ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLYNAV solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:

Qualitative composition of excipients and other constituents
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate heptahydrate
Sodium chloride
Purified water

A clear, colourless, particulate-free solution.

3. CLINICAL INFORMATION

3.1 Target species

Atlantic salmon (*Salmo salar*).

3.2 Indications for use for each 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).

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:

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:

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

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Atlantic salmon:

Very common (>1 animal / 10 animals treated):	Abnormal swimming in fish[1] Fish colour change[2], Inappetence[3]
Common (1 to 10 animals / 100 animals treated):	Puncture wound[4]

[1] for up to two days.
[2] for up to seven days.
[3] for up to nine days.
[4] Needle injuries can persist in up to 5% of fish for at least 90 days and can be seen both macroscopically and microscopically.

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

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

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

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 epaxial muscle. Position the needle at 90° in the epaxial muscle, in the area immediately anterior and lateral to the dorsal fin, along a line equidistant to the dorsal fin and the mid-line, and at the point of the muscle's maximum girth.

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.

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

No effects other than those described in section 3.6 have been observed following the administration of a ten-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

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero degree days.

4. IMMUNOLOGICAL INFORMATION

4.1 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 14 months.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

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

5.4 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.

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

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/197/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/06/2017.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLYNAV solution for injection.

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. PACKAGE SIZE

250 ml

4. TARGET SPECIES

Atlantic salmon (*Salmo salar*).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.
Shake product gently before use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days

8. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once opened use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

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

Elanco GmbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/16/197/001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BAG (250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLYNAV solution for injection.

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. TARGET SPECIES

Atlantic salmon (*Salmo salar*)

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.
Shake product gently before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days

6. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once opened use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

CLYNAV solution for injection

2. Composition

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

A clear, colourless, particulate-free solution.

3. Target species

Atlantic salmon (*Salmo salar*).

4. Indications for use

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. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

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:

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

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

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

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 effects other than those described in the section "Adverse events" have been observed following the administration of a ten-fold overdose.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

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

7. Adverse events

Atlantic salmon:

Very common (> 1 animal / 10 animals treated):
Abnormal swimming in fish[1] Fish colour change[2], Inappetence[3]
Common (1 to 10 animals / 100 animals treated):
Puncture wound[4]

[1] for up to two days.
[2] for up to seven days.
[3] for up to nine days.
[4] Needle injuries can persist in up to 5% of fish for at least 90 days and can be seen both macroscopically and microscopically.

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

Intramuscular use.

Anaesthetise the fish to immobilise them and administer 0.05 ml of the vaccine by intramuscular injection 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, in the area immediately anterior and lateral to the dorsal fin, along a line equidistant to the dorsal fin and the mid-line, and at the point of the muscle's maximum girth.

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 periods

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 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/2/16/197/001

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.

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:
Elanco GmbH
Heinz-Lohmann-Straβe 4
27472 Cuxhaven
Germany

België/Belgique/Belgien
Tél/Tel: + 32 33000338
PV.BEL@elancoah.com

Република България
Тел: +48 221047815
PV.BGR@elancoah.com

Česká republika
Tel: +420 228880231
PV.CZE@elancoah.com

Danmark
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PV.DNK@elancoah.com

Deutschland
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PV.DEU@elancoah.com

Eesti
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PV.SWE@elancoah.com

United Kingdom (Northern Ireland)
Tel: +44 3308221732
PV.XXI@elancoah.com

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

17. 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.