ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substance:
Porcine circovirus type 2 ORF2 subunit antigen: at least 4.5 $\log_2$ ELISA units*

* Antibody titre obtained according to the *in vivo* potency test in chickens.

Adjuvants
Dl-α-tocopheryl acetate 25 mg
Light liquid paraffin 346 mg

Excipient:
Polysorbate 80

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Emulsion for injection

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

For the active immunisation of pigs to reduce the virus load in blood and lymphoid tissues and to reduce mortality and weight loss associated with PCV2 infection occurring during the fattening period.

Onset of immunity: 2 weeks
Duration of immunity: 22 weeks

4.3 Contraindications

None

4.4 Special warnings

From the data provided, it can be concluded that a single dose regimen of vaccination breaks through up to medium levels and double dose regimen through medium to high levels of maternally derived antibodies in piglets.
No data are available on the use of the vaccine in breeding boars.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.

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

To the user:
This 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 insert with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This 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 at the injection site may occur after vaccination mainly in the form of a hard, warm and sometimes painful swelling (diameter up to 10 cm). These reactions resolve spontaneously over a period of approximately 14-21 days without any major consequence on the general health status of the animals. Immediate systemic hypersensitivity-like reactions may occur after vaccination, resulting in minor neurological symptoms such as tremors and/or excitation, which normally resolve within minutes without requiring treatment. A transient increase in body temperature, normally not exceeding 1°C, may occur until 2 days after vaccination. Occasionally, an increase of rectal temperature up to 2.5 °C lasting less than 24 hours may occur. Some piglets may be depressed and show a reduced feed intake for up to 5 days. Vaccination may result in a transient impairment of growth rate in the immediate period after administration of the vaccine.

4.7 Use during pregnancy, lactation or lay

Do not use 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 decided 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 and shake well before use. Avoid multiple vial broaching. Use sterile syringes and needles. Avoid introduction of contamination. Avoid use of vaccination equipment with rubber parts.

Vaccination
Administer one dose of 2 ml by intramuscular injection in the neck, in the area behind the ear, according to the following schedule:

In the case of low to medium levels of maternally derived antibodies against PCV2 a single vaccination (2 ml) to pigs from an age of 3 weeks onwards is advised.

When it is expected that higher levels of maternally derived antibodies against PCV2 are present, the following schedule of two vaccinations is advised: the first injection (2 ml) can be given from an age of 3-5 days, the second injection (2 ml) 2-3 weeks later.

High levels of MDA may be expected when sows/gilts are vaccinated against PCV2 virus or when sows/gilts have recently been exposed to high levels of PCV2 virus. In such cases it is advised to perform PCV2 serology, using suitable diagnostics, to select the most appropriate vaccination schedule. In case of doubt, apply the two shot vaccination schedule.

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

Following the administration of a double dose of vaccine no side effects other than those described in section 4.6 have been observed.

4.11 Withdrawal period

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated Porcine circovirus vaccine.

ATCvet code: QI09AA07

Vaccine to stimulate active immunity against Porcine circovirus type 2

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Simethicon
Water for injections

6.2 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 light.

6.5 Nature and composition of immediate packaging

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

Vials are closed with a nitryl rubber stopper and a coded aluminium 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 local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/01/2009

10. DATE OF REVISION OF THE TEXT