ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro AE
Suspension for use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each dose contains:
Avian encephalomyelitis virus, strain 1143 Calnek, live $10^{3.0}$ - $10^{4.5}$ EID_{50}*

*EID_{50} = 50 % embryo infective dose: the viral titre required to induce an infection in 50 % of embryos inoculated with the virus.

Excipients:

Qualitative composition of excipients and other constituents
Disodium hydrogen phosphate
Lactose monohydrate
Potassium dihydrogen phosphate
Skim milk powder
Water for injections

Appearance: yellow-brown, cloudy liquid

3. CLINICAL INFORMATION

3.1 Target species

Chickens

3.2 Indications for use for each target species

For active immunisation of future layers and breeding chickens from 10 weeks of age against avian encephalomyelitis virus, to prevent vertical transmission of the virus and to induce passive immunity in embryos and young chickens against infection with avian encephalomyelitis virus.

Onset of immunity: 10 weeks demonstrated by challenge of progeny. Specific antibodies are detected from 3 weeks post-vaccination onwards in vaccinated animals.

Duration of immunity: 39 weeks demonstrated by challenge of progeny. Specific antibodies are detected at least until 44 weeks post-vaccination in vaccinated animals.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
Eggs of vaccinated breeding birds may be used for breeding purposes not earlier than 4 weeks after vaccination.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The vaccine virus is able to spread horizontally from vaccinated to non-vaccinated chickens. Avian encephalomyelitis virus can naturally infect partridges, turkeys, pheasants, and pigeons.
Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to non-vaccinated chickens, partridges, turkeys, pheasants, pigeons, and other susceptible species. All animals in the population must be vaccinated at the same time.

To avoid additional stress for the vaccinated animals, no other immunisations should be performed for two weeks before and after the vaccination against avian encephalomyelitis.

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

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:
None known.

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:
Do not use in birds in lay or breeding birds and within 4 weeks before the start of the laying period.

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 administration via drinking water.
One vaccine dose per animal aged 10 weeks and older.
All animals of the population must be vaccinated.

The vaccine should be dissolved in the amount of drinking water consumed by the animals within 2 hours. The vaccine must be administered to the drinkers immediately after dissolution so that it is consumed by the animals within 2 hours at most after dilution.

To ensure the vaccine is consumed quickly, drinking water should be withheld from the animals for 1 -2 hours prior to vaccination. It must be ensured that all animals have adequate access to the vaccine suspension, but not have access to normal drinking water until the vaccine has been consumed.

Administration via drinking water

- Determine the required number of vaccine doses and the quantity of water (see below).
- Use the total contents of the vaccine bottles per one chicken house or drinker systems.
- All equipment used for vaccination (lines, hoses, drinkers etc.) should be thoroughly cleaned and must be free from residues of cleaning agents and disinfectants.
- Use only cool, clean, and fresh water, preferably free of chlorine and metal ions. Skimmed milk powder (2 - 4 g/litre water) or skimmed milk (20 - 40 ml/litre water) can improve the quality of the drinking water and prolong the activity of the vaccine; however, this supplement should be added to the water 10 minutes **before** adding the vaccine.
- Open the vaccine bottle under water and dilute its contents. Ensure that any remaining vaccine is completely emptied by rinsing the bottle and rubber stopper with water.
- Lines filled with water must be emptied before administering the vaccine suspension.

Add the diluted vaccine suspension to cold, fresh water such that, as a rule of thumb, 1,000 vaccine doses are dissolved in one litre of water per age in days for 1,000 chickens, e. g. 10 litres would be required for 1,000 chickens aged 10 days old.

Under hot climatic conditions and for heavy breeds, this amount may be increased to a maximum of 40 litres per 1,000 animals. In case of doubt, the daily water consumption should be determined before vaccination.

To reduce the risk of infection before the onset of immunity, the litter should be removed, and the chicken house cleaned between treatment cycles in the breeding unit.

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

No adverse reactions have been observed after 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:

QI01AD02

The vaccine contains the enterotropic avian encephalomyelitis virus strain 1143 Calnek which is not adapted to eggs. The parent animals are vaccinated at a time, in which they are usually age-resistant to

the disease. The purpose of the vaccination is the development of neutralising maternal antibodies that are transmitted via the yolk sack to the chicks to protect them against infection during the first few weeks of life.

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: 1 year.
Shelf life after dilution according to directions: 2 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Protect from frost.
Protect from direct sunlight.

Protect finished vaccine suspension against direct sunlight and temperature above 25°C as well as frost.

5.4 Nature and composition of immediate packaging

Glass vial Type I (Ph. Eur.) with type I rubber closure. The vials are sealed with aluminium tear-off caps.

The vaccine is available in the following pack sizes:
Pack with 1,000 vaccine doses
Pack with 2,500 vaccine doses
Pack with 5,000 vaccine doses
Pack with 10,000 vaccine doses

Bundle packaging:
Pack with 10 x 1,000 vaccine doses
Pack with 10 x 2,500 vaccine doses
Pack with 10 x 5,000 vaccine doses
Pack with 10 x 10,000 vaccine 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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

{DD/MM/YYYY}

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

{AT, DE, ES, FR:} 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

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro AE Suspension for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains avian encephalomyelitis virus, strain 1143 Calnek, live, $10^{3.0}$ - $10^{4.5}$ EID_{50}

3. PACKAGE SIZE

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

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

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use

7. WITHDRAWAL PERIODS

Withdrawal period: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once diluted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protect from frost.
Protect from direct sunlight.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro AE

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

AE virus, strain 1143 Calnek, live

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once diluted use within 2 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AviPro AE Suspension for use in drinking water

2. Composition

Each dose contains:

Active substance:
Avian encephalomyelitis virus, strain 1143 Calnek, live $10^{3.0}$ - $10^{4.5}$ EID_{50}*

*EID_{50} = 50 % embryo infective dose: the viral titre required to induce an infection in 50 % of embryos inoculated with the virus

Appearance: yellow-brown, cloudy liquid

3. Target species

Chickens

4. Indications for use

For active immunisation of future layers and breeding chickens from 10 weeks of age against avian encephalomyelitis virus, to prevent vertical transmission of the virus and to induce passive immunity in embryos and young chickens against infection with avian encephalomyelitis virus.

Onset of immunity: 10 weeks demonstrated by challenge of progeny. Specific antibodies are detected from 3 weeks post-vaccination onwards in vaccinated animals.

Duration of immunity: 39 weeks demonstrated by challenge of progeny. Specific antibodies are detected at least until 44 weeks post-vaccination in vaccinated animals.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.
Eggs of vaccinated breeding birds may be used for breeding purposes not earlier than 4 weeks after vaccination.

Special precautions for safe use in the target species:

The vaccine virus is able to spread horizontally from vaccinated to non-vaccinated chickens. Avian encephalomyelitis virus can naturally infect partridges, turkeys, pheasants, and pigeons.
Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to non-vaccinated chickens, partridges, turkeys, pheasants, pigeons, and other susceptible species. All animals in the population must be vaccinated at the same time.

To avoid additional stress for the vaccinated animals, no other immunisations should be performed for two weeks before and after the vaccination against avian encephalomyelitis.

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

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

Laying birds:

Do not use in birds in lay or breeding birds and within 4 weeks before the start of the laying period.

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:

No adverse reactions have been observed after 10-fold overdose.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:
None known.

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 administration via drinking water.
One vaccine dose per animal aged 10 weeks and older.
All animals of the population must be vaccinated.

The vaccine should be dissolved in the amount of drinking water consumed by the animals within 2 hours. The vaccine must be administered to the drinkers immediately after dissolution so that it is consumed by the animals within 2 hours at most after dilution.

To ensure the vaccine is consumed quickly, drinking water should be withheld from the animals for 1 - 2 hours prior to vaccination. It must be ensured that all animals have adequate access to the vaccine suspension, but not have access to normal drinking water until the vaccine has been consumed.

Administration via drinking water

- Determine the required number of vaccine doses and the quantity of water (see below).
- Use the total contents of the vaccine bottles per one chicken house or drinker systems.
- All equipment used for vaccination (lines, hoses, drinkers etc.) should be thoroughly cleaned and must be free from residues of cleaning agents and disinfectants.
- Use only cool, clean, and fresh water, preferably free of chlorine and metal ions. Skimmed milk powder (2 - 4 g/litre water) or skimmed milk (20 - 40 ml/litre water) can improve the quality of the drinking water and prolong the activity of the vaccine; however, this supplement should be added to the water 10 minutes **before** adding the vaccine.
- Open the vaccine bottle under water and dilute its contents. Ensure that any remaining vaccine is completely emptied by rinsing the bottle and rubber stopper with water.
- Lines filled with water must be emptied before administering the vaccine suspension.

Add the diluted vaccine suspension to cold, fresh water such that, as a rule of thumb, 1,000 vaccine doses are dissolved in one litre of water per age in days for 1,000 chickens, e. g. 10 litres would be required for 1,000 chickens aged 10 days old.

Under hot climatic conditions and for heavy breeds, this amount may be increased to a maximum of 40 litres per 1,000 animals. In case of doubt, the daily water consumption should be determined before vaccination.

To reduce the risk of infection before the onset of immunity, the litter should be removed, and the chicken house cleaned between treatment cycles in the breeding unit.

9. Advice on correct administration

The vaccination should not be later than 4 weeks before the start of breeding in order to avoid the transmission of the vaccine virus to the offspring.
Use the entire contents of the opened container at once.
All animals of the population must be vaccinated.

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).
Protect from frost.
Protect from direct sunlight.

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

Shelf life after dilution according to directions: 2 hours. Only the amount of vaccine may be prepared that can be consumed by the animals within 2 hours. Protect finished vaccine suspension against direct sunlight and temperature above 25°C as well as frost.

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 how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

{AT, DE, ES, FR:} Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Cardboard box containing 1 or 10 glass vials with 1,000/2,500/5,000/10,000 doses per vial.

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 contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
Lohmann Animal Health GmbH, Heinz-Lohmann Strasse 4, 27472 Cuxhaven, Germany

17. Other information

The vaccine contains the enterotropic avian encephalomyelitis virus strain 1143 Calnek which is not adapted to eggs. The parent animals are vaccinated at a time, in which they are usually age-resistant to

the disease. The purpose of the vaccination is the development of neutralising maternal antibodies that are transmitted via the yolk sack to the chicks to protect them against infection during the first few weeks of life.