ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DP PLUS lyophilisate and solvent for suspension for injection for dogs (puppies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) of reconstituted vaccine contains:

Active substances:
Live attenuated canine distemper virus strain Onderstepoort: $10^{5.1}$ – $10^{6.5}$ $TCID_{50}$*
Live recombinant canine parvovirus strain 630a: $10^{5.1}$ – $10^{6.7}$ $TCID_{50}$*

* Tissue culture infective dose 50%

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: off-white or cream-colour.
Solvent: clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs (puppies)

4.2 Indications for use, specifying the target species

For the active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection.

Onset of immunity:	for canine distemper virus: 7 days; for canine parvovirus: 3 days.
Duration of immunity:	8 weeks.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Moderate to high levels of maternally derived antibodies against canine distemper virus can reduce the efficacy of the product against canine distemper.

It is typically advised that each pup is vaccinated with this product at 6 weeks of age. In cases where there is a high risk of canine parvovirus infection and/or canine distemper virus infection, it is advised that pups are vaccinated earlier, but not before 4 weeks of age. The routine vaccinations with core vaccines against canine distemper, canine parvovirosis, canine contagious hepatitis and respiratory

disease caused by adenovirus type 2 infection should be given as indicated in the package leaflets of these products.

4.5 Special precautions for use

Special precautions for use in animals
In some puppies, the canine parvovirus vaccine strain may be found in faeces for up to 8 days after vaccination. Occasionally this virus can spread to other dogs or cats, but without causing clinical signs of disease. In cats, the virus may be shed up to 5 days and spread to other cats without causing any signs of disease. Canine distemper virus is not spread by vaccinated puppies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A small, non-painful swelling (maximum 1 cm diameter) at the injection site is very commonly observed within the first week after vaccination. The swelling will resolve completely within a few days. Reduced activity can occur in rare cases within 4 hours 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

The safety of the veterinary medicinal product has not been established during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Safety data are available which demonstrate that this vaccine can be administered on the same day but not mixed with vaccine of the Nobivac series containing *Bordetella bronchiseptica* and canine parainfluenza virus components for intranasal administration. Efficacy after concurrent use has not been tested. Therefore, while safety of concurrent use has been demonstrated, the veterinarian should take this into account when deciding to administer the products at the same time.

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

Subcutaneous use.

Administer one dose (1 ml) to puppies from 4 weeks of age onwards.

Reconstitute the vial containing the lyophilisate with the supplied solvent.

Ensure that the lyophilisate is completely reconstituted before use.

Administer the total contents of the vial.

Reconstituted product: off-pink or pink coloured suspension.

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

No adverse reactions other than those mentioned in section 4.6 were observed after administration of a 10-fold overdose of the vaccine.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live viral vaccine for dogs, canine distemper virus and canine parvovirus.
ATCvet code: QI07AD03.

The vaccine stimulates active immunity in puppies against canine parvovirus and canine distemper virus infection. Maternally derived antibodies against canine parvovirus do not interfere with the efficacy of this product. Immunity against canine distemper virus is achieved in animals of 4 weeks of age with low to moderate levels of maternal antibodies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Hydrolysed gelatine
Pancreatic digest of casein
Sorbitol
Disodium phosphate dihydrate

Solvent:
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product (lyophilisate) as packaged for sale: 2 years.
Shelf life of the solvent as packaged for sale: 4 years.
Shelf life after reconstitution according to directions: 30 minutes.

6.4. Special precautions for storage

Lyophilisate:
Store in a refrigerator (2 °C – 8 °C).
Do not transport above 30 ºC.
Do not freeze.
Protect from light.

Solvent:
No special precautions for storage.

6.5 Nature and composition of immediate packaging

Lyophilisate:
Type I clear glass vial of 1 dose closed with a chlorobutyl rubber stopper and aluminium cap.

Solvent:
Type I clear glass vial of 1 ml closed with a bromobutyl rubber stopper and aluminium cap.

Packaging:
- Plastic box with 5 x 1 dose vial of vaccine and 5 vials containing 1 ml of solvent.
- Plastic box with 25 x 1 dose vial of vaccine and 25 vials containing 1 ml of solvent.

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/2/20/265/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {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 SUBSTANCES 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 SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substances

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

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX
Plastic box with 5 x 1 dose vial of vaccine and 5 x 1 ml vial of solvent
Plastic box with 25 x 1 dose vial of vaccine and 25 x 1 ml vial of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DP PLUS lyophilisate and solvent for suspension for injection for dogs (puppies)

2. STATEMENT OF ACTIVE SUBSTANCES

Live attenuated canine distemper virus strain Onderstepoort: $10^{5.1}$ – $10^{6.5}$ $TCID_{50}$
Live recombinant canine parvovirus strain 630a: $10^{5.1}$ – $10^{6.7}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

5 x 1 dose of vaccine including 1 ml solvent
25 x 1 dose of vaccine including 1 ml solvent

5. TARGET SPECIES

Dogs (puppies)

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 30 minutes.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not transport above 30 ºC.
Do not freeze.
Protect from light.

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.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/265/001 (5 x 1 dose; 5 x 1 ml)
EU/2/20/265/002 (25 x 1 dose; 25 x 1 ml)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VACCINE VIAL LABEL (LYOPHILISATE)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DP PLUS

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live attenuated canine distemper virus
Live recombinant canine parvovirus

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SOLVENT VIAL LABEL

1. NAME OF THE SOLVENT

Solvent for Nobivac DP PLUS

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

1 ml

3. ROUTE(S) OF ADMINISTRATION

SC

4. STORAGE CONDITIONS

No special storage conditions.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Nobivac DP PLUS lyophilisate and solvent for suspension for injection for dogs (puppies)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DP PLUS lyophilisate and solvent for suspension for injection for dogs (puppies)

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

Each dose (1 ml) of reconstituted vaccine contains:

Live attenuated canine distemper virus strain Onderstepoort: $10^{5.1} – 10^{6.5}$ $TCID_{50}$*
Live recombinant canine parvovirus strain 630a: $10^{5.1} – 10^{6.7}$ $TCID_{50}$*

* Tissue culture infective dose 50%

Lyophilisate: off-white or cream-colour.
Solvent: clear colourless solution.

4. INDICATION(S)

For the active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection.

Onset of immunity:	for canine distemper virus: 7 days; for canine parvovirus: 3 days.
Duration of immunity:	8 weeks.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A small, non-painful swelling (maximum 1 cm diameter) at the injection site is very commonly observed within the first week after vaccination. The swelling will resolve completely within a few days. Reduced activity can occur in rare cases within 4 hours 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

Dogs (puppies)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous use.

Administer one dose (1 ml) to puppies from 4 weeks of age onwards.

Reconstitute the vial containing the lyophilisate with the supplied solvent.

Administer the total contents of the vial.

Reconstituted product: off-pink or pink coloured suspension.

9. ADVICE ON CORRECT ADMINISTRATION

Ensure that the lyophilisate is completely reconstituted before use.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Lyophilisate: Store in a refrigerator (2 °C – 8 °C). Do not transport above 30 ºC. Do not freeze. Protect from light.

Solvent: This veterinary medicinal product does not require any special temperature storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after reconstitution according to directions: 30 minutes.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Moderate to high levels of maternally derived antibodies against canine distemper virus can reduce the efficacy of the product against canine distemper.
It is typically advised that each pup is vaccinated with this product at 6 weeks of age. In cases where there is a high risk of canine parvovirus infection and/or canine distemper virus infection, it is advised that pups are vaccinated earlier, but not before 4 weeks of age. The routine vaccinations with core vaccines against canine distemper, canine parvovirosis, canine contagious hepatitis and respiratory disease caused by adenovirus type 2 infection should be given as indicated in the package leaflets of these products.

Special precautions for use in animals
In some puppies the canine parvovirus vaccine strain may be found in faeces for up to 8 days after vaccination. Occasionally this virus can spread to other dogs or cats, but without causing clinical signs of disease. In cats the virus may be shed up to 5 days and spread to other cats without causing any signs of disease. Canine distemper virus is not spread by vaccinated puppies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:
The safety of the veterinary medicinal product has not been established during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Safety data are available which demonstrate that this vaccine can be administered on the same day but not mixed with vaccine of the Nobivac series containing *Bordetella bronchiseptica* and parainfluenza virus components for intranasal administration. Efficacy after concurrent use has not been tested. Therefore, while safety of concurrent use has been demonstrated, the veterinarian should take this into account when deciding to administer the products at the same time.

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.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions other than those mentioned in section “Adverse Reactions” were observed after administration of a 10-fold overdose of the vaccine.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except solvent supplied for use with the 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

Detailed information on this product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Pack sizes:
- Plastic box with 5 x 1 dose vial of vaccine and 5 vials containing 1 ml of solvent.
- Plastic box with 25 x 1 dose vial of vaccine and 25 vials containing 1 ml of solvent.

Not all pack sizes may be marketed.

The vaccine stimulates active immunity in puppies against canine parvovirus and canine distemper virus infection. Maternally derived antibodies against canine parvovirus do not interfere with the efficacy of this product. Immunity against canine distemper virus is achieved in animals of 4 weeks of age with low to moderate levels of maternal antibodies.