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.

Excipients:

Qualitative composition of excipients and other constituents
Sorbitan oleate Polysorbate 80 Ethyl alcohol Glycerol Sodium chloride Water for injections

Homogenous white to nearly white emulsion after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (for fattening).

3.2 Indications for use for each 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

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs (for fattening):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]
Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site swelling[2] Decreased activity[3] Lying down[3] Uncomfortable[3]
Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reaction[4]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reaction[5]

[1] 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.

[2] < 2 cm diameter. 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.

[3] Up to one day after vaccination.

[4] After the first vaccination of the two- dose vaccination schedule.

[5] For the single dose vaccination: May be life threatening. If such reactions occur, appropriate treatment is recommended.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See section 'Contact details' of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data in pigs from 3 weeks of age onwards are available, which demonstrate that this vaccine can be given at the same time with Porcilis Lawsonia and/or Porcilis PRRS. When Porcilis PCV M Hyo is given at the same time with Porcilis Lawsonia, these products should be mixed (see section 3.9 below), whereas Porcilis PRRS should always be given at a separate site (preferably at the opposite side of the neck). The product literature of Porcilis Lawsonia and/or Porcilis PRRS should be consulted before administration.

In individual pigs the temperature increase after associated use may commonly exceed 2°C. The temperature returns to normal from 1 to 2 days after the peak temperature is observed. Transient local injection site reactions, which are restricted to a slight swelling (maximum 2 cm diameter), may commonly occur directly after vaccination, but reactions may not appear until 12 days after vaccination. All these reactions disappear within 6 days. Hypersensitivity reactions after vaccination may occur uncommonly.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above.
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.

3.9 Administration routes and dosage

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.

Mixed use with Porcilis Lawsonia
The Porcilis PCV M Hyo emulsion may be used to reconstitute Porcilis Lawsonia lyophilisate shortly before vaccination in pigs from 3 weeks of age onwards as follows:

Porcilis Lawsonia lyophilisate	Porcilis PCV M Hyo
50 doses	100 ml

100 doses	200 ml

For proper reconstitution and correct administration, use the following procedure:
1. Allow Porcilis PCV M Hyo to reach room temperature and shake well before use.
2. Add 5-10 ml Porcilis PCV M Hyo to the Porcilis Lawsonia lyophilisate and mix briefly.
3. Withdraw the reconstituted concentrate from the vial and inject it back into the vial with Porcilis PCV M Hyo. Shake briefly to mix.
4. Use the vaccine mixture within 6 hours of reconstitution. Any vaccine remaining at the end of this time should be discarded.

Dosage:
A single dose (2 ml) of Porcilis Lawsonia mixed with Porcilis PCV M Hyo is given intramuscularly in the neck.

Visual appearance after reconstitution: homogenous white to nearly white emulsion after shaking.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No data available.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AL08.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Porcilis Lawsonia lyophilisate.

5.2 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.

5.3 Special precautions for storage

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

5.4 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 vial of 20 ml.
Cardboard box with 1 vial of 50 ml.
Cardboard box with 1 vial of 100 ml.
Cardboard box with 1 vial of 200 ml.
Cardboard box with 1 vial of 500 ml.

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

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/175/001
EU/2/14/175/002
EU/2/14/175/003
EU/2/14/175/004
EU/2/14/175/005
EU/2/14/175/006
EU/2/14/175/007
EU/2/14/175/008
EU/2/14/175/009
EU/2/14/175/010

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 07/11/2014.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

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

2. STATEMENT OF ACTIVE SUBSTANCES

Per 2 ml:

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

3. PACKAGE SIZE

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

4. TARGET SPECIES

Pigs (for fattening)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 8 hours.

9. SPECIAL STORAGE PRECATIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV

14. MARKETING AUTHORISATION NUMBERS

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)

15. BATCH NUMBER

Lot {number}

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

2. STATEMENT OF ACTIVE SUBSTANCES

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

100 ml
200 ml
500 ml

3. TARGET SPECIES

Pigs (for fattening)

4. ROUTES OF ADMINISTRATION

Intramuscular use. Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV

9. BATCH NUMBER

Lot {number}

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

20 ml
50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porcilis PCV M Hyo emulsion for injection for pigs

2. 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.

Homogenous white to nearly white emulsion after shaking.

3. Target species

Pigs (for fattening).

4. Indications for use

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. Special warnings

Special warnings:
Vaccinate healthy animals only.

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 veterinary medicinal 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.

Special precautions for the protection of the environment:
Not applicable.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data in pigs from 3 weeks of age onwards are available, which demonstrate that this vaccine can be given at the same time with Porcilis Lawsonia and/or Porcilis PRRS. When Porcilis PCV M Hyo is given at the same time with Porcilis Lawsonia, these products should be mixed, whereas Porcilis PRRS should always be given at a separate site (preferably at the opposite side of the neck). The product literature of Porcilis Lawsonia and/or Porcilis PRRS should be consulted before administration.

In individual pigs the temperature increase after associated use may commonly exceed 2°C. The temperature returns to normal from 1 to 2 days after the peak temperature is observed. Transient local injection site reactions, which are restricted to a slight swelling (maximum 2 cm diameter), may commonly occur directly after vaccination, but reactions may not appear until 12 days after vaccination. All these reactions disappear within 6 days. Hypersensitivity reactions after vaccination may occur uncommonly.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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:
No data available.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except Porcilis Lawsonia.

7. Adverse events

Pigs (for fattening):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]
Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site swelling[2] Decreased activity[3] Lying down[3] Uncomfortable[3]
Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reaction[4]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic type reaction[5]

1 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.

2 < 2 cm diameter. 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.

3 Up to one day after vaccination.

4 After the first vaccination of the two dose vaccination schedule.

5 For the single dose vaccination. May be life threatening. If such reactions occur, appropriate treatment is recommended.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes 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.

Mixed use with Porcilis Lawsonia
The Porcilis PCV M Hyo emulsion may be used to reconstitute Porcilis Lawsonia lyophilisate shortly before vaccination in pigs from 3 weeks of age onwards as follows:

Porcilis Lawsonia lyophilisate	Porcilis PCV M Hyo
50 doses	100 ml
100 doses	200 ml

For proper reconstitution and correct administration, use the following procedure:
1. Allow Porcilis PCV M Hyo to reach room temperature and shake well before use.
2. Add 5-10 ml Porcilis PCV M Hyo to the Porcilis Lawsonia lyophilisate and mix briefly.

3. Withdraw the reconstituted concentrate from the vial and inject it back into the vial with Porcilis PCV M Hyo. Shake briefly to mix.
4. Use the vaccine mixture within 6 hours of reconstitution. Any vaccine remaining at the end of this time should be discarded.

Dosage:
A single dose (2 ml) of Porcilis Lawsonia mixed with Porcilis PCV M Hyo is given intramuscularly in the neck.

Visual appearance after reconstitution: homogenous white to nearly white emulsion after shaking.

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 periods

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 after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 8 hours.

12. Special precautions for disposal

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/14/175/001-10.

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

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: + 420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
Tel: + 37052196111

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

17. Other information

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