ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 5 emulsion for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.05 ml) contains:

Active substances:
Formaldehyde inactivated cultures of:

Aeromonas salmonicida subsp. *salmonicida*	≥ 12.6 $\log_2$ ELISA units[1]
*Vibrio anguillarum** serotype O1	RPS[2] ≥ 75
*Vibrio anguillarum** serotype O2a	RPS[2] ≥ 75
Vibrio salmonicida	RPS[2] ≥ 90
Moritella viscosa	≥ 10.7 $\log_2$ ELISA units[1]

[1] ELISA units: serological response in Atlantic salmon
[2] RPS: Relative Percentage Survival is based on results from challenge studies on Atlantic salmon at 60% mortality in the control group.
* *Vibrio anguillarum* is synonymous with *Listonella anguillarum.*

Adjuvant:
Paraffin, light liquid (mineral oil): 23 mg.

Excipients:

Qualitative composition of excipients and other constituents
Emulsifier:
Sorbitan oleate
Polysorbate 80

3. CLINICAL INFORMATION

3.1 Target species

Atlantic salmon (*Salmo salar*) of a minimum weight of 25 g.

3.2 Indications for use for each target species

For active immunisation of Atlantic salmon to reduce clinical signs and mortality caused by infections with *Aeromonas salmonicida* (furunculosis), *Vibrio salmonicida* (coldwater vibriosis), *Vibrio anguillarum* serotype O1and O2a (classical vibriosis) and *Moritella viscosa* (winter ulcer).

Onset of immunity: 520 degree days post vaccination.

Duration of immunity: Minimum 12 months.

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:
Vaccination should preferably be performed at water temperatures of 15°C or below.
Do not vaccinate at water temperatures below 3°C or above 18°C.
Avoid vaccination during smoltification.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to fish vaccines should avoid contact with the veterinary medicinal product. Protective equipment consisting of guarded needles should be used during manual vaccination. Ensure that the method of fixation and handling of the fish minimises the risk of accidental self-injection. Repeated self-injections may aggravate the adverse effects or increase the risk of anaphylactic shock.

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

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

3.6 Adverse events

Target species: Atlantic salmon

Very common (>1 animal / 10 animals treated):	Adhesion in fish[1] (average Speilberg score 2) Visible vaccine in fish[2]
Common (1 to 10 animals / 100 animals treated):	Melanin accumulation in fish[3]

[1] Mild visceral adhesions were found 21 days after vaccination with twice the recommended dose.
[2] Vaccine residues were found shortly after vaccination.
[3] Melanisation in the abdominal cavity was found 21 days after vaccination with twice the recommended dose.

Oil adjuvants are associated with increased risk of local reactions in the form of adhesions in the abdomen and pigmentation on the viscera in fish.

The severity of adverse reactions may be influenced by different factors such as sanitation, vaccination technique, fish size at vaccination and water temperature during vaccination and in the first 6-12 weeks 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 also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The potential effect of vaccination on spawning function has not been investigated.
Vaccination of broodfish should only be done according to a benefit-risk assessment by the responsible veterinarian/fish health biologist.

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

Posology
Administer a single dose of 0.05 ml per fish. Fish should not be vaccinated more than once.

Administration route
The vaccine should be administered by intraperitoneal (i.p) injection into the midline about one fin length anterior to the base of the pelvic fin. To reduce the risk of adverse reactions, it is important to deposit the entire dose in the abdominal cavity. The injection needle used should have appropriate length to penetrate the abdominal wall and 1-2 mm into the abdominal cavity.

It is recommended to starve the fish for a minimum of 48 hours before vaccination.
The fish should be anaesthetised prior to injection.

Let the vaccine slowly reach 15-20°C by keeping it at room temperature.
Ensure a homogenous emulsion prior to use by squeezing and shaking the vaccine bag for approx. 2 minutes.

Only administer the vaccine if it appears as a homogenous, white to cream coloured emulsion. The vaccine should not be used if the vaccine shows signs of a brownish water phase in the bottom of the container. Contact the distributor for further advice.

The injection devices used for vaccination, i.e. automatic vaccination machines or manual syringes, must be designed and suitable for administration of the recommended dose volume in the target species. The devices must be operated by trained personnel and should be calibrated according to the manufacturers' recommendation prior to use. Special care should be taken to ensure air is removed from the injection equipment (chambers and tubes) prior to vaccination. Regular dose controls are recommended.

The vaccination equipment should be thoroughly cleaned/sterilized before use.

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

Following administration of 0.1 ml of the vaccine (double dose) no other adverse reactions than those described in section 3.6 have been observed.

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 degree days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI10AB 03

Stimulates development of active immunity against *Aeromonas salmonicida, Vibrio anguillarum* serotype O1, *Vibrio anguillarum* serotype O2a, *Vibrio salmonicida* and *Moritella viscosa* in Atlantic salmon.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

The vaccine has not been tested in co-injection with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 15 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).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Bags made of a multilayer plastic foil with inner layer of ethylene vinyl acetate (EVA).
The giving port is closed with a bromobutyl rubber stopper. The bag is packed in a zip-lock bag or cardboard box.

Pack sizes: 250 ml, 500 ml and 10 x 500 ml.

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.

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

Pharmaq AS

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

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

Zip-lock bag or cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 5
Emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

0.05 ml (1 dose)
Formaldehyde inactivated cultures of:

Aeromonas salmonicida subsp. *salmonicida*	≥ 12.6 $\log_2$ ELISA units
Vibrio anguillarum serotype O1	RPS ≥ 75
Vibrio anguillarum serotype O2a	RPS ≥ 75
Vibrio salmonicida	RPS ≥ 90
Moritella viscosa	≥ 10.7 $\log_2$ ELISA units

3. PACKAGE SIZE

250 ml
500 ml
10 x 500 ml

4. TARGET SPECIES

Atlantic salmon

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intraperitoneal injection.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days.

8. EXPIRY DATE

Exp.

Once broached use within 10 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

Pharmaq AS

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vaccine bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 5
Emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

0.05 ml (1 dose)
Formaldehyde inactivated cultures of:

Aeromonas salmonicida subsp. *salmonicida*	≥ 12.6 $\log_2$ ELISA units
Vibrio anguillarum serotype O1	RPS ≥ 75
Vibrio anguillarum serotype O2a	RPS ≥ 75
Vibrio salmonicida	RPS ≥ 90
Moritella viscosa	≥ 10.7 $\log_2$ ELISA units

3. TARGET SPECIES

Atlantic salmon

4. ROUTES OF ADMINISTRATION

Intraperitoneal injection.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days.

6. EXPIRY DATE

Exp.

Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Pharmaq AS

9. BATCH NUMBER

Lot

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ALPHA JECT micro 5 emulsion for injection for Atlantic salmon

2. Composition

1 dose (0.05 ml) contains:

Active substances:
Formaldehyde inactivated cultures of:

Aeromonas salmonicida subsp. *salmonicida*	≥ 12.6 $\log_2$ ELISA units
Vibrio anguillarum serotype O1	RPS ≥ 75
Vibrio anguillarum serotype O2a	RPS ≥ 75
Vibrio salmonicida	RPS ≥ 90
Moritella viscosa	≥ 10.7 $\log_2$ ELISA units

ELISA units: serological response in Atlantic salmon
RPS: Relative Percentage Survival in challenge studies on Atlantic salmon
Vibrio anguilllarum is synonymous with *Listonella anguillarum*

Adjuvant: Paraffin, light liquid (mineral oil): 23 mg.

White to cream coloured emulsion.

3. Target species

Atlantic salmon (*Salmo salar*).

4. Indications for use

For active immunisation of Atlantic salmon to reduce clinical signs and mortality caused by infections with *Aeromonas salmonicida* (furunculosis), *Vibrio salmonicida* (coldwater vibriosis), *Vibrio anguillarum* serotype O1and O2a (classical vibriosis) and *Moritella viscosa* (winter ulcer).

Onset of immunity: 520 degree days post vaccination.

Duration of immunity: Minimum 12 months.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy fish only.

Special precautions for safe use in the target species:
Vaccination should preferably be performed at water temperatures of 15°C or below.
Do not vaccinate at water temperatures below 3°C or above 18°C.

Avoid vaccination during smoltification.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to fish vaccines should avoid contact with the veterinary medicinal product. Protective equipment consisting of guarded needles should be used during manual vaccination. Ensure that the method of fixation and handling of the fish minimises the risk of accidental self-injection. Repeated self-injections may aggravate the adverse effects or increase the risk of anaphylactic shock.

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy, lactation and lay:
The potential effect of vaccination on spawning function has not been investigated.
Vaccination of broodfish should only be done according to a benefit-risk assessment by the responsible veterinarian/fish health biologist.

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:
Following administration of 0.1 ml of the vaccine (double dose) no other adverse reactions than those described in section "Adverse reactions" have been observed.

Major incompatibilities:
The vaccine has not been tested in co-injection with other veterinary medicinal products.

7. Adverse events

Target species: Atlantic salmon

- Adhesion in fish[1] (average Speilberg score 2)
- Visible vaccine in fish[2]

Common (>1 animal / 100 animals treated):

- Melanin accumulation in fish[3]

[1] Mild visceral adhesions were found 21 days after vaccination with twice the recommended dose
[2] Vaccine residues were found shortly after vaccination
[3] Melanisation in the abdominal cavity were found 21 days after vaccination with twice the recommended dose

Oil adjuvants are associated with increased risk of local reactions in the form of adhesions in the abdomen and pigmentation on the viscera in fish.

The severity of adverse reactions may be influenced by different factors such as sanitation, vaccination technique, fish size at vaccination and water temperature during vaccination and in the first 6-12 weeks 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

Dosage
Administer a single dose of 0.05 ml per fish of a minimum weight of 25 g.
Fish should not be vaccinated more than once.

Administration route
The vaccine should be administered by intraperitoneal (i.p) injection into the midline about one fin length anterior to the base of the pelvic fin. It is recommended to starve the fish for a minimum of 48 hours before vaccination. The fish should be anaesthetised prior to injection.

9. Advice on correct administration

To reduce the risk of adverse reactions, it is important to deposit the entire dose in the abdominal cavity. The injection needle used should have appropriate length to penetrate the abdominal wall and 1-2 mm into the abdominal cavity.

Let the vaccine slowly reach 15-20°C by keeping it at room temperature.
Ensure a homogenous emulsion prior to use by squeezing and shaking the vaccine bag for approx. 2 minutes.

Only administer the vaccine if it appears as a homogenous, white to cream coloured emulsion after shaking. Do not use Alpha Ject micro 5 if you notice signs of a brownish water phase in the bottom of the container. Contact the distributor for further advice.

The injection devices used for vaccination, i.e. automatic vaccination machines or manual syringes, must be designed and suitable for administration of the recommended dose volume in the target species. The devices must be operated by trained personnel and should be calibrated according to the manufacturers' recommendation prior to use. Special care should be taken to ensure air is removed from the injection equipment (chambers and tubes) prior to vaccination. Regular dose controls are recommended.

The vaccination equipment should be thoroughly cleaned/sterilized before use.

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 freeze. Protect from light.

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.

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

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

[MA number]

Pack sizes: Zip-lock bag with 1 x 250 ml or 500 ml vaccine bag, or cardboard box with 10 x 500 ml vaccine bag.
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:
PHARMAQ AS
7863 Overhalla
Norway
E-mail: phq.phvig@zoetis.com
Tel: +47 23 29 85 00