ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 2000 emulsion for injection for sea bass

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.05 ml) contains:

Active substances:

Inactivated *Vibrio (Listonella) anguillarum* serotype O1, strain AL 112	≥ 2.5 antigenicity units[1]
Inactivated *Photobacterium damselae* subsp. *piscicida*, strain AL 5051	titre[2] ≥9.6 $\log_2$

[1] quantity of antigen measured in vaccine (short version AgU)
[2] serological response in sea bass

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White to cream coloured homogeneous emulsion when shaken.

4. CLINICAL PARTICULARS

4.1 Target species

Sea bass (*Dicentrarchus labrax*)

4.2 Indications for use, specifying the target species

For active immunisation of sea bass to reduce mortality of vibriosis caused by *Vibrio anguillarum* O1 and of pasteurellosis caused by *Photobacterium damselae* subsp. *piscicida*.

Onset of immunity:	2 weeks at 22°C (324 degree days) for *V. anguillarum* O1 3 weeks at 22°C (499 degree days) for *P. damselae* subsp. *piscicida*
Duration of immunity:	9 months (5755 degree days) for *V. anguillarum* O1 3 months (1977 degree days) for *P. damselae* subsp. *piscicida*

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
Due to handling, vaccination may be followed by temporary reduced appetite.

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.
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.

4.6 Adverse reactions (frequency and seriousness)

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.

Very common (> 1/10):
- Mild abdominal adhesions have been shown in laboratory studies.
- Small amounts of melanin, seen as few spots covering very limited areas of the viscera often close to the injection site have been observed in laboratory studies.

Common (>1 and <10/100):
- Vaccine residues have been shown shortly after vaccination in laboratory studies.

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 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.

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

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. 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. 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 lengths posterior to the base of the pelvic fin.

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

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

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

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for pisces, others
ATCvet code: QI10X

Cross protection between different serotypes has not been investigated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, light liquid (mineral oil)
Sorbitan oleate
Polysorbate 80
Water for injections

The vaccine may contain formaldehyde as a residue after inactivation

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

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).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Injection bags made of a multilayer plastic foil with inner layer of ethylene vinyl acetate. The giving port is closed with a bromobutyl rubber stopper.

Pack sizes:
250 ml bag corresponding to approximately 5 000 doses.
500 ml bag corresponding to approximately 10 000 doses.

Not all pack sizes may be marketed.

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

PHARMAQ AS
7863 Overhalla
Norway

8. MARKETING AUTHORISATION NUMBER(S)

To be updated locally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

To be updated locally

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for 250 ml bag
Label for 500 ml bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 2000 emulsion for injection for sea bass

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose (0.05 ml):
Formaldehyde inactivated cultures of:
Vibrio (Listonella) anguillarum O1 ≥ 2.5 AgU
Photobacterium damselae subsp. *piscicida* titre ≥ 9.6 $\log_2$

Paraffin, light liquid: 23 mg

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

250 ml bag corresponding to approximately 5 000 doses
500 ml bag corresponding to approximately 10 000 doses

5. TARGET SPECIES

Sea bass (Dicentrarchus labrax)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero degree days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental injection is dangerous.

10. EXPIRY DATE

EXP:
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

PHARMAQ AS
7863 Overhalla
Norway

16. MARKETING AUTHORISATION NUMBER(S)

To be updated locally

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
ALPHA JECT micro 2000 emulsion for injection for sea bass

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

Marketing authorisation holder and manufacturer responsible for batch release:
PHARMAQ AS
7863 Overhalla
Norway

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 2000 emulsion for injection for sea bass

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each dose (0.05 ml) contains:

Active substances:

Inactivated *Vibrio* (*Listonella*) *anguillarum* serotype O1, strain AL 112	≥ 2.5 antigenicity units[1]
Inactivated *Photobacterium damselae* subsp. *piscicida*, strain AL 5051	titre[2] ≥ 9.6 $\log_2$

[1] quantity of antigen measured in vaccine (short version AgU)
[2] serological response in sea bass

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

Pharmaceutical form:
Emulsion for injection.
White to cream coloured homogeneous emulsion when shaken.

4. INDICATION(S)

For active immunisation of sea bass to reduce mortality of vibriosis caused by *Vibrio anguillarum* O1 and of pasteurellosis caused by *Photobacterium damselae* subsp. *piscicida*.

Onset of immunity:	2 weeks at 22°C (324 degree days) for *V. anguillarum* O1 3 weeks at 22°C (499 degree days) for *P. damselae* subsp. *piscicida*
Duration of immunity:	9 months (5755 degree days) for *V. anguillarum* O1 3 months (1977 degree days) for *P. damselae* subsp. *piscicida*

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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.

Very common (> 1/10):
- Mild abdominal adhesions have been shown in laboratory studies.
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The frequency of adverse reactions is defined using the following convention:
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- 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

Sea bass (*Dicentrarchus labrax*)

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

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. 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 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 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 container: 10 hours.

12. SPECIAL WARNING(S)

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

Special precautions for use in animals:
Due to handling, vaccination may be followed by temporary reduced appetite.

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.
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.

Pregnancy/Lactation/Lay/Fertility:
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 (symptoms, emergency procedures, antidotes):
Effects of an overdose have not been investigated as it is not required for inactivated vaccines.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Ask your veterinary surgeon or pharmacist 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

To be updated locally

15. OTHER INFORMATION

Package sizes:
250 ml bag corresponding to approximately 5 000 doses
500 ml bag corresponding to approximately 10 000 doses

Not all pack sizes may be marketed.