ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV ID emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.2 ml contains:

Active substance:

Porcine circovirus type 2 ORF2 subunit antigen	≥ 1436 AU[1]

Adjuvants:

dl-α-tocopheryl acetate	0.6 mg
Light liquid paraffin	8.3 mg

[1] Antigenic units as determined in the *in vitro* potency test (antigenic mass assay).

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Simethicone
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

Homogenous, white to nearly white emulsion after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

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 and virus shedding caused by PCV2 infection. To reduce loss of daily weight gain and mortality associated with PCV2 infection.

Onset of immunity: 2 weeks after vaccination.
Duration of immunity: 23 weeks after 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:
Use of the vaccine in boars has not been evaluated.

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.

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

3.6 Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site swelling*

* mostly consisting of hard non-painful swellings of up to 2 cm diameter. A biphasic pattern of the injection site swelling, consisting of an increase and decrease followed by another increase and decrease of the size, is commonly observed. In individual pigs the size may increase to 6.5 cm and redness and/or scabs may be observed. The injection site swellings disappear completely within approximately 7 weeks after vaccination

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 its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be administered mixed with Porcilis Lawsonia ID (see section 3.9 below) and/or non-mixed with Porcilis M Hyo ID ONCE and/or non-mixed with Porcilis PRRS (intradermal route). The administration site of non-mixed vaccines should be separated by at least 3 cm. The product literature of Porcilis Lawsonia ID, Porcilis M Hyo ID ONCE and Porcilis PRRS should be consulted before administration.

Adverse events are as described in section 3.6, except for injection site swelling where a maximum size of up to 7 cm may occur in individual pigs. Injection site swelling may last up to 7 weeks and are very commonly accompanied by redness and crusts. If the crust is rubbed off, some small skin damage may be commonly observed. Elevated temperature on the day of vaccination (mean 0.3 °C, in

individual pigs up to 2°C) is common. The animal's temperature returns to normal within 1-2 days after the peak temperature is observed. Lying down and malaise can be uncommonly observed in vaccinated pigs.

Indications are as described in section 3.2, except for a duration of immunity of 26 weeks after vaccination is demonstrated.

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

For intradermal use.

Before using the vaccine allow it to reach room temperature (15℃ – 25℃) and shake well before use. Avoid multiple broaching.

Intradermal administration of 0.2 ml per animal, preferably at the sides of the neck, along the muscles of the back or in the hind leg (all pigs) or perianal area (in pigs for reproduction) using a multi-dose needle-free injection device for intradermal application of liquids suitable to deliver a "jet-stream" volume of vaccine (0.2 ml ± 10 %) through the epidermal layers of the skin.

Safety and efficacy of Porcilis PCV ID have been demonstrated using the device IDAL.

Vaccination scheme:
Vaccinate once from an age of 3 weeks onwards and re-vaccination at 23 weeks interval is recommended.

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

Porcilis Lawsonia ID lyophilisate	Porcilis PCV ID
50 doses	10 ml
100 doses	20 ml

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

Dosage:
A single dose (0.2 ml) of Porcilis Lawsonia ID mixed with Porcilis PCV ID is given intradermally in the neck.

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

Avoid introduction of a contamination by multiple broaching.

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: QI09AA07

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except those mentioned in section 3.8.

5.2 Shelf life

Shelf-life of the veterinary medicinal 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

Glass vial (type I) of 10 ml closed with a nitryl-based rubber stopper and sealed with an aluminium cap.

PET (polyethylene terephthalate) vial of 20 ml closed with a nitryl-based rubber stopper and sealed with an aluminium cap.

Pack size:
Cardboard box with 1 glass vial of 10 ml.
Cardboard box with 10 glass vials of 10 ml.
Cardboard box with 1 PET vial of 20 ml.
Cardboard box with 10 PET vials of 20 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 THEMARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/15/187/001
EU/2/15/187/002
EU/2/15/187/003
EU/2/15/187/004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 28/08/2015.

9. DATE OF THE LAST REVISION OFSUMMARY 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 ID emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Per 0.2 ml:
PCV2 ORF2 subunit antigen ≥ 1436 AU

3. PACKAGE SIZE

10 ml
20 ml
10 x 10 ml
10 x 20 ml

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intradermal use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

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 B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/15/187/001 (1x 10ml)
EU/2/15/187/002 (10x 10ml)
EU/2/15/187/003 (1x 20ml)
EU/2/15/187/004 (10x 20ml)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIALS OF 10 AND 20 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV ID

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

PCV2 ORF2 subunit antigen

10 ml
20 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Porcilis PCV ID emulsion for injection for pigs

2. Composition

Each dose of 0.2 ml contains:

Active substance:

Porcine circovirus type 2 ORF2 subunit antigen	≥ 1436 AU[1]

Adjuvants:

dl-α-tocopheryl acetate	0.6 mg
Light liquid paraffin	8.3 mg

[1]Antigenic units as determined in the *in vitro* antigenic mass assay.

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

3. Target species

Pigs.

4. Indications for use

For the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues and virus shedding caused by PCV2 infection. To reduce loss of daily weight gain and mortality associated with PCV2 infection.

Onset of immunity: 2 weeks after vaccination.
Duration of immunity: 23 weeks after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Use of the vaccine in boars has not been evaluated.

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.

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

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

Interaction with other medicinal products and other forms of interaction
Safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be administered mixed with Porcilis Lawsonia ID (see section 8 below) and/or non-mixed with Porcilis M Hyo ID ONCE and/or non-mixed with Porcilis PRRS (intradermal route). The administration site of non-mixed vaccines should be separated by at least 3 cm. The product literature of Porcilis Lawsonia ID, Porcilis M Hyo ID ONCE and Porcilis PRRS should be consulted before administration.
Adverse events are as described in section 7, except for injection site swelling where a maximum size of up to 7 cm may occur in individual pigs. Injection site swelling may last up to 7 weeks and are very commonly accompanied by redness and crusts. If the crust is rubbed off, some small skin damage may be commonly observed. Elevated temperature on the day of vaccination (mean 0.3 °C, in individual pigs up to 2°C) is common. The animal's temperature returns to normal within 1-2 days after the peak temperature is observed. Lying down and malaise can be uncommonly observed in vaccinated pigs.
Indications are as described in section 4, except for a duration of immunity of 26 weeks after vaccination is demonstrated.

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

Major incompatibilities
Do not mix with any other veterinary medicinal product except those mentioned above.

7. Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site swelling*

* mostly consisting of hard non-painful swellings of up to 2 cm diameter. A biphasic pattern of the injection site swelling, consisting of an increase and decrease followed by another increase and decrease of the size, is commonly observed. In individual pigs the size may increase to 6.5 cm and redness and/or scabs may be observed. The injection site swellings disappear completely within approximately 7 weeks after vaccination

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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

For intradermal use.
Intradermal administration of 0.2 ml per animal, preferably at the sides of the neck, along the muscles of the back or in the hind leg (all pigs) or perianal area (in pigs for reproduction) using a multi-dose needle-free injection device for intradermal application of liquids suitable to deliver a "jet-stream" volume of vaccine (0.2ml ± 10%) through the epidermal layers of the skin.
Safety and efficacy of Porcilis PCV ID have been demonstrated using the device IDAL.

Vaccination scheme:
Vaccinate once from an age of 3 weeks onwards and re-vaccination at 23 weeks interval is recommended.

Mixed use with Porcilis Lawsonia ID
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1. Allow Porcilis PCV ID to reach room temperature and shake well before use.
2. Add approximately 5-10 ml of Porcilis PCV ID to the Porcilis Lawsonia ID lyophilisate and mix briefly.
3. Withdraw the reconstituted concentrate from the vial and transfer it back into the vial with the Porcilis PCV ID. Shake briefly to mix.
4. Use the vaccine suspension within 6 hours of reconstitution. Any vaccine remaining at the end of this time should be discarded.

Dosage:
A single dose (0.2 ml) of Porcilis Lawsonia ID mixed with Porcilis PCV ID is given intradermally in the neck.

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

Avoid introduction of a contamination by multiple broaching.

9. Advise on correct administration

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

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.
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 or pharmacist on 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/2/15/187/001-004.

Cardboard box with 1 or 10 vials of 10 or 20 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this 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:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:

België/Belgique/Belgien
MSD Animal Health Belgium BV-SRL
Tél/Tel: + 32 (0)2 370 94 01

Република България
Intervet International B.V.
Тел: + 359 28193749

Česká republika
Intervet s.r.o.
Tel: + 420 233 010 242

Danmark
MSD Animal Health A/S
Tlf: + 45 44 82 42 00

Deutschland
Intervet Deutschland GmbH
Tel: + 49 (0)8945614100

Eesti
Intervet International B.V.
Tel: + 37052196111

Ελλάδα
Intervet Hellas A.E.
Τηλ: + 30 210 989 7452

España
Merck Sharp & Dohme Animal Health S.L.
Tel: + 34 923 19 03 45

France
Intervet S.A.S / Intervet / MSD Santé Animale
Tél: + 33 (0)241228383

Hrvatska
Intervet International B.V. podružnica u Republici Hrvatskoj
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Latvija
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Tel: + 37052196111

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

17. Other information