ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn CSF Marker lyophilisate and solvent for suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:
Lyophilisate:
Live Recombinant E2 gene deleted Bovine Viral Diarrhoea Virus
containing Classical Swine Fever E2 (CP7_E2alf) $10^{4.8}$* to $10^{6.5}$ TCID**$_{50}$

* min 100 PD_{50}
** Tissue culture infectious dose

Solvent:
Sodium chloride 9 mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: Off-white pellet
Solvent: Clear colourless liquid

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

For active immunisation of pigs from 7 weeks of age onwards to prevent mortality and reduce infection and disease caused by classical swine fever virus (CSFV).

Onset of immunity: 14 days
Duration of immunity: at least 6 months

4.3 Contraindications

None.

4.4 Special warnings for each target species

Documentation provided for this vaccine supports that it is only to be used in an outbreak situation in herds within restricted control zones.

Challenge studies have shown lack of protection against transplacental transmission of CSFV. Therefore sows should not be vaccinated, due to the risk of birth of immunotolerant persistently

infected offspring. Persistently infected immunotolerant piglets represent a very high risk since they are shedding field virus and they cannot be identified serologically due to their seronegative status.

The vaccine has shown reduced protection in studies of piglets with maternally derived antibodies compared to studies of piglets without maternally derived antibodies.

Studies in vaccinated breeding boars addressing potential shedding of virulent challenge virus in semen have not been conducted. Use of the vaccine in experimental studies in breeding boars has not revealed safety concerns.
Therefore the decision to vaccinate breeding boars and piglets with maternally derived antibodies should be taken based on the actual outbreak case and associated control zones.

RT-PCR tools could be used in outbreak situations to differentiate between the vaccine virus genome and those of fields strains based on sequences unique to the CP7_E2alf.

4.5 Special precautions for use

Special precautions for use in animals

Only vaccinate healthy animals.

Vaccine virus genome is rarely detectable by RT-PCR in tonsils and lymph nodes for up to 63 days after vaccination and vaccine virus is very rarely detectable by virus isolation in tonsil for the first week after vaccination. Shedding of vaccine virus has however not been detected but cannot be excluded.

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)

None known.

4.7 Use during pregnancy, lactation or lay

See section 4.4

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.

Reconstitute the lyophilisate aseptically with the solvent to obtain a suspension for injection.

After reconstitution, the suspension should be slightly pink clear liquid.

Primary vaccination
A single 1 ml dose should be administered intramuscularly to pigs from 7 weeks of age.

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

None known.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live viral vaccines, live recombinant E2 gene deleted Bovine Viral Diarrhoea Virus containing Classical Swine Fever E2, ATC vet code: QI09AD04

To stimulate active immunity to Classical Swine Fever virus.

The vaccine is a live recombinant E2 gene deleted Bovine Viral Diarrhoea Virus containing Classical Swine Fever E2. The virus is grown in porcine cells.

Challenge studies were conducted with the Koslov strain (genotype 1) of CSFV. Limited studies in young pigs support protection against CSF1045 (genotype 2, Germany 2009) and CSF1047 (genotype 2, Israel 2009) field strains.

The recombinant vaccine virus has potential marker properties for use in DIVA (differentiation between field virus infected and solely vaccinated animals). Diagnostic tools targeted to detection of antibody responses could enable DIVA strategies. Serological DIVA tools based on detection of CSFV antibodies other than those raised against E2, such as Erns antibody detection should be able to differentiate between antibody responses against Erns-BVDV after solely herd vaccination with CP7_E2alf from responses against Erns-CSFV after natural field CSFV infection.

DIVA efficiency depends on the performance of tests related to fitness for purpose in outbreak situations. Serological DIVA concept has been shown in principle, while actual DIVA tools remain to be tested on large panels of samples from emergency vaccination in outbreak situations.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Dextran 40
Casein hydrolysate
Lactose monohydrate
Sorbitol 70% (solution)
Sodium hydroxide

Solvent:
Sodium chloride
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after reconstitution according to directions: use immediately.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

6.5 Nature and composition of immediate packaging

Type I hydrolytic glass vials containing 10 or 50 doses of lyophilisate and 10 or 50 ml of solvent.

Lyophilisate: bromobutyl rubber stoppers and aluminium caps
Solvent: chlorobutyl rubber stoppers and aluminium caps

Cardboard box containing 1 vial with 10 doses of lyophilisate and 1 vial with 10 ml solvent.
Cardboard box containing 1 vial with 50 doses of lyophilisate and 1 vial with 50 ml solvent.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/179/001–002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/02/2015

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

Council Directive 2001/89/EC and Commission Decision 2002/106 prohibit prophylactic vaccination within the European Union. Specific derogation is required to use this vaccine in an outbreak situation.

The manufacture, import, possession, sale, supply and/or use of Suvaxyn CSF Marker vaccine may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and/or use Suvaxyn CSF Marker vaccine must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

ANNEX II

A. MANUFACTURERS 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 substance

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

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

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.

According to Community Legislation on classical swine fever (Council Directive 2001/89/EC, as amended), in the European Union:

a) the use of classical swine fever vaccines is prohibited. However, the use of vaccines may be authorised in the framework of an emergency vaccination plan, implemented by the competent authority of a Member State following confirmation of disease, in accordance with Community Legislation on control and eradication of classical swine fever.

b) the manipulation, manufacture, storage, supply, distribution and sale of classical swine fever vaccines must be carried out under supervision and in accordance with the eventual instructions established by the competent authority of the Member State.

c) special provisions regulate the movement of pigs from areas where classical swine fever vaccine is being or has been used and the processing or marking of pig meat from vaccinated pigs.

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 (including adjuvants) 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

Boxes of 1 vial of 10 or 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn CSF Marker lyophilisate and solvent for suspension for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live Recombinant E2 gene deleted Bovine Viral Diarrhoea Virus containing Classical Swine Fever E2 (CP7_E2alf)	$10^{4.8}$ to $10^{6.5}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection for pigs

4. PACKAGE SIZE

10 doses
50 doses

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted, use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 °C – 8 °C).

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/2/14/179/001 (10 doses)
EU/2/14/179/002 (50 doses)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial label (10 and 50 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn CSF Marker lyophilisate for suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCES

Live recombinant (CP7-E2Alf)

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

10 doses
50 doses

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

6 BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent vial (10 and 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Suvaxyn CSF Marker

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

10 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6 BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}
Use immediately after broaching.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Suvaxyn CSF Marker lyophilisate and solvent for 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 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 CSF Marker lyophilisate and solvent for suspension for injection for pigs

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

Active substance:
Live Recombinant E2 gene deleted Bovine Viral Diarrhoea Virus
containing Classical Swine Fever E2 (CP7_E2alf) $10^{4.8}$* to $10^{6.5}$ TCID**$_{50}$

* min 100 PD_{50}
** Tissue culture infectious dose

Solvent:
Sodium chloride 9 mg/ml

After reconstitution, the suspension should be slightly pink clear liquid.

4. INDICATION(S)

For active immunisation of pigs from 7 weeks of age onwards to prevent mortality and reduce infection and disease caused by classical swine fever virus.

Onset of immunity: 14 days
Duration of immunity: at least 6 months

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

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

Intramuscular use.

Primary vaccination
A single 1 ml dose should be administered to pigs from 7 weeks of age.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitute the lyophilisate aseptically with the solvent to obtain a suspension for injection.

10. WITHDRAWAL PERIOD

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 use after the expiry date stated on the label after EXP {month/year}.
Shelf-life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Documentation provided for this vaccine supports that it is only to be used in an outbreak situation in herds within restricted control zones.

Challenge studies have shown lack of protection against transplacental transmission of CSFV. Therefore sows should not be vaccinated, due to the risk of birth of immunotolerant persistently infected offspring. Persistently infected immunotolerant piglets represent a very high risk since they are shedding field virus and they cannot be identified serologically due to their seronegative status.

The vaccine has shown reduced protection in studies of piglets with maternally derived antibodies compared to studies of piglets without maternally derived antibodies.

Studies in vaccinated breeding boars addressing potential shedding of virulent challenge virus in semen have not been conducted. Use of the vaccine in experimental studies in breeding boars has not revealed safety concerns. Therefore the decision to vaccinate breeding boars and piglets with maternally derived antibodies should be taken based on the actual outbreak case and associated control zones.

RT-PCR tools could be used in outbreak situations to differentiate between the vaccine virus genome and those of fields strains based on sequences unique to the CP7_E2alf.

Special precautions for use in animals:
Only vaccinate healthy animals.
Vaccine virus genome is rarely detectable by RT-PCR in tonsils and lymph nodes for up to 63 days after vaccination and vaccine virus is very rarely detectable by virus isolation in tonsil for the first week after vaccination. Shedding of vaccine virus has however never been observed.

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:
Challenge studies have shown lack of protection against transplacental transmission of CSFV. Therefore sows should not be vaccinated, due to the risk of birth of immunotolerant persistently infected offspring.

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.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

DIVA tests:
The recombinant vaccine virus has potential marker properties for use in DIVA (differentiation between field virus infected and solely vaccinated animals). Diagnostic tools targeted to detection of antibody responses could enable DIVA strategies. Serological DIVA tools based on detection of CSFV antibodies other than those raised against E2, such as Erns antibody detection should be able to differentiate between antibody responses after solely herd vaccination with CP7_E2alf from responses after natural field CSFV infection.

DIVA efficiency depends on the performance of tests related to fitness for purpose in outbreak situations. Serological DIVA concept has been shown in principle, while actual DIVA tools remain to be tested on large panels of samples from emergency vaccination in outbreak situations.

Council Directive 2001/89/EC and Commission Decision 2002/106 prohibit prophylactic vaccination within the European Union. Specific derogation is required to use this vaccine in an outbreak situation.

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 product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/.

15. OTHER INFORMATION

Cardboard box containing 1 vial with 10 doses of lyophilisate and 1 vial with 10 ml solvent.
Cardboard box containing 1 vial with 50 doses of lyophilisate and 1 vial with 50 ml solvent.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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