ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA DIP Vib concentrate for dip suspension for sea bass

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose contains:

Active substances:
Vibrio anguillarum, serotype O1, strain AL 112, Inactivated RPS[1] ≥ 75

[1] RPS (Relative Percentage Survival) is based on results from challenge studies and calculated according to the following quotation: [1-(% mortality in vaccinated fish/%mortality in mock vaccinated fish)] x 100.

Excipients:

Qualitative composition of excipients and other constituents
Water for injections.

Opaque, light yellow to brownish suspension.

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 infection with *Vibrio (Listonella) anguillarum* serotype O1 (vibriosis).

Onset and duration of immunity after vaccination according to recommended vaccination regime:
Onset of immunity: 321 degree days (2 weeks at 21 +/- 2 °C).
Duration of immunity: 1467 degree days (10 weeks at 21 +/- 2 °C).

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:
The vaccine may contain formaldehyde as a residue after inactivation.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid skin and eye contact. Personal protective equipment consisting of gloves and goggles should be worn when handling the veterinary medicinal product. In case of accidental spillage onto skin (or in the eyes) of vaccine concentrate or dilution, rinse immediately with clean water and seek medical advice immediately and show the package leaflet or the label to the physician. Do not drink or eat while handling the vaccine.

After vaccination wash the equipment used for vaccination thoroughly.

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

3.6 Adverse events

None known.

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 its local representative 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 as this veterinary medicinal product is intended for vaccination of juveniles.

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

Administration by dipping.

Temper the vaccine and shake the vaccine bottle prior to use.

Appearance before reconstitution: Opaque, light yellow to brownish suspension.
Dilute one litre of vaccine with 19 litres of clean sea water (1:20 dilution). Mix well.

Method of administration and posology
The following dip vaccination scheme is recommended:

First dose
Immerse fish of an average weight of 1 gram (1-2 grams) in a 1:20 vaccine to sea water dilution for 60 seconds. Discard the vaccine when a total of 20 kg of 1 gram fish has been immersed per 10 litre of the diluted vaccine.

Second dose
Immerse fish of an average weight of 5 grams (4-8 grams) in a 1:20 vaccine to sea water dilution for 60 seconds. Discard the vaccine when a total of 100 kg of 5-gram fish have been immersed per 10 litre of the diluted vaccine.

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

Not known.

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

3.12 Withdrawal periods

Zero degree-days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI10X

To stimulate active immunity in sea bass against *Vibrio anguillarum*

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: 42 months.
Shelf life after first opening the immediate packaging: use immediately.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from direct sunlight.

5.4 Nature and composition of immediate packaging

Polyethylene terephthalate (PET) bottle with a high-density polyethylene (HDPE) screw cap. The container is tamper evident.

Pack sizes:
500 ml bottle
1000 ml bottle

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 IMMEDIATE PACKAGE

PET bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA DIP Vib concentrate for dip suspension

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose:
Vibrio anguillarum, serotype O1, strain AL 112, Inactivated RPS $\geq$ 75

3. TARGET SPECIES

Sea bass (*Dicentrarchus labrax*)

4. ROUTES OF ADMINISTRATION

Administration by dipping.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached/reconstituted use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from direct sunlight.

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 DIP Vib, concentrate for dip suspension for sea bass.

2. Composition

1 dose contains:

Active substance:
Vibrio anguillarum, serotype O1, stain AL 112, Inactivated RPS[1] ≥75.

[1] RPS (Relative Percentage Survival) is based on results from challenge studies and calculated according to the following quotation: [1-(% mortality in vaccinated fish/%mortality in mock vaccinated fish)] x 100.

Opaque, light yellow to brownish suspension.

3. Target species

Sea bass (*Dicentrarchus labrax*)

4. Indications for use

For active immunisation of sea bass to reduce mortality caused by infection with *Vibrio (Listonella) anguillarum* serotype O1 (vibriosis).

Onset and duration of immunity after vaccination according to recommended vaccination regime:
Onset of immunity: 321 degree days (2 weeks at 21 +/- 2 °C).
Duration of immunity: 1467 degree days (10 weeks at 21 +/- 2 °C).

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
The vaccine may contain formaldehyde as a residue after inactivation.
Due to handling stress, vaccination may be followed by temporary reduced appetite.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid skin and eye contact. Personal protective equipment consisting of gloves and goggles should be used when handling the veterinary medicinal product. In case of accidental spillage onto skin (or in the eyes) of vaccine concentrate or dilution, rinse immediately with clean water and seek medical advice immediately and show the package leaflet or the label to the physician. Do not drink or eat while handling the vaccine.
After vaccination wash the equipment used for vaccination thoroughly.

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

Fertility:
The safety of the veterinary medicinal product has not been established for use in broodstock as this veterinary medicinal product is intended for vaccination of juveniles.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of 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:
Not known.

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

7. Adverse events

None known.

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 its local representative 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

Administration by dipping.
The following dip vaccination scheme is recommended:

First dose: Immerse fish of an average weight of 1 gram (1-2 grams) in a 1:20 vaccine to sea water dilution for 60 seconds.

Second dose: Immerse fish of an average weight of 5 grams (4-8 grams) in a 1:20 vaccine to sea water dilution for 60 seconds.

9. Advice on correct administration

Temper the vaccine and shake the vaccine bottle prior to use. Dilute one litre of vaccine with 19 litres of clean sea water (1:20 dilution). Mix well.

Discard the vaccine when a total of 20 kg of 1 gram fish and 100 kg of 5-gram fish have been immersed per 10 litre of the diluted vaccine respectively.

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 direct sunlight.

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: use immediately.
Shelf life after reconstitution according to directions: use immediately.

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]

Pack sizes:
500 ml bottle
1000 ml bottle

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
Skogmo Industriområde
Industrivegen 50
7863 Overhalla
Norway

Contact details to report suspected adverse reactions:
To be completed nationally.

Local representatives and contact details to report suspected adverse reactions:
To be completed nationally.

Local representative:
To be completed nationally.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information