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:
For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White homogeneous emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

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

Serum antibodies could be expected to persist for at least 12 months after administration of two doses of vaccine.

4.3 Contraindications

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

4.4 Special warnings for each 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.

4.5 Special precautions for use

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)

A transient diffuse swelling may very commonly occur at the vaccination site, which persists for about 14 days.

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

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

4.8 Interactions 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

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 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.

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

Following the administration of a double dose, no adverse reactions other than those described in section 4.6 have been observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Aves*; Inactivated viral vaccines, avian influenza virus.

ATC-vet code: QI01AA23.

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

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.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid light paraffin
Polysorbate 80
Sorbitane mono-oleate
Glycine

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:
PET vials: 2 years.
Glass vials: 1 year.

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box with 250 or 500 ml hydrolytical type II glass or polyethylene terephthalate (PET) bottles. The bottles are closed with a nitryl rubber stopper and sealed with a coded aluminium cap.

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

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

8. MARKETING AUTHORISATION NUMBER

EU/2/06/061/001-004

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01/09/2006
Date of last renewal: 23/08/2011

10. DATE OF REVISION OF THE TEXT

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

The manufacture, import, possession, sale, supply and/or use of Nobilis Influenza H5N2 may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and/or use Nobilis Influenza H5N2 must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, 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 AND USE

C. STATEMENT OF THE MRLs

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

Name and address of the manufacturers of the biological active substance

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Intervet International BV, site De Bilt
Ambachtstraat 2-6
3732 CN De Bilt
Netherlands

Merck Sharp & Dohme Animal Health S.L.
Poligono Industrial El Montalvo I
C/Zeppelin 6, Parcela 38
37008 Carbajosa de la Sagrada
Salamanca
Spain

Name and address of the manufacturer responsible for batch release
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND 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, prohibitthe manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or 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 product is intended to confer immunity is largely absent from the territory in question.

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

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX
250ml; 500ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza H5N2 emulsion for injection for chickens

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.

Adjuvant:
Liquid light paraffin 234.8 mg

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

250 ml
500 ml

5. TARGET SPECIES

Chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze.

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.

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

14. THE WORDS "KEEP OUT OF THE SIGHTAND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/061/001-004

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING

BOTTLE LABEL
250ml/500ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza H5N2 emulsion for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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.

Adjuvant: Liquid light paraffin 234.8 mg

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

250 ml
500 ml

4. ROUTE(S) OF ADMINISTRATION

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

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use within 8 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Nobilis Influenza H5N2 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 and manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza H5N2 emulsion of injection for chickens.

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

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.

4. INDICATION(S)

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

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.

Serum antibodies could be expected to persist for at least 12 months after administration of two doses of vaccine.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

A transient diffuse swelling may very commonly occur at the vaccination site, which persists for about 14 days.

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

Chickens.

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 or 0.5ml 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. ADVICE 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 PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C). Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf life after first opening the container: 8 hours.

12. SPECIAL WARNINGS

Special warnings for each 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
Special warning for 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.

Lay
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.

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

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 Community legislation on the control of Avian Influenza.

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

Not all pack sizes may be marketed.