ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 1 PD emulsion for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.05 ml) contains:

Active substance:
Salmon pancreas disease virus, strain AL V405, inactivated $RPS_{end} \geq 80$ %

RPS_{end} : Relative percentage survival at end control mortality in a laboratory test in Atlantic salmon

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

Excipients:

Qualitative composition of excipients and other constituents
Sorbitan oleate
Polysorbate 80

White to cream coloured emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Atlantic salmon (*Salmo salar* L) with a minimum weight of 28 g.

3.2 Indications for use for each target species

For active immunisation of Atlantic salmon to reduce mortality, lesions in the heart and pancreas, and impaired growth caused by Pancreas Disease (PD).

Onset of immunity: 516 degree days.
Duration of immunity: at least 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 lower. Avoid vaccination during smoltification.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The use of needle guards is recommended in order to reduce the risk of accidental self-injection.

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

Atlantic salmon:

Very common (>1 animal / 10 animals treated):	Adhesion (Speilberg score 1-2)[1], melanin accumulation[1], visible vaccine[1]
Common (1 to 10 animals / 100 animals treated):	Adhesion (Speilberg score 3)[1], fish body deformity[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Adhesion (Speilberg score ≥ 4)[1]

[1] In the abdominal cavity
[2] Spinal deformities of the so-called “cross-stitch vertebrae” type, primarily in fish put at sea in the autumn (S0-generation). These deformities are believed to have multifactorial causes and are possibly linked to the vaccine’s PD component. However, a causal relationship has not been proven.

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

Vaccination of broodfish is not recommended and should be subject to a risk benefit evaluation of the prescribing veterinarian/fish health biologist.

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 simultaneously with PHARMAQ's oil adjuvanted multivalent vaccines containing the following antigens: *Aeromonas salmonicida*, *Listonella anguillarum* O1 and O2a, *Vibrio salmonicida*, *Moritella*

viscosa and Infectious Pancreas Necrosis Virus (IPNV). The vaccines are administered intraperitoneally either simultaneously (one injection) or in immediate succession (two injections) while fish are anaesthetised.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products 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

Posology
A single dose of 0.05 ml per fish.

Administration route
The vaccine will be administered by intraperitoneal (i.p) injection. The fish should be anaesthetised prior to injection. It is recommended to starve the fish for a minimum of 48 hours before vaccination.

The vaccine should be left to slowly reach 15 20 °C by keeping it at room temperature. 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 vaccine should be well shaken prior to use by squeezing and shaking for approx. 2 minutes. Only administer if the vaccine appears as a homogenous, white to cream coloured emulsion.

To reduce the risk of adverse reactions, it is important to deposit the entire dose into the abdominal cavity. The injection needle used should have appropriate length to penetrate the abdominal wall by 1-2 mm. The entire needle should be inserted into the midline about one fin length anterior to the base of the pelvic fin.

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 (number of injections per bag) are recommended.

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

Administration of the vaccine in 0.1 ml (double dose) shows no other adverse reactions than those described in section 3.6.

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 : QI10AA 01

Stimulates development of active immunity against Pancreas Disease. Reduction of mortality during clinical outbreaks of Pancreas Disease has been documented up to 15 months post vaccination under field conditions.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal products.

5.2 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.

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. The giving port is closed with a rubber stopper. The bag is packed in a zip-lock bag or cardboard box.

Pack sizes:
Zip-lock bag: 250 ml and 500 ml
Cardboard box: 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 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

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 1 PD emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

0.05 ml (1 dose):
Inactivated Salmon pancreas disease virus AL V405 $RPS_{end} \geq 80$ %

3. PACKAGE SIZE

250 ml
500 ml
10 x 500 ml

4. TARGET SPECIES

For Atlantic salmon

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intraperitoneal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days

8. EXPIRY DATE

Exp. {dd/mm/yyyy}

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 {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Plastic bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 1 PD emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

0.05 ml (1 dose):
Inactivated Salmon pancreas disease virus, AL V405 $RPS_{end} \geq 80$ %

3. TARGET SPECIES

For Atlantic salmon

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days

6. EXPIRY DATE

Exp. {dd/mm/yyyy}

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 {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ALPHA JECT micro 1 PD emulsion for injection for Atlantic salmon

2. Composition

1 dose (0.05 ml) contains:

Active substance:
Salmon pancreas disease virus, strain AL V405, inactivated $RPS_{end} \geq 80$ %

RPS_{end} : Relative percentage survival at end control mortality in a laboratory test in Atlantic salmon

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

White to cream coloured emulsion.

3. Target species

Atlantic salmon (*Salmo salar* L) with a minimum weight of 28 g.

4. Indications for use

For active immunisation of Atlantic salmon to reduce mortality, lesions in the heart and pancreas, and impaired growth caused by Pancreas Disease (PD).

Onset of immunity: 516 degree days.
Duration of immunity: at least 12 months.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Vaccination should preferably be performed at water temperatures of 15 °C or lower. Avoid vaccination during smoltification.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The use of needle guards is recommended in order to reduce the risk of accidental self-injection.

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.

Fertility:
Vaccination of broodfish is not recommended and should be subject to a risk benefit evaluation of the prescribing veterinarian/fish health biologist.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered with PHARMAQ's oil adjuvanted multivalent vaccines containing the following antigens: *Aeromonas salmonicida*, *Listonella anguillarum* O1 and O2a, *Vibrio salmonicida*, *Moritella viscosa* and Infectious Pancreas Necrosis Virus (IPNV). The vaccines are administered intraperitoneally either simultaneously (one injection) or in immediate succession (two injections) while fish are anaesthetised.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products 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 the vaccine in 0.1 ml (double dose) shows no other adverse reactions than those described in the section "Adverse events".

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

7. Adverse events

Atlantic salmon:

Very common (>1 animal / 10 animals treated):
- Adhesion (Speilberg score 1-2)[1]
- Melanin accumulation[1]
- Visible vaccine[1]

Common (1 to 10 animals / 100 animals treated):
- Adhesion (Speilberg score 3)[1]
- Fish body deformity[2]

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
- Adhesion (Speilberg score ≥ 4)[1]

[1] In the abdominal cavity.
[2] Spinal deformities of the so-called “cross-stitch vertebrae” type, primarily in fish put at sea in the autumn (S0-generation). These deformities are believed to have multifactorial causes and are possibly linked to the vaccine’s PD component. However, a causal relationship has not been proven.

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
A single dose of 0.05 ml per fish with a minimum weight of 28 g.

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.

9. Advice on correct administration

The vaccine should be left to slowly reach 15-20 °C by keeping it at room temperature. Do not use if the vaccine shows signs of a brownish water phase in the bottom of the container before shaking. Contact the manufacturer for further advice. The vaccine should be well shaken prior to use by squeezing and shaking for approx. 2 minutes. Only administer if the vaccine appears as a homogenous, cream coloured emulsion.

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

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

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 (number of injections per bag) are recommended.

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 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 fish health biologist 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

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

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, manufacturer responsible for batch release and contact details to report suspected adverse events:
PHARMAQ AS
7863 Overhalla
Norway
Tel: +47 23 29 85 00
E-mail: phq.phvig@zoetis.com

<17. Other information>