ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fevaxyn Pentofel, suspension for injection for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml (single dose syringe):

Active components	**Relative potency (R.P.)**
Inactivated feline panleucopenia virus, strain CU4	≥ 8.50
Inactivated feline calicivirus, strain 255	≥ 1.26
Inactivated feline rhinotracheitis virus, strain 605	≥ 1.39
Inactivated *Chlamydophila felis*, strain Cello	≥ 1.69
Inactivated feline leukaemia virus, strain 61E	≥ 1.45
Adjuvants	
Ethylene/maleic anhydride (EMA-31)	1% (v/v)
Neocryl	3% (v/v)
Emulsigen SA	5% (v/v)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Vaccine appearance is a pale milky pink liquid which should be free from solid particles.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

For the active immunisation of healthy cats 9 weeks or older against feline panleucopenia and feline leukaemia viruses and against respiratory diseases caused by feline rhinotracheitis virus, feline calicivirus and *Chlamydophila felis.*

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccination does not affect the course of feline leukaemia virus (FeLV) infection in cats already infected with FeLV at the time of vaccination, implying that such cats will excrete FeLV irrespective of vaccination; consequently, these animals will constitute a hazard to susceptible cats in their environment. It is therefore recommended that cats with a significant risk of having been exposed to FeLV be tested for FeLV antigen prior to vaccination. Test negative animals can be vaccinated, while test-positive cats should be isolated from other

cats and retested within 1–2 months. Cats positive at the second testing should be considered as being permanently infected with FeLV and should be handled accordingly. Cats negative at second testing can be vaccinated since, in all likelihood, they have overcome the FeLV infection.

4.5 Special precautions for use

Special precautions for use in animals

In case of anaphylactoid reaction, adrenaline should be administered intramuscularly.
Vaccination of FeLV positive cats is of no benefit. See section 4.4 for further details.

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

To the user:
This veterinary medicinal 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 veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal 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)

Vaccinated cats may develop post-vaccinal reactions including transient fever, vomiting, anorexia and/or depression which usually disappear within 24 hours.

A local reaction with swelling, pain, pruritus or hair loss at the injection site may be observed.

Anaphylactic reactions with oedema, pruritus, respiratory and cardiac distress, severe gastrointestinal signs (including haematemesis and haemorrhagic diarrhoea) or shock have been seen during the first hours after vaccination in very rare cases. See section 4.5 for guidance about 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 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

Pregnancy:
The safety of the vaccine in pregnant queens has not been investigated. Vaccination of pregnant queens is not recommended.

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

The contents of the single dose syringe should be shaken well and administered aseptically by subcutaneous injection. When administering the product, care must be taken to attach the enclosed sterile needle aseptically to the syringe before use.

Basic vaccination of cats *9* weeks and older: two doses at an interval of 3 to 4 weeks. An additional dose is recommended for kittens living in high-risk FeLV environments whose first dose was administered before 12 weeks of age.

Revaccination: one vaccination annually.

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

No undesirable effects other than those observed and mentioned in section 4.6 “Adverse reactions” have been observed.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for felidae, inactivated viral and inactivated bacterial vaccines for cats.
ATC vet code: QI06AL01.

Fevaxyn Pentofel stimulates the development of active immunity against feline panleucopenia virus, feline rhinotracheitis virus, feline calicivirus, *Chlamydophila felis* and feline leukaemia virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Eagles Earles Medium with Hepes

6.2 Major 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Single dose disposable Type I glass syringes containing one dose (l ml) of vaccine. The syringes are sealed with rubber tips.

Packaging:
One cardboard box containing 10, 20 or 25 single dose (1 ml) pre-filled syringes and 10, 20 or 25 sterile needles respectively.

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 product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/96/002/001-003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5 February 1997.
Date of last renewal: 27 February 2007.

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 MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

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

Name and address of the manufacturers of the biological active substances

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

Name and address of the manufacturers responsible for batch release

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR 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 OF 10 x 1 ML SINGLE DOSE SYRINGES, 20 x 1 ML SINGLE DOSE SYRINGES, 25 x 1 ML SINGLE DOSE SYRINGES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fevaxyn Pentofel suspension for injection for cats

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 1 ml:
Inactivated FPV / FCV / FVR / Chlam / FeLV.

Adjuvant: mineral oil.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 x 1 ml single dose syringes
20 x 1 ml single dose syringes
25 x 1 ml single dose syringes

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)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL 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

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/96/002/001	10 x 1 ml
EU/2/96/002/002	20 x 1 ml
EU/2/96/002/003	25 x 1 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SINGLE DOSE SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fevaxyn Pentofel for cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

FPV / FCV / FVR / Chlam / FeLV

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

1 ml

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.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Fevaxyn Pentofel, suspension for injection 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 responsible for batch release:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fevaxyn Pentofel, suspension for injection for cats

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

Per dose of 1 ml (single dose syringe):

Active components	**Relative potency (R.P.)**
Inactivated feline panleucopenia virus, strain CU4	≥ 8.50
Inactivated feline calicivirus, strain 255	≥ 1.26
Inactivated feline rhinotracheitis virus, strain 605	≥ 1.39
Inactivated *Chlamydophila felis*, strain Cello	≥ 1.69
Inactivated feline leukaemia virus, strain 61E	≥ 1.45
Adjuvants	
Ethylene/maleic anhydride (EMA-31)	1% (v/v)
Neocryl	3% (v/v)
Emulsigen SA	5% (v/v)

4. INDICATION(S)

For the active immunisation of healthy cats 9 weeks or older against feline panleucopenia and feline leukaemia viruses and against respiratory diseases caused by feline rhinotracheitis virus, feline calicivirus and *Chlamydophila felis.*

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Vaccinated cats may develop post-vaccinal reactions including transient fever, vomiting, anorexia and/or depression which usually disappear within 24 hours.

A local reaction with swelling, pain, pruritus or hair loss at the injection site may be observed.

Anaphylactic reactions with oedema, pruritus, respiratory and cardiac distress, severe gastrointestinal signs (including haematemesis and haemorrhagic diarrhoea) or shock have been seen during the first hours after vaccination in very rare cases.

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

Cats.

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

1 ml. Subcutaneous use.

Primary vaccination of cats *9* weeks and older: two doses at an interval of 3 to 4 weeks. An additional dose is recommended for kittens living in high-risk feline leukaemia virus (FeLV) environments whose first dose was administered before 12 weeks of age.

Revaccination: one vaccination annually.

9. ADVICE ON CORRECT ADMINISTRATION

The contents of the single dose syringe should be shaken well and administered aseptically by subcutaneous injection. When administering the product, care must be taken to attach the enclosed sterile needle aseptically to the syringe before use.

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.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccination does not affect the course of FeLV infection in cats already infected with FeLV at the time of vaccination, implying that such cats will excrete FeLV irrespective of vaccination; consequently, these animals will constitute a hazard to susceptible cats in their environment. It is therefore recommended that cats with a significant risk of having been exposed to FeLV be tested for FeLV antigen prior to vaccination. Test negative animals can be vaccinated, while test-positive cats should be isolated from other cats and retested within 1–2 months. Cats positive at the second testing should be considered as being permanently infected with FeLV and should be handled accordingly. Cats negative at second testing can be vaccinated since, in all likelihood, they have overcome the FeLV infection.

Special precautions for use in animals:
In case of an anaphylactoid reaction, adrenaline should be administered intramuscularly.
Vaccination of FeLV positive cats is of no benefit.

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

To the user:
This veterinary medicinal 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 veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal 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.

Pregnancy:
The safety of the vaccine in pregnant queens has not been investigated. Vaccination of pregnant queens is not recommended.

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.

Overdose (symptoms, emergency procedures, antidotes):
No undesirable effects other than those mentioned in section 6 have been observed.

Incompatibilities:
Do not mix with any other 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 veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

10 x 1 ml presentation: Box containing 10 single dose prefilled syringes and 10 sterile needles.
20 x 1 ml presentation: Box containing 20 single dose prefilled syringes and 20 sterile needles.
25 x 1 ml presentation: Box containing 25 single dose prefilled syringes and 25 sterile needles.

Not all pack sizes may be marketed.