on average 1 °C) was very commonly observed during the first 24 hours after vaccination in laboratory and field trials. In individual pigs the temperature increase compared to pre-treatment may commonly exceed 2 °C. This resolves spontaneously within 48 hours without treatment.
Local tissue reactions in the form of swelling at the injection site, which may be associated with local heat, redness and pain at palpation, are very common and may last for up to 2 days (based on laboratory safety studies). The area of local tissue reactions is in general below 2 cm in diameter. In a laboratory study, a post-mortem examination of the injection site, performed 4 weeks after the administration of a repeated single dose of the vaccine, very commonly revealed a mild inflammatory response, as evidenced by the absence of tissue necrosis and little fibrosis.
Immediate mild hypersensitivity-like reactions were uncommonly observed after vaccination, resulting in transient clinical signs such as vomiting, diarrhea or depression, in field efficacy studies. These clinical signs normally resolve without treatment. Anaphylaxis may occur in very rare cases. 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 (for fattening).

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

Intramuscular use.
Single intramuscular injection in the neck behind the ear of one dose (2 ml) to pigs from 3 weeks 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.
A slight black deposit may appear and the emulsion may separate into two distinct phases during storage. Upon shaking, the black deposit disappears and the emulsion becomes homogenous again.

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 vial after EXP. The expiry date refers to the last day of that month.

Once broached use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate only healthy animals.

Special precautions for use in animals:
No information is available on the safety of this vaccine in breeding boars. Do not use in breeding boars.

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:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation.
Do not use during pregnancy and lactation.

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.

Overdose (symptoms, emergency procedures, antidotes):
A transient increase in body temperature (on average 0.8 °C) was observed 4 hours after administration of a 2-fold overdose. This resolved spontaneously within 24 hours without treatment.
Local tissue reaction in the form of swelling (below 2 cm in diameter) at the injection site was commonly observed and resolved within 2 days.

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 contains an inactivated recombinant chimeric Porcine Circovirus type 1 containing the Porcine Circovirus type 2 ORF2 protein and inactivated *Mycoplasma hyopneumoniae.* It is intended to stimulate active immunity against PCV2 and *Mycoplasma hyopneumoniae* in pigs.

Cardboard box of 1 vial of 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses).
Cardboard box of 10 vials of 50 ml (25 doses) or 100 ml (50 doses).
Cardboard box of 4 vials of 250 ml (125 doses).

Not all pack sizes may be marketed.