ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLYNAV solution for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.05 ml dose contains:

Active substance:
pUK-SPDV-poly2#1 DNA plasmid coding for salmon pancreas disease virus proteins: 6.0 – 9.4 µg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless, particulate-free solution.

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon (*Salmo salar*).

4.2 Indications for use, specifying the target species

For the active immunisation of Atlantic salmon to reduce impaired daily weight gain, and reduce mortality, and cardiac, pancreatic and skeletal muscle lesions caused by pancreas disease following infection with salmonid alphavirus subtype 3 (SAV3).
Onset of immunity occurs within 399 degree days (mean water temperature in °C multiplied by number of holding days) following vaccination.
Duration of immunity: 1 year for reduction in impaired daily weight gain, and cardiac, pancreatic and skeletal muscle lesions and 9.5 months for reduction of mortality (demonstrated in a laboratory efficacy study in saltwater conditions using a cohabitation challenge model).

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
A minimum body weight of 25 g is recommended at vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Personal protective equipment, for example, consisting of appropriate protective gloves, should be worn when handling the veterinary medicinal product.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Transient changes in swimming behaviour, pigmentation and inappetence are very common and can be observed for up to 2, 7 and 9 days, respectively.
Needle injuries at the site of injection are common following administration of the vaccine which can persist in up to 5% of fish for at least 90 days, and can be seen both macroscopically and microscopically.

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 effect of vaccine on reproductive performance has not been investigated. Do not use in broodstock.

4.8 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.

4.9 Amounts to be administered and administration route

Intramuscular use.

Shake product gently before use.

Transfer tubing kit instructions: using the spiked end, screw the transfer tubing set onto the fill port of the ethyl vinyl acetate (EVA) bag with a ¼ turn in order to secure the line in place. Connect the other end of the transfer tubing set to the vaccine injection equipment (gun).

Anaesthetise the fish to immobilise them, and administer 0.05 ml of the vaccine by intramuscular injection in the area immediately anterior and lateral to the dorsal fin in the epaxial muscle.
Position the needle at 90° in the epaxial muscle, central to the dorsal fin and above the mid-line.

Based on a 25 g fish weight a standard 0.5 mm diameter 3mm depth needle is recommended to be used routinely. Consideration should be made for the weight of the fish before the final selection is made. Injection equipment should be calibrated and inspected regularly to ensure appropriate dosing of the fish.

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

No effects other than those described in section 4.6 have been observed following the administration of a ten-fold overdose.

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Atlantic salmon.
ATCvet code: QI10AX.

CLYNAV stimulates active immunity against salmonid alphavirus subtype 3 (SAV3).

CLYNAV contains a supercoiled DNA plasmid which expresses proteins of salmon alphavirus which induces a protective immune response in vaccinated Atlantic salmon.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate heptahydrate
Sodium chloride
Purified water

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

6.5 Nature and composition of immediate packaging

250 ml sterile, flexible, ethyl vinyl acetate (EVA) bags with a locking snap down port. A sterile and individually packaged transfer tube set is included in the final product packaging.

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

Elanco GmbH
Heinz-Lohmann-Straβe 4
27472 Cuxhaven
Germany

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/197/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27/06/2017

10 DATE OF REVISION OF THE TEXT

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

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

Name and address of the manufacturer of the biological active substance
Elanco Canada Ltd
37 McCarville Street
Charlottetown, PEI
C1E 2A7
CANADA

Name and address of the manufacturer responsible for batch release

Lohmann Animal Health GmbH
Heinz-Lohmann-Straβe 4

27472 Cuxhaven
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

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 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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLYNAV solution for injection for Atlantic salmon.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.05 ml dose contains:
pUK-SPDV-poly2#1 DNA plasmid coding for salmon pancreas disease virus proteins: 6.0 – 9.4 µg.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Atlantic salmon (*Salmo salar*).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero degree days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 °C – 8 °C).

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. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Straβe 4
27472 Cuxhaven
Germany

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/197/001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

EVA (250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLYNAV solution for injection for Atlantic salmon.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 0.05 ml dose contains:
pUK-SPDV-poly2#1 DNA plasmid coding for salmon pancreas disease virus proteins: 6.0 – 9.4 μg.

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

250 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero degree days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
CLYNAV solution for injection for Atlantic salmon

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Elanco GmbH
Heinz-Lohmann-Straβe 4
27472 Cuxhaven
Germany

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLYNAV solution for injection for Atlantic salmon.

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

Each 0.05 ml dose contains:

Active substance:
pUK-SPDV-poly2#1 DNA plasmid coding for salmon pancreas disease virus proteins: 6.0– 9.4 µg.

4. INDICATION(S)

For the active immunisation of Atlantic salmon to reduce impaired daily weight gain, and reduce mortality, and cardiac, pancreatic and skeletal muscle lesions caused by pancreas disease following infection with salmonid alphavirus subtype 3 (SAV3).
Onset of immunity occurs within 399 degree days (mean water temperature in °C multiplied by number of holding days) following vaccination.
Duration of immunity: 1 year for reduction in impaired daily weight gain, and cardiac, pancreatic and skeletal muscle lesions and 9.5 months for reduction of mortality (demonstrated in a laboratory efficacy study in saltwater conditions using a cohabitation challenge model).

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Transient changes in swimming behaviour, pigmentation and inappetence are very common and can be observed for up to 2, 7 and 9 days, respectively.
Needle injuries at the site of injection are common following administration of the vaccine which can persist in up to 5% of fish for at least 90 days, and can be seen both macroscopically and

microscopically.

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

Atlantic salmon *(Salmo salar).*

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular use.

Anaesthetise the fish to immobilise them, and administer 0.05 ml of the vaccine by intramuscular injection in the area immediately anterior and lateral to the dorsal fin in the epaxial muscle.

9. ADVICE ON CORRECT ADMINISTRATION

Shake product gently before use.

Transfer tubing kit instructions: using the spiked end, screw the transfer tubing set onto the fill port of the ethyl vinyl acetate (EVA) bag with a ¼ turn in order to secure the line in place. Connect the other end of the transfer tubing set to the vaccine injection equipment (gun).

Position the needle at 90° in the epaxial muscle, central to the dorsal fin and above the mid-line. Based on a 25 g fish weight a standard 0.5 mm diameter 3mm depth needle is recommended to be used routinely. Consideration should be made for the weight of the fish before the final selection is made. Injection equipment should be calibrated and inspected regularly to ensure appropriate dosing of the fish.

10. WITHDRAWAL PERIOD

Zero degree days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf life after first opening the immediate packaging: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for the target species:
Vaccinate healthy animals only.

Special precautions for use in animals:

A minimum body weight of 25 g is recommended at vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment, for example, consisting of appropriate protective gloves, should be worn when handling the veterinary medicinal product.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Fertility:
The effect of vaccine on reproductive performance has not been investigated. Do not use in broodstock.

Interaction~~s~~ 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 (symptoms, emergency procedures, antidotes):
No effects other than those described in section 6 have been observed following the administration of a ten-fold overdose.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with any other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
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 product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

CLYNAV stimulates active immunity against salmonid alphavirus subtype 3 (SAV3).

CLYNAV contains a supercoiled DNA plasmid which expresses proteins of salmon alphavirus which induces a protective immune response in vaccinated Atlantic salmon.

Pack size:
250 ml sterile, flexible, ethyl vinyl acetate (EVA) bags with a locking snap down port. A sterile and individually packaged transfer tube set is included in the final product packaging.