ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB Primer lyophilisate for suspension for oculonasal use, ocular use or use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substances:

Avian infectious bronchitis virus, strain H120, Massachusetts, Live: $10^{3.0} – 10^{5.4}$ EID_{50}*
Avian infectious bronchitis virus, strain D274, Live: $10^{3.0} – 10^{5.4}$ EID_{50}*

*EID_{50} = 50% embryo infective dose.

Excipients:

Qualitative composition of excipients and other constituents
D-Mannitol
Gelatin
Myo-Inositol
NZ Case Plus

Off-white to cream coloured lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For active immunisation of chickens against Massachusetts serotype strains and D274 like strains of avian infectious bronchitis virus (IBV).

Onset of immunity: 27 days after vaccination.
Duration of immunity: 16 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The vaccine strain may spread to unvaccinated chickens. Safety and reversion to virulence trials have shown that the vaccine strain is safe for chickens. It is recommended to vaccinate all birds on a site at the same time.

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

Personal protective equipment consisting of goggles and dust masks or a helmet with filtered air circulation should be worn when handling the veterinary medicinal product especially while vaccination according to the spraying method.

Personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots).

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]

[1]Generally mild and transient in nature.

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 its local representative> 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 the veterinary medicinal product has been demonstrated when administered during lay.

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 administered from day of age onwards by coarse spray and eyedrop before administration of Poulvac IB QX (where authorised) with a 7 to 14 day interval between both administrations. For the associated use, the onset of immunity is 21 days after the Poulvac IB QX vaccination for the claimed protection against QX-like IBV strain and the onset of immunity is 27 days against Massachusetts serotype and D274-like strains of IBV after the Poulvac IB Primer vaccination. An onset of immunity of 21 days after the second vaccination against IBV Variant 2 (IS-1494-like) and 793B serotype strains has also been established for the associated use, with Poulvac IB QX as detailed above, as demonstrated by a reduction of respiratory signs caused by Variant 2 (IS-1494-like) and 793B serotype strains of IBV (as assessed by the ciliary activity of tracheal explants). The possible interference of MDAs on efficacy against Variant 2 and 793B serotype strains was not investigated. The safety parameters and adverse events are not different from those described for the vaccines administered separately.

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

Vaccination scheme:
Broilers: vaccination from first day of life.
Future layers or breeders: vaccination from first day of life or during the 3rd to 4th week of life for immediate protection of young chickens and priming for subsequent vaccinations with an inactivated vaccine.
Layer or breeders: vaccination from onset of lay.

One dose of vaccine per bird administered by spray, eye drop or drinking water. The amount of water to be used depends on the method of administration:

For spray administration (oculonasal use):
Dilute and administer the reconstituted vaccine at a rate of one dose of reconstituted vaccine per bird, according to the directions of your specific coarse spray vaccination equipment. Recommended volume for one dose is between 0.1 and 0.5 ml.
The spray device used must be set to a droplet size of 0.12 to 0.15 mm in diameter. The distance from the spray head to the bird should be approximately 50 cm.

During spraying and for about 20 - 30 minutes thereafter, ventilation should be switched off or reduced. Dimming light sources is recommended to avoid unsettling the animals.

For eye drop administration (ocular use):
50 ml per 1,000 birds.
One drop (0.05 ml) of the vaccine solution is administered into an eye. In doing so, the head of the animal must be fixed so that the drop does not run down. 1,000 doses of the vaccine are dissolved in 50 ml water.

For drinking water administration (use in drinking water):
Depending on the age of the birds: The amount of water in litres per 1,000 chickens should be set according to the age of the chickens in days (up to a maximum of 40 litres).

Water containing a high level of chlorine or metal ions should not be used and conduit pipes, tubing, etc. should be thoroughly clean and free of traces of disinfectants and detergents. It is recommended to add protective proteins in the form of skimmed milk powder (2 g per litre of water) or skimmed milk (1 litre per 50 litres of water) to the water.

The birds should be deprived from water about 2 hours before vaccination. For vaccination, use as many litres of water as the age of the birds in days, per 1,000 birds, up to a maximum of 40 litres as indicated above.

Prepare the amount of vaccine to be used within 4 hours. Remove the sealing cap and stopper from the vaccine vial and suspend the vaccine in the corresponding amount of water and mix carefully. Care should be taken to empty the ampoule completely and administer the diluted vaccine immediately. Make sure that birds do not have access to untreated water until the treated water has been consumed.

One day before and after vaccination no drugs or disinfectants should be applied to the chickens.

Upon reconstitution, transparent to white opaque suspension (depending on the volume of water used).

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

Administration of a 10-fold overdose does not result in symptoms different from those mentioned under section 3.6 “Adverse events”.

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

The vaccine provides active immunisation against avian infectious bronchitis virus (IBV) Massachusetts and D274 like strains.

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: 18 months.
Shelf life after reconstitution according to directions: 4 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I glass vials closed with a Type I chlorobutyl rubber stopper and sealed with an aluminium cap.
The vaccine is supplied in boxes of ten vials of 1,000, 2,500 or 5,000 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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: *To be completed nationally.*

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

To be completed nationally.

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of ten glass vials of 1,000, 2,500 or 5,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB Primer lyophilisate for suspension for oculonasal use, ocular use or use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Avian infectious bronchitis virus, strain H120, Massachusetts, Live: $10^{3.0} – 10^{5.4}$ EID_{50}/dose*
Avian infectious bronchitis virus, strain D274, Live: $10^{3.0} – 10^{5.4}$ EID_{50}/dose*
*EID_{50} = 50% embryo infective dose.

3. PACKAGE SIZE

10 x 1,000 doses
10 x 2,500 doses
10 x 5,000 doses

4. TARGET SPECIES

Chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spraying, eye drops or use in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
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

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials with 1,000 / 2,500 / 5,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB Primer

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Avian Infectious Bronchitis Virus, strain H120, Massachusetts, Live: $10^{3.0} – 10^{5.4}$ EID_{50}/dose
Avian Infectious Bronchitis Virus, strain D274, Live: $10^{3.0} – 10^{5.4}$ EID_{50}/dose

1,000 doses
2,500 doses
5,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Poulvac IB Primer lyophilisate for suspension for oculonasal use, ocular use or use in drinking water for chickens

2. Composition

Each dose contains:

Active substances:

Avian infectious bronchitis virus, strain H120, Massachusetts, Live: $10^{3.0} – 10^{5.4}$ EID_{50}*
Avian infectious bronchitis virus, strain D274, Live: $10^{3.0} – 10^{5.4}$ EID_{50}*

*EID_{50} = 50% embryo infective dose.

Off-white to cream coloured lyophilisate.

3. Target species

Chickens.

4. Indications for use

For active immunisation of chickens against Massachusetts serotype strains and D274 like strains of avian infectious bronchitis virus (IBV).

Onset of immunity: 27 days after vaccination.
Duration of immunity: 16 weeks after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
The vaccine strain may spread to unvaccinated chickens. Safety and reversion to virulence trials have shown that the vaccine strain is safe for chickens. It is recommended to vaccinate all birds on a site at the same time.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of goggles and dust masks or a helmet with filtered air circulation should be worn when handling the veterinary medicinal product especially while vaccination according to the spraying method.

Personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots).

Laying birds:
The safety of the medicinal product has been demonstrated when administered during lay.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered from day of age onwards by coarse spray and eyedrop before administration of Poulvac IB QX (where authorised) with a 7 to 14 day interval between both administrations. For the associated use, the onset of immunity is 21 days after the Poulvac IB QX vaccination for the claimed protection against QX-like IBV strain and the onset of immunity is 27 days against Massachusetts serotype and D274-like strains of IBV after the Poulvac IB Primer vaccination. An onset of immunity of 21 days after the second vaccination against IBV Variant 2 (IS-1494-like) and 793B serotype strains has also been established for the associated use, with Poulvac IB QX as detailed above, as demonstrated by a reduction of respiratory signs caused by Variant 2 (IS-1494-like) and 793B serotype strains of IBV (as assessed by the ciliary activity of tracheal explants). The possible interference of MDAs on efficacy against Variant 2 and 793B serotype strains was not investigated. The safety parameters and adverse events are not different from those described for the vaccines administered separately.

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:
Administration of a 10-fold overdose does not result in symptoms different from those mentioned under section 7 “Adverse events”.

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

7. Adverse events

Chickens:

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

[1]Generally mild and transient in nature.

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 <or its local representative> 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

Broilers: vaccination from first day of life.
Future layers or breeders: vaccination from first day of life or during the 3rd to 4th week of life for immediate protection of young chickens and priming for subsequent vaccinations with an inactivated vaccine.
Layer or breeders: vaccination from onset of lay.

One dose of vaccine per bird administered by spray, eye drop or drinking water. The amount of water to be used depends on the method of administration.

9. Advice on correct administration

For spray administration (oculonasal use):
Dilute and administer the reconstituted vaccine at a rate of one dose of reconstituted vaccine per bird, according to the directions of your specific coarse spray vaccination equipment. Recommended volume for one dose is between 0.1 and 0.5 ml.
The spray device used must be set to a droplet size of 0.12 to 0.15 mm in diameter. The distance from the spray head to the bird should be approximately 50 cm.

During spraying and for about 20 - 30 minutes thereafter, ventilation should be switched off or reduced. Dimming light sources is recommended to avoid unsettling the animals.

For eye drop administration (ocular use):
50 ml per 1,000 birds.
One drop (0.05 ml) of the vaccine solution is administered into an eye. In doing so, the head of the animal must be fixed so that the drop does not run down. 1,000 doses of the vaccine are dissolved in 50 ml water.

For drinking water administration (use in drinking water):
Depending on the age of the birds: The amount of water in litres per 1,000 chickens should be set according to the age of the chickens in days (up to a maximum of 40 litres).

Water containing a high level of chlorine or metal ions should not be used and conduit pipes, tubing, etc. should be thoroughly clean and free of traces of disinfectants and detergents. It is recommended to add protective proteins in the form of skimmed milk powder (2 g per litre of water) or skimmed milk (1 litre per 50 litres of water) to the water.

The birds should be deprived from water about 2 hours before vaccination. For vaccination, use as many litres of water as the age of the birds in days, per 1,000 birds, up to a maximum of 40 litres as indicated above.

Prepare the amount of vaccine to be used within 4 hours. Remove the sealing cap and stopper from the vaccine vial and suspend the vaccine in the corresponding amount of water and mix carefully. Care should be taken to empty the ampoule completely and administer the diluted vaccine immediately. Make sure that birds do not have access to untreated water until the treated water has been consumed.

One day before and after vaccination no drugs or disinfectants should be applied to the chickens.

Upon reconstitution, transparent to white opaque suspension (depending on the volume of water used).

10. Withdrawal periods

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. Protect from light.
Do not use this veterinary medicinal product after the expiry date stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: 4 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

To be completed nationally.

The vaccine is supplied in boxes of ten vials of 1,000, 2,500 or 5,000 doses.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

To be completed nationally.

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 contact details to report suspected adverse events>:
To be completed nationally.

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

<Local representatives <and contact details to report suspected adverse events>:>
To be completed nationally (if applicable).

17. Other information

The vaccine provides active immunisation against avian infectious bronchitis virus (IBV) Massachusetts and D274 like strains.