ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Netvax emulsion for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.5ml) contains:

Active substance:	
Clostridium perfringens Type A alpha toxoid	Not less than 6.8 IU *
Adjuvant	
Light Mineral Oil	0.31 ml
Excipients	
Thiomersal	0.035-0.05 mg

* International units per ml of rabbit serum determined by haemolysis inhibition assay

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection
Off white oily emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

For the active immunization of chickens to provide passive immunisation against necrotic enteritis to their progeny, during the laying period.

To reduce mortality and the incidence and severity of lesions caused by *Clostridium perfringens* Type A induced necrotic enteritis. Efficacy was demonstrated by challenge of chicks approximately three weeks after hatching.

The onset of passive transfer of immunity: 6 weeks following completion of the vaccination procedure

The duration of passive transfer of immunity: 51 weeks following completion of the vaccination procedure

4.3 Contraindications

None

4.4 Special warnings

None.

4.5 Special precautions for use

None

Special precautions for use in animals
None

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

To the user:
This 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 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 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)

No systemic reactions to vaccination were seen following intramuscular vaccination. Vaccination may result in moderate swelling of the breast tissue which will resolve within 30 days. Following the second vaccination swelling may persist for at least 35 days. Swelling was very common.

4.7 Use during pregnancy, lactation or lay

The vaccine is safe for use in laying and breeding birds.

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

Vaccinate chickens by the intramuscular route into the breast.
One dose of 0.5 ml should be given at 10 to 14 weeks of age.
A second dose of 0.5 ml should be administered 4 to 10 weeks after the first vaccination. The second dose should be administered no later than 6 weeks before the onset of lay.
Shake well before use. Syringes and needles must be sterile before use. Follow usual aseptic procedures.

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

After administration of a double dose, local reactions may increase slightly. (see section 4.6)..

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for aves, ATC vet code: QI01AB08

To stimulate active immunity in chickens, in order to provide passive protection to the progeny against *Clostridium perfringens* Type A induced necrotic enteritis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light Mineral Oil
Thiomersal
Formaldehyde
Sorbitan oleate
Polysorbate 80
Benzyl Alcohol
Triethanolamine
EDTA
Sodium Chloride

6.2 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: 18 months.
Shelf-life after first opening the immediate packaging: 8 hours

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

500ml high density polyethylene (HDPE) flexible bottle closed with a chlorobutyl rubber closure held in place with an aluminium seal with centre hole.

Pack Sizes
1 x 500ml
6 x 500ml
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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/093/001
EU/2/09/093/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/04/2009

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance(s)

Schering-Plough Animal Health
33 Whakatiki Street
Upper Hutt
New Zealand

Name and address of the manufacturer responsible for batch release

S-P Veterinary Ltd
Breakspear Road South
Harefield
Uxbridge
UB9 6LS
United Kingdom

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

According to Article 71 of Directive 2001/82/EC as amended, Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

a) the administration of the veterinary medicinal product to animals will interfere with the implementation of a national programme for the diagnosis, control and eradication of animal disease, 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.

D. STATEMENT OF THE MRLs

Pharmacologically active substance(s)	Animal species	Other provisions
Thiomersal	All food producing species	Annex II of Council Regulation (EEC) No. 2377/90
EDTA	All food producing species	Annex II of Council Regulation (EEC) No. 2377/90
Formaldehyde	All food producing species	Annex II of Council Regulation (EEC) No. 2377/90
Mineral oil	All food producing species	Annex II of Council Regulation (EEC) No. 2377/90
Benzyl alcohol	All food producing species	Annex II of Council Regulation (EEC) No. 2377/90

Triethanolamine (at doses up to 0.25 mg/kg bw) is considered not within the scope of Council Regulation (EEC) No. 2377/90.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Netvax
Emulsion for injection for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 0.5ml:
Clostridium perfringens Type A alpha toxoid: ≥ 6.8 IU*
Light mineral oil: 0.31 ml
Thiomersal: 0.035-0.05 mg

* International units per ml of rabbit serum determined by haemolysis inhibition assay

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

1 x 500ml
6 x 500ml

5. TARGET SPECIES

Chickens

6. INDICATION(S)

Vaccine against necrotic enteritis

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Shake well before use. Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – read package leaflet before use.

10. EXPIRY DATE

EXP month/year
Once opened, use within 8 hours

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2ºC- 8ºC). 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 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
5831AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/093/001
EU/2/09/093/002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Netvax
Emulsion for injection for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 0.5ml:
Clostridium perfringens Type A alpha toxoid: ≥ 6.8 IU*
Light mineral oil: 0.31 ml
Thiomersal: 0.035-0.05 mg

* International units per ml of rabbit serum determined by haemolysis inhibition assay

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

1 x 500ml
6 x 500ml

5. TARGET SPECIES

Chickens

6. INDICATION(S)

Vaccine against necrotic enteritis

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Shake well before use. Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – read package leaflet before use.

10. EXPIRY DATE

EXP month/year
Once opened, use within 8 hours

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2ºC- 8ºC).
Do not freeze
Protect from light

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

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
5831AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/093/001
EU/2/09/093/002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR

Netvax emulsion for injection for chickens

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

Marketing authorisation holder :

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

Manufacturer for the batch release:

S-P Veterinary Ltd
Breakspear Road South
Harefield
Uxbridge
Middlesex, UB9 6LS
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Netvax emulsion for injection for chickens

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

One dose (0.5ml) contains:

Active substance:	
Clostridium perfringens Type A alpha toxoid	Not less than 6.8 IU *
Adjuvant	
Light Mineral Oil	0.31 ml
Excipients	
Thiomersal	0.035-0.05 mg

* International units per ml of rabbit serum determined by haemolysis inhibition assay

4. INDICATION(S)

For the active immunization of chickens to provide passive immunisation against necrotic enteritis to their progeny, during the laying period.

To reduce mortality and the incidence and severity of lesions caused by *Clostridium perfringens* Type A-induced necrotic enteritis. Efficacy was demonstrated by challenge of chicks approximately three weeks after hatching.

The onset of passive transfer of immunity: 6 weeks following completion of the vaccination procedure

The duration of passive transfer of immunity: 51 weeks following completion of the vaccination procedure

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

No systemic reactions to vaccination were seen following intramuscular vaccination. Vaccination may result in moderate swelling of the breast tissue which will resolve within 30 days. Following the second vaccination swelling may persist for at least 35 days. Swelling was very common.
After administration of a double dose, local reactions may increase slightly.

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

7. TARGET SPECIES

Chickens

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

Vaccinate chickens by the intramuscular route into the breast.
One dose of 0.5 ml should be given at 10 to 14 weeks of age.
A second dose of 0.5 ml should be administered 4 to 10 weeks after the first vaccination. The second dose should be administered no later than 6 weeks before the onset of lay.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.
Syringes and needles must be sterile before use. Follow usual aseptic procedures.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport refrigerated (2ºC- 8ºC). Do not freeze.
Protect from light.
Do not use after the expiry date stated on the carton.
Shelf-life after first opening the immediate packaging: 8 hours

12. SPECIAL WARNING(S)

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

To the user:
This 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 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 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.

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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

To stimulate active immunity in chickens, in order to provide passive protection to the progeny against *Clostridium perfringens* Type A induced necrotic enteritis.
Pack sizes:
1 x 500ml
6 x 500ml
Not all pack sizes may be marketed

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.