ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard 7 lyophilisate and solvent for solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:
Freeze dried fraction: Vanguard DA_2Pi
Canine distemper virus, strain N-CDV (live attenuated) minimum titre: $10^{3.0}$ $CCID_{50}$*
Canine adenovirus Type 2, strain Manhattan (live attenuated) minimum titre: $10^{3.2}$ $CCID_{50}$*
Canine parainfluenza virus, strain NL-CPI-5 (live attenuated) minimum titre: $10^{6.0}$ $CCID_{50}$*

Liquid fraction: Vanguard CPV-L
Canine Parvovirus, strain NL-35-D, low passage (live attenuated) minimum titre : $10^{7.0}$ $CCID_{50}$*
Leptospira canicola (inactivated) between 420 and 740 RU**/dose
Leptospira icterohaemorrhagiae (inactivated) between 463 to 915 RU**/dose

*Cell culture infectious dose-50
** Relative units

Excipients:

Qualitative composition of excipients and other constituents
Modified Eagles medium
Dextran 40
Casein hydrolysate
Lactose
Sorbitol 70% (solution)
Sodium hydroxide
Water for Injection

Freeze-dried: lightly colored pellets.
Liquid: pinkish pink, transparent to slightly cloudy.

3. CLINICAL INFORMATION

3.1 Target species

Dogs from 6 weeks of age.

3.2 Indications for use for each target species

Active immunisation of dogs to prevent clinical signs of disease and reduce infection caused by canine adenovirus Type 2, to prevent mortality and clinical signs including leucopenia and reduce viral shedding caused by canine parvovirus (types 2a, 2b and 2c), to prevent clinical signs of disease caused by canine distemper virus and canine adenovirus Type 1, to reduce pathological signs of disease caused by parainfluenzavirus and to reduce infection caused by *Leptospira canicola* and *Leptospira icterohaemorrhagiae*.

Onset of immunity: 2 weeks after the last dose of the Basic Vaccination Scheme.

7 days after a single dose when animals are vaccinated from 9 weeks of age for the canine parvovirus component (type 2b)

Duration of immunity: 12 months after the last dose of the Basic Vaccination Scheme based on serology/challenge data for all of the antigens with the exception of the CPi component which is based on the anamnestic response observed following challenge infection 1 year after dosing.

3.3 Contraindications

Do not use in unhealthy animals.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The canine adenovirus Type 2 and canine parvovirus vaccinal strains may be shed from vaccinated animals for a number of days following vaccination. However, due to the low pathogenicity of these strains, it is not necessary to keep vaccinated animals separated from non-vaccinated animals.

Due to the presence of maternally derived antibodies, a small percentage of pups may fail to mount an adequate immune response to vaccination and may be at risk from disease where the local disease challenge is sufficiently high. The percentage of puppies that fail to mount an adequate immune response to vaccination is greater when the final vaccination is given at 10 weeks of age than it is when the final vaccination is given at 12 weeks or older, when the amounts of maternally derived antibodies will be lower. Therefore, where the circumstances of the individual case permit, consideration should be given to administering the final vaccination at 12 weeks of age, even in pups that are first presented at six to eight weeks of age.

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

In case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	allergic oedema anaphylactic-type reaction[1] collapse digestive tract disorders dyspnoea erythema injection site swelling[2] pale mucous membranes urticaria

[1] If an anaphylactic reaction occurs, administer adrenaline or equivalent products.
[2] Transient, within 4-6 hours after vaccination which resolves after approximately 7 days.

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during the pregnancy.

3.8 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.

3.9 Administration routes and dosage

Dosage and route of administration:
Reconstitute one vial of the freeze-dried fraction (Vanguard DA_2Pi) aseptically using the contents of one vial of the liquid fraction (Vanguard CPV-L) as diluent.
Shake well and immediately inject the entire contents of the reconstituted vial (1 ml) subcutaneously. Do not use chemically sterilised syringes or needles, as these will interfere with the effectiveness of the vaccine.

Basic Vaccination Scheme:
Puppies between 6 and 12 weeks of age:
Two doses of Vanguard 7 at least 14 days apart. The second dose should not be given until at least 10 weeks of age.
Puppies 12 weeks of age or older:
A single 1 ml dose of Vanguard 7 followed by a single 1 ml dose of Vanguard Lepto ci at least 14 days later.

Re-vaccination Scheme:
A single 1 ml dose of Vanguard 7 to be given annually thereafter. Annual booster vaccinations are recommended. However, should Veterinary Practitioners conduct a risk-benefit analysis for individual animals to determine the frequency of revaccination, they should be aware of the following information. Serological data has indicated that most dogs, when given at least the first annual booster, can maintain protective levels of immunity to the CPV, CAV2 and CDV viral components of Vanguard 7 for at least 4 years. Although an equivalent duration of serological response has been demonstrated for the CPi component, a correlation between antibody levels and protection has not been established for this virus. For further information, please contact the company

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

No reactions other than those listed in Section 3.6 are observed after an overdose. No treatment is necessary in most cases of overdose. However, if a systemic anaphylactic reaction occurs (eg vomiting), administer adrenaline or an equivalent.

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

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AI02

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except diluent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
For the freeze-dried fraction (Vanguard DA_2Pi) - 2 years
For the liquid diluent fraction (Vanguard CPV-L) - 4 years

Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2°C – 8°C)
Do not freeze.

5.4 Nature and composition of immediate packaging

The vaccine is filled in 1 dose vials glass type I (Ph.Eur.). Vials of the freeze-dried fraction are closed with a bromobutyl rubber stopper and a varnished aluminium cap. Vials of the liquid fraction are closed with a chlorobutyl rubber stopper and a varnished aluminium cap.

Pack contains 1, 10, 25 or 100 vials of Vanguard DA_2Pi freeze-dried fraction and 1, 10, 25 or 100 vials of 1 ml Vanguard CPV-L liquid fraction.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10387/082/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 07/07/2005

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

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).