ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Bb lyophilisate and solvent for suspension for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.2 ml) of reconstituted suspension contains:

Lyophilisate:

Active substance:
$10^{6.3}$-$10^{8.3}$ colony forming units (CFU) of live *Bordetella bronchiseptica* bacteria strain B-C2

Solvent:
Water for injection

Excipients:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension.
Lyophilisate: Off-white or cream-coloured pellet
Solvent: clear colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

For active immunisation of cats, of 1 month of age or older to reduce clinical signs of *Bordetella bronchiseptica* associated upper respiratory tract disease.

Onset of immunity: Onset of immunity was established in 8 week old cats as early as 72 hours after vaccination.

Duration of immunity: The duration of immunity is up to 1 year.

No data on the influence of maternal antibodies on the effect of vaccination with Nobivac Bb for cats are available. From literature it is considered that this type of intranasal vaccine is able to induce an immune response without interference from maternally derived antibodies.

4.3 Contraindications

None known.

4.4 Special warnings

If any antibiotic is administered within one week after vaccination, the vaccination should be repeated after the antibiotic treatment has been completed.

4.5 Special precautions for use

Special precautions for use in animals

Only healthy cats should be vaccinated.

Sneezing by cats after administration does not adversely affect the efficacy of the veterinary medicinal product.

Do not administer during antibiotic treatment or in conjunction with any other intranasal veterinary medicinal products.

Vaccinated animals can spread the vaccine strain of *Bordetella bronchiseptica* for six weeks, and there may be intermittent shedding for at least one year.

Although the risk of immunocompromised humans becoming infected with *Bordetella bronchiseptica* is extremely low, it is advised that cats, which are in close contact with immunocompromised humans are not vaccinated with this vaccine.

Dogs, pigs and unvaccinated cats may react to the vaccine strain with mild and transient respiratory signs. Other animals, such as rabbits and small rodents, have not been tested.

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

In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician.

Appropriate disinfection procedures should be used following use of this live bacterial vaccine.

Although the risk that immunocompromised humans become infected with *Bordetella bronchiseptica* is extremely low, such individuals should be aware that cats can shed the organism for up to 1 year after vaccination.

4.6 Adverse reactions (frequency and seriousness)

After administration, occasionally sneezing, coughing, mild and transient discharge from the eyes or nose, may occur. In cats that show more severe signs, appropriate antibiotic treatment may be indicated.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating queens.

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 made on a case by case basis.

4.9 Amounts to be administered and administration route

Nasal use.

Vaccination scheme:
One dose, of 0.2 ml of reconstituted vaccine at least 72 hours prior to period of anticipated risk.

Allow the solvent to reach room temperature. Aseptically reconstitute the lyophilisate with 0.3 ml of the sterile solvent provided. Shake well.
Withdraw 0.2 ml of reconstituted vaccine into a 1 ml or 2 ml syringe, remove the needle and administer the whole contents of the syringe into one of the cat's nostrils.

The head of the cat should be held with its nose pointing upwards and its mouth closed, so that it is forced to breathe through its nostrils. Place the syringe in front of one of the nostrils and carefully administer the whole contents of the syringe into the nasal cavity via this nostril. The vaccine is administered directly from the tip of the syringe onto the opening of the nostril and enters the nasal cavity during inhalation.

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

No adverse reactions other than those mentioned in section 4.6 were observed after the administration of an overdose of the vaccine.

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for felidae – cat - live bacterial vaccines.
ATC vet code: QI06AE02

To stimulate active immunity against *Bordetella bronchiseptica.*

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Gelatin
Sorbitol
Phosphate buffers.

Solvent:
Water for injections.

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after reconstitution: use within 4 hours.

6.4 Special precautions for storage

Store at 2 – 8°C.
Protect from light.

6.5 Nature and composition of immediate packaging

One 3 ml unit-dose vial (glass Type I) of lyophilisate sealed with a halogenobutyl rubber stopper and an aluminium cap, supplied with a vial (glass Type I) of 0.5 ml sterile solvent sealed with a halogenobutyl rubber stopper.

Presentations:
Carton box containing 5 vials of 1 dose of lyophilisate and 5 vials of solvent.
Plastic box containing 5 vials of 1 dose of lyophilisate and 5 vials of solvent.

Not all presentations 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

Dispose of waste material that has had contact with the active substance by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/02/034/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/09/2002
Date of last renewal: 30/08/2012

10. DATE OF REVISION OF THE TEXT

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

The import, sale, supply and/or use of Nobivac Bb for cats is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use Nobivac Bb for cats must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

ANNEX II

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

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

Manufacturers of the biological active substance

Intervet Inc.
21960 Intervet Lane,
Delaware 19966, Millsboro
U.S.A.

Intervet Inc.
375 South Lake Street,
Minnesota 56187, Worthington
U.S.A.

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

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of their territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of national programmes for the diagnosis, control and eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the veterinary medicinal product is intended to confer immunity is largely absent from the territory.

C. STATEMENT OF THE MRLs

Not applicable

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Pharmacovigilance system

The marketing authorisation holder must ensure that the system of pharmacovigilance, as described in Part 1 of the marketing authorisation application, is in place and functioning before and whilst the veterinary medicinal product is on the market.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Box label:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Bb lyophilisate and solvent for suspension for cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.2 ml dose contains:
$10^{6.3}$- $10^{8.3}$ CFU of live *Bordetella bronchiseptica* bacteria strain B-C2.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension..

4. PACKAGE SIZE

5 unit-dose vials of lyophilisate and 5 vials of solvent.

5. TARGET SPECIES

Cats

6. INDICATION

Live vaccine against feline upper respiratory tract disease caused by *Bordetella bronchiseptica*.

7. METHOD AND ROUTE OF ADMINISTRATION

For nasal use.
Read the package leaflet before.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use for special warnings for immunocompromised humans.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store at 2 - 8°C.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/02/034/001
EU/2/02/034/002

17. MANUFACTURER'S BATCH NUMBER

Lot/Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for the vaccine vial:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Bb for cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

$10^{6.3}$- $10^{8.3}$ CFU/dose *B. bronchiseptica*

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

1 dose.

4. ROUTE(S) OF ADMINISTRATION

Nasal use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for the solvent vial:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Nobivac Bb

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 dose

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

0.5 ml

4. ROUTE OF ADMINISTRATION

See package leaflet.

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR

Nobivac Bb lyophilisate and solvent for suspension for cats

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Bb lyophilisate and solvent for suspension for cats

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each dose (0.2 ml) of reconstituted suspension contains:

Lyohpilisate:

$10^{6.3}$-$10^{8.3}$ colony forming units (CFU) of live *Bordetella bronchiseptica* strain B-C2

Solvent:
Water for injections

Lyophilisate: Off-white or cream-coloured pellet
Solvent: clear colourless solution

4. INDICATION(S)

For active immunisation of cats, of 1 month of age or older, to reduce clinical signs of *Bordetella bronchiseptica* associated upper respiratory tract disease.

The onset of immunity was established in 8 week old cats as early as 72 hours after vaccination.

The duration of immunity is up to 1 year.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating queens.

6. ADVERSE REACTIONS

After administration, occasionally sneezing, coughing, mild and transient discharge from the eyes or nose may occur. After overdose, identical signs appear particularly in very young susceptible kittens. In cats that show more severe signs, appropriate antibiotic treatment may be indicated.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

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

One dose, of 0.2 ml of reconstituted vaccine at least 72 hours prior to period of anticipated risk.

For nasal use.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the solvent to reach room temperature. Aseptically reconstitute the freeze-dried vaccine with 0.3 ml of the sterile solvent provided. Shake well after addition of the solvent. Withdraw 0.2 ml of reconstituted vaccine into a 1 ml or 2 ml syringe, remove the needle and administer the whole contents of the syringe into one of the cat's nostrils.

The head of the cat should be held with its nose pointing upward and its mouth closed, so that it is forced to breathe through its nostrils. Place the syringe in front of one of the nostrils and carefully administer the whole contents of the syringe into the nasal cavity via this nostril. The vaccine is administered directly from the tip of the syringe onto the opening of the nostril and enters the nasal cavity during inhalation.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children
Store at 2 - 8°C. Protect from light.
Do not use after the expiry date which is stated on the label.
Shelf-life after reconstitution according to directions: 4 hours

12. SPECIAL WARNINGS

Only healthy cats should be vaccinated.

Sneezing by cats after administration does not adversely affect the efficacy of the veterinary medicinal product.

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

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.

Do not administer during antibiotic treatment, or in conjunction with any other intranasal veterinary medicinal product.

If any antibiotic is administered within one week after vaccination, the vaccination should be repeated after the antibiotic treatment has been completed.

Vaccinated animals can spread the *Bordetella bronchiseptica* vaccine strain for six weeks; in individual cases for at least one year. Intermittent spreading is possible as well.

Although the risk of immunocompromised humans becoming infected with *Bordetella bronchiseptica* is extremely low, it is advised that cats that are in close contact with immunocompromised humans are not vaccinated with this vaccine. Such individuals should also be aware that cats can shed the organism for up to 1 year after vaccination.

Dogs, pigs and unvaccinated cats may react to the vaccine strain with mild and transient respiratory signs. Other animals, such as rabbits and small rodents, have not been tested.
Appropriate disinfection procedures should be used following use of this live bacterial vaccine.

In case of accidental self-administration seek medical advice immediately and show the package leaflet or the label to the physician.

The import, sale, supply and/or use of Nobivac Bb for cats is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use Nobivac Bb for cats must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material that has had contact with the active substance by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

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

15. OTHER INFORMATION

For animal treatment only.

Presentations:
Carton box containing 5 vials of 1 dose of lyophilisate and 5 vials of solvent
Plastic box containing 5 vials of 1 dose of lyophilisate and 5 vials of solvent

Not all presentations may be marketed.