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).

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 fattening 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.

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 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)

Transient local reactions mostly consisting of hard non-painful swellings of up to 2 cm diameter were very commonly observed in laboratory studies and field trials. A biphasic pattern of the local reactions, 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 4 cm and redness may be observed. The local reactions disappear completely within approximately 5 weeks 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

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be given with Porcilis M Hyo ID ONCE on the same day from 3 weeks of age, either at different sites (e.g. alternate sides of the neck), or at the same site providing that intradermal administration of each vaccine is separated by at least 3 cm.
The product literature of Porcilis M Hyo ID ONCE should be consulted. In case both vaccines are used on the same day the size of the local reactions may increase up to 6 cm in individual pigs, may last 7 weeks and are very commonly accompanied by redness and crusts. In the event that the crust is rubbed off, some small skin damage may be commonly observed. Moreover, a transient increase in body temperature on the day of vaccination of about 0.2 °C is common. In individual pigs this temperature may increase up to 2 °C. The animal's temperature returns to normal within 1-2 days after the peak temperature is observed.
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.

4.9 Amounts to be administered and administration route

For intradermal use.

Before using the vaccine allow it to reach room temperature (15°C – 25°C) 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 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.

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

No data available.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Suidae, inactivated viral vaccines for pigs.
ATCvet code: QI09AA07

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Simethicone
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
dl-α-tocopheryl acetate
Light liquid paraffin
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 medicinal 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

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.

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/2/015/187/001-004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28/08/2015
Date of last renewal: DD/MM/YYYY

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 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. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

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

Name and address of the manufacturer responsible for batch release

Intervet International B.V.
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 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

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. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs for fattening

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intradermal 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.
Accidental 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. 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

Intervet International B.V.
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER'S BATCH NUMBER

Lot

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

PCV2 ORF2 subunit antigen

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

10 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

Intradermal use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Porcilis PCV ID 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 B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV ID emulsion for injection for pigs

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

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.

4. INDICATION(S)

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. ADVERSE REACTIONS

Transient local reactions mostly consisting of hard non-painful swellings of up to 2 cm diameter were very commonly observed in laboratory studies and field trials. A biphasic pattern of the local

reactions, 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 4 cm and redness may be observed. The local reactions disappear completely within approximately 5 weeks 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)

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

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 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.

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 multiple broaching.

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 healthy animals only.

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 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
Safety and efficacy data are available which demonstrate that this vaccine can be given with Porcilis M Hyo ID ONCE on the same day from 3 weeks of age, either at different sites (e.g. alternate sides of the neck), or at the same site providing that intradermal administration of each vaccine is separated by at least 3 cm.
The product literature of Porcilis M Hyo ID ONCE should be consulted. In case both vaccines are used on the same day the size of the local reactions may increase up to 6 cm in individual pigs, may last 7 weeks and are very commonly accompanied by redness and crusts. In the event that the crust is rubbed off, some small skin damage may be commonly observed. Moreover, a transient increase in body temperature on the day of vaccination of about 0.2 °C is common. In individual pigs this temperature may increase up to 2 °C. The animal's temperature returns to normal within 1-2 days after the peak temperature is observed.
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.

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

DD/MM/YYYY

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

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.