ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respiporc FLU3 suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:

Strains of inactivated Influenza A virus/swine/	
Bakum/IDT1769/2003 (H3N2)	$\geq$ 10.53 $\log_2$ GMNU[1]
Haselünne/IDT2617/2003 (H1N1)	$\geq$ 10.22 $\log_2$ GMNU[1]
Bakum/1832/2000 (H1N2)	$\geq$ 12.34 $\log_2$ GMNU[1]

[1]GMNU = Geometric mean of neutralizing units induced in Guinea pigs after twice immunisation with 0.5 ml of this vaccine

Adjuvant:

Carbomer 971 P NF	2.0 mg

Excipient:

Thiomersal	0.21 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Clear, yellowish orange to pink coloured suspension for injection.

4. CLINICAL PARTICULARS

4.1. Target species

Pigs

4.2. Indication for use, specifying the target species

Active immunisation of pigs from the age of 56 days onwards including pregnant sows against swine influenza caused by subtypes H1N1, H3N2 and H1N2 to reduce clinical signs and viral lung load after infection.

Onset of immunity:	7 days after primary vaccination
Duration of immunity:	4 months in pigs vaccinated between the age of 56 and 96 days and 6 months in pigs vaccinated for the first time at 96 days and above.

Active immunisation of pregnant sows after finished primary immunisation by administration of a single dose 14 days prior to farrowing to develop high colostral immunity which provides clinical protection of piglets for at least 33 days after birth.

4.3. Contraindications

None.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection only a minor injection site reaction is expected.

4.6. Adverse reactions (frequency and seriousness)

A transient slight swelling may occur on very rare occasions after vaccination at the site of injection, regressing within 2 days. On very rare occasions, a slight transient rectal temperature increase might occur after vaccination.

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

Can be used 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

For intramuscular use.

Piglets:
Primary vaccination: 2 injections of one dose (2 ml)
- From the age of 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 6 months.
or
- Between the age of 56 and 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 4 months.

Gilts and sows:
Primary vaccination: see above
A booster is possible at each stage of pregnancy and lactation. When vaccination is performed 14 days prior to farrowing with one dose (2 ml), it provides maternally-derived immunity to the piglets which protects them from clinical signs of influenza at least until day 33 after birth.

Maternally-derived immunity in the piglets interacts with antibody induction. Generally, maternally-derived antibodies induced by vaccination last for approx. 5-8 weeks after birth. In particular cases of multiple contacts of the sows with antigens (field infections + vaccination) the antibodies transmitted to the piglets may last until week 12 of life. In the latter case piglets should be vaccinated after the age of 96 days.

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

After administration of a double dose (4 ml), no adverse reactions other than those described in section 4.6 were observed.

4.11. Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals, Inactivated viral vaccines
ATCvet code: QI09AA03

The vaccine stimulates an active immunity against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2. It induces neutralizing and haemagglutination inhibiting antibodies against each of the three subtypes. When a single dose of the vaccine is administered 14 days prior to farrowing as a booster to previously vaccinated sows, the vaccine stimulates active immunity in order to provide maternally-derived immunity to the progeny against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Carbomer 971 P NF
Thiomersal
Sodium chloride solution (0.9%)

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 packaged for sale: 2 years.
Shelf life after first opening the vial: 10 hours.

6.4. Special precautions for storage

Store in a refrigerator (2 ºC − 8 ºC). Do not freeze.
Keep the vial in the outer carton in order to protect from light.

6.5. Nature and composition of immediate packaging

Glass vial:	20 ml vials, glass type I 50 ml vials, glass type II 100 ml vials, glass type II
PET vials:	20 ml Polyethylene terephthalate (PET) vials, clear 50 ml PET vials, clear 100 ml PET vials, clear 500 ml PET vials, clear
Stoppers:	Bromobutyl rubber stoppers
Caps:	Flanged caps

Package sizes:
Cardboard box with 1 glass vial of 10 doses (20 ml), 25 doses (50 ml) or 50 doses (100 ml) with a rubber stopper and flanged cap.
Cardboard box with 1 PET vial of 10 doses (20 ml), 25 doses (50 ml) or 50 doses (100 ml) with a rubber stopper and flanged cap.
Cardboard box with 8 PET vials of 250 doses (500 ml) with a rubber stopper and flanged cap.

Not all pack sizes may be marketed.

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 products should be disposed of in accordance with the local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

8. MARKETING AUTHORISATION NUMBER

EU/2/09/103/001-007

9. DATE OF FIRST AUTHORISATION

Date of first authorisation: 14/01/2010
Date of last renewal: 04/12/2014

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

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

Not applicable.

ANNEX II

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substances

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Name and address of the manufacturers responsible for batch release

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Ceva-Phylaxia Veterinary Biologicals Co. Ltd.
Szállás u. 5.
1107 Budapest
Hungary

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

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 (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

Cardboard box for 20ml, 50 ml, 100 ml, 8 x 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respiporc FLU3 suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Strains of inactivated Influenza A virus/swine/
Bakum/IDT1769/2003 (H3N2) ≥ 10.53 $\log_2$ GMNU*
Haselünne/IDT2617/2003(H1N1) ≥ 10.22 $\log_2$ GMNU*
Bakum/1832/2000 (H1N2) ≥ 12.34 $\log_2$ GMNU*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

20 ml (10 doses)
50 ml (25 doses)
100 ml (50 doses)
8 x 500 ml (250 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(S)

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. Keep the bottle in the outer carton in order to protect from light.

12. SPECIFIC 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

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/103/001
EU/2/09/103/002
EU/2/09/103/003
EU/2/09/103/004
EU/2/09/103/005
EU/2/09/103/006
EU/2/09/103/007

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 100 ml and 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respiporc FLU3 suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Strains of inactivated Influenza A virus/swine/
Bakum/IDT1769/2003 (H3N2) ≥ 10.53 $\log_2$ GMNU*
Haselünne/IDT2617/2003(H1N1) ≥ 10.22 $\log_2$ GMNU*
Bakum/1832/2000 (H1N2) ≥ 12.34 $\log_2$ GMNU*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml (50 doses)
500 ml (250 doses)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. Keep the bottle in the outer carton in order to 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

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/103/003
EU/2/09/103/006
EU/2/09/103/007

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 20 ml and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respiporc FLU3 suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Strains of inactivated Influenza A virus/swine
(H3N2) ≥ 10.53 log_2 GMNU, (H1N1) ≥ 10.22 log_2 GMNU, (H1N2) ≥ 12.34 log_2 GMNU

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

20 ml (10 doses)
50 ml (25 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP {month/year}
Once opened, use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Respiporc FLU3 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

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

Manufacturer responsible for batch release:

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Ceva-Phylaxia Veterinary Biologicals Co. Ltd.
Szállás u. 5.
1107 Budapest
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respiporc FLU3 suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each dose of 2 ml contains:

Active substances:

Strains of inactivated Influenza A virus/swine/	
Bakum/IDT1769/2003 (H3N2)	≥ 10.53 $\log_2$ GMNU[1]
Haselünne/IDT2617/2003 (H1N1)	≥ 10.22 $\log_2$ GMNU[1]
Bakum/1832/2000 (H1N2)	≥ 12.34 $\log_2$ GMNU[1]

[1]GMNU = Geometric mean of neutralizing units induced in Guinea pigs after twice immunisation with 0.5 ml of this vaccine

Adjuvant:

Carbomer 971 P NF	2.0 mg

Excipient:
Thiomersal 0.21 mg

Clear, yellowish orange to pink coloured suspension for injection.

4. INDICATION(S)

Active immunisation of pigs from the age of 56 days onwards including pregnant sows against swine influenza caused by subtypes H1N1, H3N2 and H1N2 to reduce clinical signs and viral lung load after infection.

Onset of immunity: 7 days after primary vaccination
Duration of immunity: 4 months in pigs vaccinated between the age of 56 and 96 days and
6 months in pigs vaccinated for the first time at 96 days and above.

Active immunisation of pregnant sows after finished primary immunisation by administration of a single dose 14 days prior to farrowing to develop high colostral immunity which provides clinical protection of piglets for at least 33 days after birth.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A transient slight swelling may occur on very rare occasions after vaccination at the site of injection, regressing within 2 days. On very rare occasions, a slight transient rectal temperature increase might occur after vaccination ("very rare" corresponds to a frequency of adverse reactions less than 1 animal in 10,000 animals treated, including isolated reports).

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

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

For intramuscular use.

Piglets:
Primary vaccination: 2 injections of one dose (2 ml)
- From the age of 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 6 months.
or
- Between the age of 56 and 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 4 months.

Gilts and sows:
Primary vaccination: see above
A booster is possible at each stage of pregnancy and lactation. When vaccination is performed 14 days prior to farrowing with one dose (2 ml), it provides maternally-derived immunity to the piglets which protects them from clinical signs of influenza at least until day 33 after birth.

Maternally-derived immunity in the piglets interacts with antibody induction. Generally, maternally-derived antibodies induced by vaccination last for approx. 5-8 weeks after birth. In particular cases of multiple contacts of the sows with antigens (field infections + vaccination) the antibodies transmitted to the piglets may last until week 12 of life. In the latter case piglets should be vaccinated after the age of 96 days.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 ºC − 8 ºC).
Do not freeze.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP.
Shelf-life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

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

In case of accidental self-injection only a minor injection site reaction is expected.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interactions:
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.

Incompatibilities:
Do not mix with any other 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

{MM/YYYY}

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 stimulates an active immunity against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2. It induces neutralizing and haemagglutination inhibiting antibodies against each of the three subtypes. When a single dose of the vaccine is administered 14 days prior to farrowing as a booster to previously vaccinated sows, the vaccine stimulates active immunity in order to provide maternally-derived immunity to the progeny against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2.

Package sizes:
Cardboard box with 1 glass or PET vial of 10 doses (20 ml), 25 doses (50 ml) or 50 doses (100 ml) with a rubber stopper and flanged cap.
Cardboard box with 8 PET vials of 250 doses (500 ml) with a rubber stopper and flanged cap.

Not all pack sizes may be marketed.