ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza H5N2 emulsion for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.5 ml contains:

Active substance:
Inactivated whole avian influenza virus antigen of H5N2 subtype (strain A/duck/Potsdam/1402/86), inducing an HI titre of ≥ 6.0 $\log_2$ as tested according to the potency test.

Adjuvant:
Liquid light paraffin 234.8 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Sorbitan mono-oleate
Glycine
Water for injections

White to nearly white homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For active immunisation of chickens against avian influenza type A, subtype H5.

Onset of immunity: Efficacy has been evaluated on the basis of preliminary results in chickens. Reduction of clinical signs, mortality and excretion of virus after challenge were shown by three weeks after vaccination.

Duration of immunity: Not established. Serum antibodies could be expected to persist for at least 1 year after administration of two doses of vaccine.

3.3 Contraindications

Do not administer intramuscularly in chickens less than 2 weeks old.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This vaccine has been tested for safety in chickens. If used in other avian species that are considered at risk of infection, its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of birds prior to mass vaccination.
The level of efficacy for other species may differ from that observed in chickens.
The level of efficacy attained may vary depending on the degree of antigenic homology between the vaccine strain and circulating field strains.

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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]

[1] A diffuse swelling which persists for about 14 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See section "Contact details" of the package leaflet.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

For subcutaneous or intramuscular use.

Allow the vaccine to reach a temperature of 15 °C – 25 °C.
Shake well before use.
Use sterile syringes and needles.
It is recommended to use a closed multiject vaccination system.

From 8 – 14 days old: administer 0.25 ml subcutaneously.
From 14 days to 6 weeks old: administer 0.25 ml or 0.5 ml subcutaneously or intramuscularly.
6 weeks and older: administer 0.5 ml subcutaneously or intramuscularly.

Future laying hens and breeders: administer a second 0.5 ml dose 4-6 weeks after the first vaccination.

No information is available on vaccination in the presence of maternally derived antibodies.
Immunisation of progeny from vaccinated birds should therefore be delayed until such antibodies have declined.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Following the administration of a double dose, no adverse events other than those described in section 3.6 have been observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AA23.

The vaccine stimulates active immunity against avian influenza virus type A, subtype H5.

If the circulating avian influenza field virus has a different N component to the N2 included in the vaccine, it may be possible to differentiate between vaccinated and infected birds by using a diagnostic test to detect Neuraminidase antibodies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
PET bottle: 2 years.
Glass bottle: 1 year.

Shelf life after first opening the immediate packaging: use within 8 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Bottle (hydrolytical type II glass or polyethylene terephthalate) of 250 ml or 500 ml closed with a nitryl rubber stopper and sealed with a coded aluminium cap.

Pack sizes:
Cardboard box with one PET or glass bottle of 250 or 500 ml.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/061/001-004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 01/09/2006.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (250 ml, 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza H5N2 emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

One dose of 0.5 ml contains:
Inactivated whole avian influenza virus antigen of H5N2 subtype (strain A/duck/Potsdam/1402/86), inducing an HI titre of ≥ 6.0 $\log_2$ as tested according to the potency test.

3. PACKAGE SIZE

250 ml
500 ml

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use (0.25 to 0.5 ml, depending on the age).

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/06/061/001 (250 ml glass bottle)
EU/2/06/061/002 (500 ml glass bottle)
EU/2/06/061/003 (250 ml PET bottle)
EU/2/06/061/004 (500 ml PET bottle)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE LABEL (PET, GLASS)
250 ml, 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza H5N2 emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

250 ml
500 ml

Inactivated whole avian influenza virus antigen of H5N2 subtype (strain A/duck/Potsdam/1402/86), inducing an HI titre of ≥6.0 $\log_2$/dose

3. TARGET SPECIES

Chickens

4. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobilis Influenza H5N2 emulsion of injection for chickens

2. Composition

One dose of 0.5 ml contains:

Active substance:
Inactivated whole avian influenza virus antigen of H5N2 subtype (strain A/duck/Potsdam/1402/86), inducing an HI titre of ≥ 6.0 $\log_2$ as tested according to the potency test.

Adjuvant:
Liquid light paraffin 234.8 mg

White to nearly white homogeneous emulsion.

3. Target species

Chickens.

4. Indications for use

For active immunisation of chickens against avian influenza type A, subtype H5.

Onset of immunity:
Efficacy has been evaluated on the basis of preliminary results in chickens. Reduction of clinical signs, mortality and excretion of virus after challenge were shown by three weeks after vaccination.
Duration of immunity: Not established. Serum antibodies could be expected to persist for at least 1 year after administration of two doses of vaccine.

5. Contraindications

Do not administer intramuscularly in chickens less than 2 weeks old.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
This vaccine has been tested for safety in chickens. If used in other avian species that are considered at risk of infection, its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of birds prior to mass vaccination.
The level of efficacy for other species may differ from that observed in chickens.
The level of efficacy attained may vary depending on the degree of antigenic homology between the vaccine strain and circulating field strains.

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 veterinary medicinal 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.

Special precautions for the protection of the environment:
Not applicable.

Laying birds:
The safety of the veterinary medicinal product has not been established during lay.

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.

Overdose:
Following the administration of a double dose, no adverse events other than those described under section “Adverse events” have been observed.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State’s competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]

[1] A diffuse swelling which persists for about 14 days.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

For subcutaneous or intramuscular use.

From 8 – 14 days old: 0.25 ml subcutaneously.
From 14 days to 6 weeks old: 0.25 ml or 0.5 ml subcutaneously or intramuscularly.
6 weeks and older: 0.5ml subcutaneously or intramuscularly.

Future laying hens and breeders: administer a second 0.5 ml dose 4-6 weeks after the first vaccination.

No information is available on vaccination in the presence of maternally derived antibodies.
Immunisation of progeny from vaccinated birds should therefore be delayed until such antibodies have declined.

9. Advise on correct administration

Allow the vaccine to reach a temperature of 15 °C – 25 °C.
Shake well before use.
Use sterile syringes and needles. It is recommended to use a closed multiject vaccination system.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 8 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/06/061/001-004.

Pack sizes:
Cardboard box with one 250 ml or 500 ml glass bottle.
Cardboard box with one 250 ml or 500 ml PET bottle.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)..

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands.

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: +420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: +30 210 989 7452

Latvija
Tel: + 37052196111

Slovenská republika
Tel: +420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

17. Other information

If the circulating avian influenza field virus has a different N component to the N2 included in the vaccine, it may be possible to differentiate between vaccinated and infected birds by using a diagnostic test to detect Neuraminidase antibodies.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Union legislation on the control of Avian Influenza.