ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCP FeLV lyophilisate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml or 0.5 ml:

Lyophilisate:
Active substances:
Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain) ..... $\geq 10^{4.9}$ $CCID_{50}$[1]
Inactivated feline calicivirus (FCV 431 and G1 strains) antigens..... ≥ 2.0 ELISA U.
Attenuated feline panleucopenia virus (PLI IV) ..... $\geq 10^{3.5}$ $CCID_{50}$[1]

Excipient:
Gentamicin, at most..... 23 µg

Solvent:
Active substance:
FeLV recombinant canarypox virus (vCP97) ..... $\geq 10^{7.2}$ $CCID_{50}$[1]

[1] cell 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: homogeneous beige pellet.
Solvent: clear colourless liquid with presence of cell debris in suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

Active immunisation of cats aged 8 weeks and older:
- against feline viral rhinotracheitis to reduce clinical signs,
- against calicivirus infection to reduce clinical signs,
- against feline panleucopenia to prevent mortality and clinical signs,
- against leukaemia to prevent persistent viraemia and clinical signs of the related disease.

Onsets of immunity:
- Rhinotracheitis, calicivirus and panleucopenia components: 1 week after primary vaccination course.
- Feline leukaemia component: 2 weeks after primary vaccination course.

Duration of immunity:
- Rhinotracheitis, calicivirosis and panleucopenia components: 1 year after primary vaccination course and 3 years after the last re-vaccination.
- Feline Leukaemia component: 1 year after the last re-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
It is recommended that a test for FeLV antigenaemia be carried out prior to vaccination.
Vaccination of FeLV positive cats is of no benefit.

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)

Transient apathy and anorexia as well as hyperthermia (lasting usually for 1 or 2 days) were commonly observed during safety and field studies. A local reaction (slight pain at palpation, itching or limited oedema) that disappears within 1 or 2 weeks at most was commonly observed during safety and field studies.

Emesis (mostly within 24 to 48 hours) has been observed in very rare cases based on post-marketing safety experience.

A hypersensitivity reaction has been observed uncommonly in field studies, which may require appropriate symptomatic treatment.

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 treated in 100 animals)
- uncommon (more than 1 but less than 10 animals treated in 1,000 animals)
- 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

Do not use during the whole pregnancy and lactation.

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 administered the same day but not mixed with Boehringer Ingelheim adjuvanted vaccine against rabies.

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

Subcutaneous route.

Reconstitute gently the vaccine in order to obtain a uniform suspension with limited foam formation.
Visual appearance after reconstitution: slightly yellow suspension with presence of cell debris in suspension.

After reconstitution of the lyophilisate with 0.5 ml or 1 ml of the solvent (depending on the presentation chosen) inject one dose of vaccine according to the following vaccination scheme:

Primary vaccination course:
- first injection: from 8 weeks of age,
- second injection: 3 to 4 weeks later.

Where high levels of maternal antibodies against rhinotracheitis, calicivirosis or panleucopenia components are expected to be present (e.g. in kittens of 9 to 12 weeks of age born from queens, which were vaccinated before pregnancy and/or with known or suspected previous exposure to the pathogen(s)), the primary vaccination course should be delayed until 12 weeks of age.

Revaccination:
- the first revaccination must be carried out for all components one year after the primary vaccination course,
-

Subsequent revaccinations:
- Feline leukaemia component: every year.
- Rhinotracheitis, calicivirosis and panleucopenia components: at intervals of up to three years.

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

No effect other than those already mentioned in section 4.6 “Adverse reactions” have been observed, except hyperthermia that may exceptionally last 5 days.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: QI06AH10. live feline rhinotracheitis virus + live feline panleucopenia virus / parvovirus + inactivated feline calicivirus + feline leukaemia, recombinant live canarypox virus

Vaccine against feline viral rhinotracheitis, feline calicivirosis, feline panleucopenia and feline leukaemia.
Stimulates active immunity against feline rhinotracheitis virus, feline calicivirus, feline panleucopenia virus and feline leukaemia virus.
The product was shown to reduce excretion of feline calicivirus at onset of immunity and for one year after vaccination.
The feline leukaemia vaccine strain is a recombinant canarypox virus expressing the *env* and *gag* genes of FeLV-A. Under field conditions, only sub-group A is infective and immunisation against sub-group A provides full protection against A, B and C. After inoculation, the virus expresses the protective proteins, but does not replicate in the cat. As a consequence, the vaccine induces an immune status against feline leukaemia virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sorbitol
Dextran 40
Casein hydrolysate
Collagen hydrolysate
Dipotassium phosphate
Potassium dihydrogen phosphate
Potassium hydroxide
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Magnesium chloride hexahydrate
Calcium chloride dihydrate
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after reconstitution according to directions: use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Type I glass bottle containing 1 dose of lyophilisate and type I glass bottle containing 0.5 ml or 1 ml solvent, both closed with a butyl elastomer closure and sealed with an aluminium cap.

Plastic box containing 10 bottles of 1 dose of lyophilisate and 10 bottles of 1 ml of solvent.
Plastic box containing 50 bottles of 1 dose of lyophilisate and 50 bottles of 1 ml of solvent.
Plastic box containing 10 bottles of 1 dose of lyophilisate and 10 bottles of 0.5 ml of solvent.
Plastic box containing 50 bottles of 1 dose of lyophilisate and 50 bottles of 0.5 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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/048/001-004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23/02/2005
Date of last renewal: 15/01/2010

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

Not applicable.

ANNEX II

A. MANUFACTURERS 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. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substances
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'aviation
69800 SAINT-PRIEST
FRANCE

Boehringer Ingelheim Animal Health France SCS
Laboratoire Lyon Gerland
254, Rue Marcel Mérieux
69007 LYON
FRANCE

Name and address of the manufacturer responsible for batch release
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'aviation
69800 SAINT-PRIEST
FRANCE

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

Plastic box of 10 bottles of lyophilisate and 10 bottles of solvent
Plastic box of 50 bottles of lyophilisate and 50 bottles of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCP FeLV lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 1 ml or 0.5 ml:
FHV (F2 strain) ..... $\geq 10^{4.9}$ $CCID_{50}$
FCV (431 and G1 strains) ..... ≥ 2.0 ELISA U.
FPV (PLI IV)..... $\geq 10^{3.5}$ $CCID_{50}$
FeLV recombinant canarypox virus (vCP97)..... $\geq 10^{7.2}$ $CCID_{50}$.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

Lyophilisate (10 x1 dose) + solvent (10 x1 ml)
Lyophilisate (50 x1 dose) + solvent (50 x1 ml)
Lyophilisate (10 x 1 dose) + solvent (10 x 0.5 ml)
Lyophilisate (50 x 1 dose) + solvent (50 x 0.5 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP (mm/yyyy)
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/048/001 Lyophilisate (10 x 1 dose) + solvent (10 x 1 ml)
EU/2/04/048/002 Lyophilisate (50 x 1 dose) + solvent (50 x 1 ml)
EU/2/04/048/003 Lyophilisate (10 x 1 dose) + solvent (10 x 0.5 ml)
EU/2/04/048/004 Lyophilisate (50 x 1 dose) + solvent (50 x 0.5 ml)

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCP FeLV

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

7. EXPIRY DATE

EXP (mm/yyyy)

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCP FeLV solvent

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

1 ml or 0.5 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP (mm/yyyy)

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Purevax RCP FeLV lyophilisate and solvent for suspension for injection

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

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturer responsible for the batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCP FeLV
Lyophilisate and solvent for suspension for injection.

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

Per dose of 1 ml or 0.5 ml:

Lyophilisate:
Active substances:
Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain) ..... $\geq 10^{4.9}$ $CCID_{50}$[1]
Inactivated feline calicivirus (FCV 431 and FCV G1 strains) antigens..... ≥ 2.0 ELISA U.
Attenuated feline panleucopenia virus (PLI IV) ..... $\geq 10^{3.5}$ $CCID_{50}$[1]

Excipient:
Gentamicin, at most..... 23 µg

Solvent:
Active substance:
FeLV recombinant canarypox virus (vCP97) ..... $\geq 10^{7.2}$ $CCID_{50}$[1].

[1] cell culture infective dose 50%.

Lyophilisate: homogeneous beige pellet.
Solvent: clear colourless liquid with presence of cell debris in suspension.

4. INDICATION(S)

Active immunisation of cats aged 8 weeks and older:
- against feline viral rhinotracheitis to reduce clinical signs,
- against calicivirus infection to reduce clinical signs,
- against feline panleucopenia to prevent mortality and clinical signs,
- against leukaemia to prevent persistent viraemia and clinical signs of the related disease.

Onsets of immunity:
- Rhinotracheitis, calicivirus and panleucopenia components: 1 week after primary vaccination course.
- Feline leukaemia component : 2 weeks after primary vaccination course.

Duration of immunity:
- Rhinotracheitis, calicivirosis and panleucopenia components: 1 year after primary vaccination course and 3 years after the last re-vaccination.
- Feline Leukaemia component: 1 year after the last re-vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Transient apathy and anorexia as well as hyperthermia (lasting usually for 1 or 2 days) were commonly observed during safety and field studies. A local reaction (slight pain at palpation, itching or limited oedema) that disappears within 1 or 2 weeks at most was commonly observed during safety and field studies.

Emesis (mostly within 24 to 48 hours) has been observed in very rare cases based on post-marketing safety experience.

A hypersensitivity reaction has been observed uncommonly in field studies,, which may require appropriate symptomatic treatment

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 treated in 100 animals)
- uncommon (more than 1 but less than 10 animals treated in 1,000 animals)
- 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

Cats

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

Subcutaneous route.

After reconstitution of the lyophilisate with 0.5 ml or 1 ml of the solvent (depending on the presentation chosen) inject one dose of vaccine according to the following vaccination scheme:

Primary vaccination course:
- first injection: from 8 weeks of age.
- second injection: 3 to 4 weeks later.

Where high levels of maternal antibodies against rhinotracheitis, calicivirosis or panleucopenia components are expected to be present (e.g. in kittens of 9 to 12 weeks of age born from queens which were vaccinated before pregnancy and/or with known or suspected previous exposure to the pathogen(s)), the primary vaccination course should be delayed until 12 weeks of age.

Revaccination:
- the first revaccination must be carried out for all components one year after the primary vaccination course.

Subsequent revaccinations:
- Feline leukaemia component: every year.
- Rhinotracheitis, calicivirosis and panleucopenia components: at intervals of up to three years.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitute gently the vaccine in order to obtain a uniform suspension with limited foam formation.
Visual appearance after reconstitution: slightly yellow suspension with presence of cell debris in suspension.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date, which is stated on the label after EXP
Shelf life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

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

Special precautions for use in animals:
It is recommended that a test for FeLV antigenaemia be carried out prior to vaccination.
Vaccination of FeLV positive cats is of no benefit.

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 and lactation:
Do not use during the whole pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered the same day but not mixed with Boehringer Ingelheim adjuvanted vaccine against rabies.

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

Overdose (symptoms, emergency procedures, antidotes):
No effect other than those already mentioned in section on "Adverse reactions" have been observed, except hyperthermia that may exceptionally last 5 days.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the 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 veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

The feline leukaemia vaccine strain is a recombinant canarypox virus expressing the *env* and *gag* genes of FeLV-A. Under field conditions, only sub-group A is infective and immunisation against sub-group A provides full protection against A, B and C. After inoculation, the virus expresses the protective proteins, but does not replicate in the cat. As a consequence, the vaccine induces an immune status against feline leukaemia virus.
The product was shown to reduce excretion of feline calicivirus at onset of immunity and for one year after vaccination.

Plastic box containing:
10 x 1 dose of lyophilisate and 10 x 1 ml of solvent or
50 x 1 dose of lyophilisate and 50 x 1 ml of solvent or
10 x 1 dose of lyophilisate and 10 x 0.5 ml of solvent or
50 x 1 dose of lyophilisate and 50 x 0.5 ml of solvent.

Not all pack sizes may be marketed.