ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 1 Noda, emulsion for injection for sea bass

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.05 ml) contains:

Active substance:
Inactivated Red-spotted Grouper Nervous Necrosis Virus (RGNNV) strain ALV1107
≥ 0.07 antigenicity units[1]

[1] quantity of antigen measured in vaccine (short version AgU)

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

Excipients:

Qualitative composition of excipients and other constituents
Sorbitan oleate
Polysorbate 80
Water for injection

White to cream coloured homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Sea bass (*Dicentrarchus labrax*)

3.2 Indications for use for each target species

For active immunisation of sea bass to reduce mortality caused by Red-spotted Grouper Nervous Necrosis Virus (RGNNV).

Onset of immunity: 466 degree days.
Duration of immunity: 1 year

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
Due to handling, vaccination may be followed by temporary reduced appetite.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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 during manual vaccination.

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

Seabass (*Dicentrarchus labrx*):

Very common (>1 animal / 10 animals treated):	Adhesion in fish[1] Melanin accumulation in fish[2]

[1] Mild abdominal adhesions have been shown at 12 months.
[2] Small amounts of melanin, seen as few spots covering very limited areas of the viscera often close to the injection site have been observed at 12 months.

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

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

The safety of the veterinary medicinal product has not been established for use in broodstock, and vaccination of broodstock should be subject to a risk benefit evaluation of the prescribing veterinarian.

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

Intraperitoneal use.

Posology
The recommended dose is 0.05 ml per fish of a minimum weight of 12 g.

Administration route
The vaccine should be administered by intraperitoneal (IP) injection.

The fish should be anaesthetised prior to injection. It is recommended to starve the fish for a minimum of 24 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. 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 in 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, to one and a half pelvic fin length posterior to the base of the pelvic fin.

After vaccination the equipment used for vaccination should be thoroughly cleaned.

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

Effects of an overdose have not been investigated as it is not required for inactivated vaccines.

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: QI10X

To stimulate development of active immunity in sea bass against Red-spotted Grouper Nervous Necrosis Virus. The occurrence of false positive PCR results due to vaccination when screening for presence of VNN virus in brain tissue by Real Time RT-PCR is highly unlikely.

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: 30 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

Injection bags made of a multilayer plastic foil. The giving port is closed with a rubber stopper. The vaccine bag is packed in a zip-lock bag or cardboard box.

Package 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: {DD/MM/YYYY}

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 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 Noda emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

0.05 ml (1 dose): Inactivated Red-spotted Grouper Nervous Necrosis Virus (RGNNV) ≥ 0.07 AgU

3. PACKAGE SIZE

250 ml
500 ml
10 x 500 ml

4. TARGET SPECIES

Sea bass (*Dicentrarchus labrax*)

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

Bag of 250 ml
Bag of 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 1 Noda emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

0.05 ml (1 dose):Inactivated Red-spotted Grouper Nervous Necrosis Virus (RGNNV) ≥ 0.07 AgU

3. TARGET SPECIES

Sea bass (*Dicentrarchus labrax*)

4. ROUTES OF ADMINISTRATION

Intraperitoneal use.
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 Noda, emulsion for injection for sea bass.

2. Composition

One dose (0.05 ml) contains:

Active substance:
Inactivated Red-spotted Grouper Nervous Necrosis Virus (RGNNV) strain ALV1107
≥ 0.07 antigenicity units[1]

[1] quantity of antigen measured in vaccine (short version AgU)

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

White to cream coloured homogeneous emulsion.

3. Target species

Sea bass (*Dicentrarchus labrax*)

4. Indications for use

For active immunisation of sea bass to reduce mortality caused by Red-spotted Grouper Nervous Necrosis Virus (RGNNV).

Onset of immunity: 466 degree days.
Duration of immunity: 1 year

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
Due to handling, vaccination may be followed by temporary reduced appetite.

Special precautions for safe use in the target species:
Not applicable.

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 during manual vaccination.

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.

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

Pregnancy, lactation and lay:
The safety of the veterinary medicinal product has not been established for use in broodstock, and vaccination of broodstock should be subject to a risk benefit evaluation of the prescribing veterinarian.

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:
Effects of an overdose have not been investigated as it is not required for inactivated vaccines.

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

7. Adverse events

Sea bass (*Dicentrarchus labrx*):

Very common (> 1 animal / 10 animals treated):	Adhesion in fish[1] Melanin accumulation in fish[2]

[1] Mild abdominal adhesions have been shown at 12 months.
[2] Small amounts of melanin, seen as few spots covering very limited areas of the viscera often close to the injection site have been observed at 12 months.

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

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

Intraperitoneal use.

The recommended dose is 0.05 ml per fish of a minimum weight of 12 g. The vaccine should be administered by intraperitoneal (IP) injection.

9. Advice on correct administration

The fish should be anaesthetised prior to injection. It is recommended to starve the fish for a minimum of 24 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. 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 in 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, to one and a half pelvic fin length posterior to the base of the pelvic fin.

After vaccination the equipment used for vaccination should be thoroughly cleaned.

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> <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

[MA number]

Package 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:

PHARMAQ AS
7863 Overhalla
Norway

Contact details to report suspected adverse reactions:

Ελλάδα
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
EL-15125 Αττική
Τηλ: +30 210 6791900

France
Zoetis France
10 rue Raymond David
FR-92240 Malakoff
Tél: +33 (0)800 73 00 65

Italia
Zoetis Italia S.r.l.
Via Andrea Doria 41M,
IT-00192 Roma
Tel: +39 06 3366 8111

Local representatives and contact details to report suspected adverse reactions:

Hrvatska
Zoetis B.V.

Podružnica Zagreb za promidžbu
Petra Hektorovića 2
HR-10000 Zagreb
Tel: +385 1 6441 462

España
Zoetis Spain, S.L.
Parque Empresarial Vía Norte Edificio nº1,
c/ Quintanavides nº13
ES-28050 Madrid
Tel: +34 91 4191900

Local representative:

Ελλάδα
AQUAVET S.A
Αντιοχείας 48, Ν. Φιλαδέλφεια,
EL-14341 Αθήνα
Τηλ: +302102517807