ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB Primo QX lyophilisate and solvent for oculonasal suspension for chickens
Nobilis IB Primo QX lyophilisate for oculonasal suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance:
Avian infectious bronchitis virus (IBV), type QX, strain D388, live: $10^{4.0} – 10^{5.5}$ EID_{50}[1]

[1] EID_{50}: 50% egg infective dose - the virus titre required to produce infection in 50% of the eggs inoculated

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sorbitol
Hydrolysed gelatine
Pancreatic digest of casein
Disodium phosphate dihydrate
Solvent:
Patent Blue V (E131)
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Disodium edetate dihydrate
Sodium chloride
Sodium hydroxide or hydrochloric acid (for pH adjustment)
Water for injections

Lyophilisate: off-white, predominantly sphere shaped.
Solvent (Solvent Oculo/Nasal): blue-coloured solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For active immunisation of chickens in order to reduce respiratory signs of avian infectious bronchitis caused by QX-like variants of infectious bronchitis virus (IBV).

Onset of immunity: 3 weeks.
Duration of immunity: 8 weeks.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The vaccine has been demonstrated to provide protection against QX-like variant. The protection against other circulating IB strains has not been investigated.

3.5 Special precautions for use

Special precautions for safe use in the target species:

All chickens on the site should be vaccinated at the same time.

The vaccine virus is capable of spreading to in contact birds for a minimum of 20 days after vaccination and appropriate care should be taken to separate vaccinated from non-vaccinated chickens. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided. Precautionary measures should be taken to prevent spreading to wildlife. The premises must be cleaned and disinfected after each production round.

This vaccine should only be used after it has been established that the QX-like IBV variant strain is epidemiologically relevant. It is important to avoid introduction of the IB D388 vaccine virus into premises in which the wild type strain is not present. The IB D388 vaccine should only be applied in hatcheries to chickens from 1 day of age or older if adequate controls are in place to avoid the spread of the vaccine virus to birds that will be transported to non-IB QX exposed flocks.

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

In case of coarse spray, personal protective equipment consisting of masks with eye protection should be worn when handling the veterinary medicinal product. Wash and disinfect hands and equipment after vaccination to avoid the spread of the virus.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Respiratory signs[1], Nasal discharge[1]

[1] Mild transient respiratory reaction that may occur for at least 10 days after vaccination.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
The safety of Nobilis IB Primo QX has been demonstrated when administered during lay. The efficacy of Nobilis IB Primo QX has not been demonstrated when administered during lay.

A decision to use this vaccine during lay should be made on a case by case basis.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Nobilis IB Ma5 for spray or oculonasal application. Simultaneous use of both vaccines increases the risk of recombination of viruses and potential emergence of new variants. However, the chance of a hazard occurring has been estimated very low. For the mixed products the onset of immunity is 3 weeks, and the duration of immunity is 8 weeks for the claimed protection against Massachusetts and QX-like strains of IBV. The safety parameters of the mixed vaccines are not different from those described for the vaccines administered separately. Read the product information of Nobilis IB Ma5 before use.

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

3.9 Administration routes and dosage

Oculonasal use.
The method of administration is by coarse spray or by oculonasal administration.

Administer 1 dose of reconstituted vaccine by coarse spray or by oculonasal method to chickens from 1 day of age or older. Cups may contain 3 spheres to up to 400 spheres depending on the required dosages and production yields. Do not use the product if the contents are brownish and stick to the container as this indicates that the integrity of the container has been breached.

Reconstitute the lyophilisate immediately and entirely after opening of the cup.

Coarse spray:
When spray devices are used it is advisable to consult the technical staff of the distributors before using this technique. Apply coarse spray ≥ 250 micrometres. All containers used for reconstitution should be clean and free from any traces of detergent or disinfectant.

1) Reconstitute the lyophilisate using water of good quality (e.g. free from chlorine and/or disinfectants). Measure the correct volume of water for the number of birds to be vaccinated (depends on devices used).
2) Add the contents of the correct number of cups while stirring.
3) Mix thoroughly with a clean stirrer, ensuring that all vaccine is dissolved. After reconstitution the suspension looks clear.
4) Spray on birds immediately.

Oculonasal use:
Solvent Oculo/Nasal should be used for oculonasal application.

1) The contents of a cup (1 000 doses only) can be added to Solvent Oculo/Nasal using the included adapter and administered after connecting the included dropper.
2) Shake the vaccine suspension. After reconstitution the suspension looks clear.
3) One drop containing one dose should be applied into one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird.

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

Very mild inflammatory changes have occasionally been found in the kidneys of specific pathogen free (SPF) chickens after administration of a 10-fold overdose.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD07.

To stimulate active immunity against the D388/QX type of avian infectious bronchitis virus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Nobilis IB Ma5 or Solvent Oculo/Nasal recommended for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the lyophilisate as packaged for sale: 2 years.
Shelf life of the solvent as packaged for sale: 4 years.
Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

Lyophilisate:
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

Solvent:
Store below 25 °C.
Do not freeze.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Sealed aluminium laminate cup with a polypropylene (cup) and polypropylene/polyethylene (lid) contact layer.

Solvent (Solvent Oculo/Nasal):
Low density polyethylene (LDPE) vial of 35 ml with a halogenobutyl rubber stopper and aluminium cap.

Pack sizes:
Cardboard box with 10 cups of 1 000 doses, 2 500 doses, 5 000 doses or 10 000 doses.
Cardboard box with 10 cups of 1 000 doses + cardboard box with 10 vials of solvent supplemented with dropper and adapter.
PET plastic box with 12 cups of 1 000 doses, 2 500 doses or 5 000 doses.

PET plastic box with 6 cups of 10 000 doses.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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/2/14/174/001–009

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 04/09/2014.

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 with 10 cups of lyophilisate
PET PLASTIC BOX 6 or 12 cups of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB Primo QX lyophilisate for oculonasal suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Avian infectious bronchitis virus (IBV), type QX, strain D388, live: $10^{4.0} – 10^{5.5}$ EID_{50}*/dose

*EID_{50}: 50% egg infective dose

3. PACKAGE SIZE

10 x 1 000 doses
10 x 2 500 doses
10 x 5 000 doses
10 x 10 000 doses
12 x 1 000 doses
12 x 2 500 doses
12 x 5 000 doses
6 x 10 000 doses

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oculonasal use (coarse spray or oculonasal administration).

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

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/2/14/174/001 (10 x 1 000 doses)
EU/2/14/174/002 (10 x 1 000 doses + 10 x 35 ml solvent)
EU/2/14/174/003 (10 x 5 000 doses)
EU/2/14/174/004 (10 x 10 000 doses)
EU/2/14/174/005 (10 x 2 500 doses)
EU/2/14/174/006 (12 x 1 000 doses)
EU/2/14/174/007 (12 x 2 500 doses)
EU/2/14/174/008 (12 x 5 000 doses)
EU/2/14/174/009 (6 x 10 000 doses)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX with 10 vials of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent Oculo/Nasal for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

3. PACKAGE SIZE

10 x 35 ml

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Read the vaccine package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
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/2/14/174/002

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – Lyophilisate cups

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB Primo QX

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 000 doses (3-100 spheres)
2 500 doses (3-100 spheres)
5 000 doses (3-100 spheres)
10 000 doses (3-400 spheres)

Live IBV, D388

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING

LABEL - Solvent VIALS

1. NAME OF THE VETERINARY PRODUCT

Solvent Oculo/Nasal

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

35 ml

3. ROUTE OF ADMINISTRATION

Read the vaccine package before use.

4. STORAGE CONDITIONS

Store below 25 °C.
Do not freeze.

5. BATCH NUMBER

Lot

6. EXPIRY DATE

Exp.

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobilis IB Primo QX lyophilisate and solvent for oculonasal suspension for chickens
Nobilis IB Primo QX lyophilisate for oculonasal suspension for chickens

2. Composition

Each dose of reconstituted vaccine contains:

Active substance:
Avian infectious bronchitis virus (IBV), type QX, strain D388, live: $10^{4.0} – 10^{5.5}$ EID_{50}[1]

[1] EID_{50}: 50% egg infective dose - the virus titre required to produce infection in 50% of the eggs inoculated.

Lyophilisate: off-white, predominantly sphere shaped.
Solvent (Solvent Oculo/Nasal): blue-coloured solution.

3. Target species

Chickens.

4. Indications for use

For active immunisation of chickens in order to reduce respiratory signs of avian infectious bronchitis caused by QX-like variants of infectious bronchitis virus (IBV).

Onset of immunity: 3 weeks.
Duration of immunity: 8 weeks.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
The vaccine virus is capable of spreading to in contact birds for a minimum of 20 days after vaccination and appropriate care should be taken to separate vaccinated from non-vaccinated chickens. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided. Precautionary measures should be taken to prevent spreading to wildlife. The premises must be cleaned and disinfected after each production round.

This vaccine should only be used after it has been established that the QX-like IBV variant strain is epidemiologically relevant. It is important to avoid introduction of the IB D388/QX vaccine virus into premises in which the wild type strain is not present. The IB D388/QX vaccine should only be applied

in hatcheries to chickens from 1 day of age or older if adequate controls are in place to avoid the spread of the vaccine virus to birds that will be transported to non-IB QX exposed flocks.
The vaccine has been demonstrated to provide protection against QX-like variant. The protection against other circulating IB strains has not been investigated.

All chickens on the site should be vaccinated at the same time.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of coarse spray, personal protective equipment consisting of masks with eye protection should be worn when handling the veterinary medicinal product. Wash and disinfect hands and equipment after vaccination to avoid the spread of the virus.

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

Laying birds:
The safety of Nobilis IB Primo QX has been demonstrated when administered during lay. The efficacy of Nobilis IB Primo QX has not been demonstrated when administered during lay.
A decision to use this vaccine during lay should be made on a case by case basis.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Nobilis IB Ma5 for spray or oculonasal application. Simultaneous use of both vaccines increases the risk of recombination of viruses and potential emergence of new variants. However, the chance of a hazard occurring has been estimated very low. For the mixed products the onset of immunity is 3 weeks and the duration of immunity is 8 weeks for the claimed protection against Massachusetts and QX-like strains of IBV. The safety parameters of the mixed vaccines are not different from those described for the vaccines administered separately. Read the package leaflet of Nobilis IB Ma5 before use.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product 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:
Very mild inflammatory changes have occasionally been found in the kidneys of specific pathogen free (SPF) chickens after administration of a 10-fold overdose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except Nobilis IB Ma5 or Solvent Oculo/Nasal recommended for use with the veterinary medicinal product.

7. Adverse events

Chickens:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Respiratory signs[1], Nasal discharge[1]

[1] Mild transient respiratory reaction that may occur for at least 10 days after vaccination.

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

After reconstitution, administer 1 dose of vaccine by coarse spray or by the oculonasal route of administration to chickens from 1 day of age or older.

9. Advice on correct administration

Cups may contain 3 spheres to up to 400 spheres depending on the required dosages and production yields. Do not use the product if the contents are brownish and stick to the container as this indicates that the integrity of the container has been breached. Reconstitute the lyophilisate immediately and entirely after opening of the cup.

Administration routes:

Coarse spray:
When spray devices are used it is advisable to consult the technical staff of the distributors before using this technique. Apply coarse spray ≥ 250 micrometre. All containers used for reconstitution should be clean and free from any traces of detergent or disinfectant.

1) Reconstitute the lyophilisate using water of good quality (e.g. free from chlorine and/or disinfectants). Measure the correct volume of water for the number of birds to be vaccinated (depends on devices used).
2) Add the contents of the correct number of cups while stirring.
3) Mix thoroughly with a clean stirrer, ensuring that all vaccine is dissolved. After reconstitution the suspension looks clear.
4) Spray on birds immediately.

Oculonasal use:
Solvent Oculo/Nasal should be used for oculonasal application.

1) The contents of a cup (1000 doses only) can be added to Solvent Oculo/Nasal using the included adapter and administered after connecting the included dropper.
2) Shake the vaccine suspension. After reconstitution the suspension looks clear.
3) One drop containing one dose should be applied into one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Lyophilisate: Store in a refrigerator (2 °C – 8 °C). Do not freeze. Protect from light.
Solvent: Store below 25 °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 reconstitution according to directions: 2 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/2/14/174/001–009

Pack sizes:
Cardboard box with 10 cups of 1 000 doses, 2 500 doses, 5 000 doses or 10 000 doses.
Cardboard box with 10 cups of 1 000 doses + cardboard box with 10 x 35 ml vial of solvent supplemented with dropper and adapter.
PET plastic box with 12 cups of 1 000 doses, 2 500 doses or 5 000 doses.
PET plastic box with 6 cups of 10 000 doses.

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

Lietuva
Tel: + 37052196111

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

Magyarország
Tel.: + 36 1 439 4597

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

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: +30 210 989 7452

Latvija
Tel: + 37052196111

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

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

Nobilis IB Primo QX is intended to protect chickens against clinical signs of disease caused by IBV variant strain D388 only and should not be used as a replacement for other IBV vaccines. Chickens should be vaccinated against other prevalent IBV serotypes (e.g. Massachusetts) according to the local IB vaccination programme.