ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2 ml contains:

Active substances:

Porcine circovirus type 2 (PCV2) ORF2 subunit antigen	≥ 2,828 AU[1]
Mycoplasma hyopneumoniae J strain inactivated	≥ 2.69 RPU[2]

Adjuvants:

Light mineral oil	0.268 ml
Aluminium (as hydroxide)	2.0 mg.

[1] Antigenic units as determined in the *in vitro* potency test (ELISA).
[2] Relative potency units defined against a reference vaccine.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
Homogenous white to nearly white emulsion after shaking.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs for fattening

4.2 Indications for use, specifying the target species

For the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection. To reduce the loss of daily weight gain during the finishing period in face of infections with *Mycoplasma hyopneumoniae* and/or PCV2 (as observed in field studies).

Onset of immunity with single dose vaccination:
PCV2: 2 weeks after vaccination
M. hyopneumoniae: 4 weeks after vaccination.

Onset of immunity with two dose vaccination:
PCV2: 18 days after first vaccination
M. hyopneumoniae: 3 weeks after the second vaccination.

Duration of immunity (both vaccination schedules):
PCV2: 22 weeks after (the last) vaccination
M. hyopneumoniae: 21 weeks after (the last) vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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
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 veterinary medicinal 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)

In laboratory studies and field trials:
A transient increase in body temperature very commonly occurs on the day of vaccination (mean ±1 °C, in individual pigs up to 2 °C). The animals return to normal from 1 to 2 days after the peak temperature is observed.
Mild systemic reactions may uncommonly be observed up to one day after vaccination and consist of being less active, a tendency of the animal to lie down and minor signs of discomfort. In rare cases a hypersensitivity-like reaction may be observed after the first vaccination of the two dose vaccination schedule.
Transient local injection site reactions, which are restricted to a slight swelling (< 2 cm diameter), may uncommonly occur. These reactions disappear within 12 days after the first vaccination of the two dose vaccination schedule and within 3 days after completion of either the single or the two dose vaccination schedule.

In post marketing experience (with single dose vaccination):
In very rare cases anaphylactic-type reactions can occur, which may be life-threatening. In the event of such reactions, treatment may be needed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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

Not applicable.

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

Before using the vaccine allow it to reach room temperature (15 °C – 25 °C) and shake well before use. Avoid introduction of contamination.

Vaccinate pigs by the intramuscular route in the neck.

Single dose vaccination schedule
A single dose of 2 ml in pigs starting at 3 weeks of age.

Two dose vaccination schedule.
Two injections each of 1 ml in pigs starting at 3 days of age with an interval of at least 18 days.

Needle length and diameter should be adapted to the age of the animal.

When PCV2 and/or M. *hyopneumoniae* infections occur early the two dose vaccination schedule is recommended.

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

No data available.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral and inactivated bacterial vaccines for pigs.
ATCvet code: QI09AL.

The product stimulates the development of active immunity against porcine circocvirus type 2 and *Mycoplasma hyopneumoniae* in pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light mineral oil
Aluminium hydroxide
Sorbitan oleate
Polysorbate 80
Ethyl alcohol
Glycerol
Sodium chloride
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 medical product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 8 hours.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

PET (polyethylene terephthalate) vials of 20, 50, 100, 200 or 500 ml, closed with nitrile rubber stoppers and sealed with aluminium caps.

Cardboard box with 1 or 10 vials of 20 ml.
Cardboard box with 1 or 10 vials of 50 ml.
Cardboard box with 1 or 10 vials of 100 ml.
Cardboard box with 1 or 10 vials of 200 ml.
Cardboard box with 1 or 10 vials of 500 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 medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/175/001–010

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07/11/2014.

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

Not applicable.

ANNEX II

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

Name and address of the manufacturers of the biological active substances

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

Burgwedel Biotech GmbH
Im Langen Felde 5
30938 Burgwedel
GERMANY

Intervet UK Limited
Walton Manor
Walton,
Milton Keynes
Buckinghamshire
MK7 7AJ
UK

Intervet International GmbH
Osterather Strasse 1a
50739 Köln
GERMANY

Merck Sharp & Dohme Animal Health S.L.
Poligono Industrial EI Montalvo 1
C/Zeppelin 6, Parcela 38
37008 Carbajosa de la Sagrada,
Salamanca
SPAIN

Name and address of the manufacturer responsible for batch release

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substances 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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Per 2 ml:

PCV2 ORF2 subunit antigen	≥ 2,828 AU,
M. hyopneumoniae inac.	≥ 2.69 RPU.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

20 ml
50 ml
100 ml
200 ml
500 ml
10x20 ml
10x50 ml
10x100 ml
10x200 ml
10x500 ml

5. TARGET SPECIES

Pigs for fattening

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

Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from direct sunlight.

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

Intervet International BV
5831 AN Boxmeer
The NETHERLANDS

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/175/001 (20 ml)
EU/2/14/175/002 (50 ml)
EU/2/14/175/003 (100 ml)
EU/2/14/175/004 (200 ml)
EU/2/14/175/005 (500 ml)
EU/2/14/175/006 (10x20 ml)
EU/2/14/175/007 (10x50 ml)
EU/2/14/175/008 (10x100 ml)
EU/2/14/175/009 (10x200 ml)
EU/2/14/175/010 (10x500 ml)

17. MANUFACTURER'S BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials of 100, 200 and 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

2 ml contains:
PCV2 ORF2 subunit antigen ≥ 2,828 AU,
M. hyopneumoniae inac. ≥ 2.69 RPU.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

100 ml
200 ml
500 ml

5. TARGET SPECIES

Pigs for fattening

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

Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP {month/year}

Once broached use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from direct sunlight.

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

Intervet International BV
5831 AN Boxmeer
The NETHERLANDS

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 20 and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo *[a clear pictogram of a pig]*

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

PCV2 ORF2 subunit antigen
M. hyopneumoniae inac.

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

20 ml
50 ml

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 broached use within 8 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Porcilis PCV M Hyo 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 authorisation holder and manufacturer responsible for batch release:

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo emulsion for injection for pigs

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

2 ml contains:

Active substances:

Porcine circovirus type 2 (PCV2) ORF2 subunit antigen	≥ 2,828 AU[1]
Mycoplasma hyopneumoniae J strain inactivated	≥ 2.69 RPU[2]

Adjuvants:

Light mineral oil	0.268 ml
Aluminium (as hydroxide)	2.0 mg.

[1] Antigenic units as determined in the *in vitro* potency test (ELISA).
[2] Relative potency units defined against a reference vaccine.

4. INDICATION(S)

For the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection. To reduce the loss of daily weight gain during the finishing period in face of infections with *Mycoplasma hyopneumoniae* and/or PCV2 (as observed in field studies).

Onset of immunity with single dose vaccination:
PCV2: 2 weeks after vaccination.
M. hyopneumoniae: 4 weeks after vaccination.

Onset of immunity with two dose vaccination:
PCV2: 18 days after the first vaccination.
M. hyopneumoniae: 3 weeks after the second vaccination.

Duration of immunity (both vaccination schedules):
PCV2: 22 weeks after (the last) vaccination.
M. hyopneumoniae: 21 weeks after (the last) vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In laboratory studies and field trials:
A transient increase in body temperature very commonly occurs on the day of vaccination (mean ±1 °C, in individual pigs up to 2 °C). The animals return to normal 1 to 2 days after the peak temperature is observed.
Mild systemic reactions may uncommonly be observed up to one day of vaccination and consist of being less active, a tendency of the animal to lie down and minor signs of discomfort. In rare cases a hypersensitivity-like reaction may be observed after the first vaccination of the two dose vaccination schedule.

Transient local injection site reactions, which are restricted to a slight swelling (< 2 cm diameter), may uncommonly occur. These reactions disappear within 12 days after the first vaccination of the two dose vaccination schedule and within 3 days after completion of either the single or the two dose vaccination schedule.

In post marketing experience (with single dose vaccination):
In very rare cases anaphylactic-type reactions can occur, which may be life-threatening. In the event of such reactions, treatment may be needed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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

Vaccinate pigs by the intramuscular route in the neck.

Single dose vaccination schedule
A single dose of 2 ml in pigs starting at 3 weeks of age.

Two dose vaccination schedule.
Two injections each of 1 ml in pigs starting at 3 days of age with an interval of at least 18 days.

Needle length and diameter should be adapted to the age of the animal.

When PCV2 and/or M. *hyopneumoniae* infections occur early the two dose vaccination schedule is recommended.

9. ADVICE ON CORRECT ADMINISTRATION

Before using the vaccine allow it to reach room temperature (15 °C – 25 °C) and shake well before use.
Avoid introduction of contamination.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from direct sunlight.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf life after first opening the container: 8 hours.

12. SPECIAL WARNING(S)

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

Special precautions for use in animals:
Not applicable.

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 veterinary medicinal 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.

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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

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

The vaccine stimulates active immunity against porcine circovirus type 2 and *Mycoplasma hyopneumoniae* in pigs.

Cardboard box with 1 or 10 vials of 20, 50, 100, 200 or 500 ml.

Not all pack sizes may be marketed.