ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC-VR Concentrate for dip suspension/for injection for sea bass and turbot

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:

Vibrio anguillarum, serotype O1, strain R-82, Inactivated	RPS(*) ≥ 60%
Vibrio anguillarum, serotype O2 alpha, strain RG-111, Inactivated	RPS(*) ≥ 60%
Vibrio anguillarum, serotype O2 beta, strain RV-22, Inactivated	RPS(*) ≥ 60%

(*) RPS: Relative Percentage of Survival after intraperitoneal challenge in sea bass.

Excipients:

Qualitative composition of excipients and other constituents
Tryptic soy broth
Sodium chloride
Water for injections

Yellow-brownish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sea bass (*Dicentrarchus labrax*)
Turbot (*Scopthalmus maximus*)

3.2 Indications for use for each target species

For the active immunisation of sea bass and turbot to reduce mortality produced by *Vibrio (Listonella) anguillarum* (Serotypes O1, O2α and O2β*)*.

Onset of immunity in turbot: 4 weeks after second dose at a water temperature between 16-18 ºC (448-504 degree days).

Onset of immunity in sea bass:
- Administration by immersion: 9 weeks after second dose at a water temperature between 19 – 21 ºC (1197-1323 degree days).
- Intraperitoneal administration: 6 weeks after vaccination at a water temperature between 19 – 21 ºC (798-882 degree days).

Duration of immunity: not established.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Fish shall not be stressed during 48 hours before vaccination and 15 days thereafter.

Starvate 24h before vaccination.

Culture water temperature during vaccination shall be equal to or slightly lower than the optimal culture temperature for the species.

It is necessary to maintain the oxygen level at saturation (by strong aeration) during the vaccination process and monitor the oxygen level in the vaccinal suspension.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

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

Fertility:
Do not use in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available of 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 route: dipping and intraperitoneal use.

Recommended vaccination scheme:

Turbot: vaccination by short dipping or prolonged dipping . Vaccinate for the first time when fish weight is between 0.5 g and 2 g. Administer a second dose after 4 weeks.

Sea bass:
- Vaccination by short dipping or prolonged dipping. Vaccinate for the first time when fish weight is between 0.5 g and 2 g. Administer a second dose after 6 weeks.
- Administration by intraperitoneal injection in one dose of 0.1 ml, when fish weight is at least 15 g.

Preparation and method of administration:

Shake well before use.

Vaccination by short dipping: Prepare a 1:10 (vaccine: water) dilution of the vaccine. Introduce in each 60-second immersion up to 0.5 Kg of fish per litre of diluted vaccine. The diluted vaccine can be reused for up to a maximum of 100 kg of fish per litre of vaccine.

Vaccination by prolonged dipping: add the vaccine to the culture tank considering the dilution factor 1:500 (vaccine: water). Previously, the water level will be lowered to a minimum. The vaccination period will last one hour. Thereafter the original water volume of the tank and its recirculation will be restored. Do not vaccinate more than 100 kg of fish per litre of vaccine.

Intraperitoneal injection: Fish must be anaesthetised prior to vaccination by using an authorized aesthetic for fish.

The usage of vaccination guns with 23G needles is recommended. The needle should penetrate the abdominal wall minimum by 1 mm, to deposit the entire dose in the abdominal cavity.

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

No clinical signs have been observed after the administration of a 2-fold vaccine dose.

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, QI10D.

To stimulate active immunity against Vibriosis caused by *Vibrio (Listonella) anguillarum* in turbot and sea bass.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with 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: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 - 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Package size: 1000 ml bottle.

The container-closure system consists of 1000 ml polypropylene bottles, chlorobutyl stoppers classified as Type I and aluminium caps.

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

LABORATORIOS HIPRA, S.A.

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

{DD/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 IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Bottle of 1 000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC-VR Concentrate for dip suspension/for injection for sea bass and turbot

2. COMPOSITION

Each dose contains:

Active substances:

Vibrio anguillarum, serotype O1, strain R-82, Inactivated	RPS(*) ≥ 60%
Vibrio anguillarum, serotype O2 alpha, strain RG-111, Inactivated	RPS(*) ≥ 60%
Vibrio anguillarum, serotype O2 beta, strain RV-22, Inactivated	RPS(*) ≥ 60%

(*) RPS: Relative Percentage of Survival after intraperitoneal challenge in sea bass.

Yellow-brownish suspension.

3. PACKAGE SIZE

1 000 ml

4. TARGET SPECIES

Sea bass (*Dicentrarchus labrax*)
Turbot (*Scopthalmus maximus*)

5. INDICATIONS FOR USE

Indications for use

For the active immunisation of sea bass and turbot to reduce mortality produced by *Vibrio (Listonella) anguillarum* (Serotypes O1, O2α and O2β*)*

Onset of immunity in turbot: 4 weeks after second dose at a water temperature between 16-18ºC (448-504 degree days).

Onset of immunity in sea bass:
- Administration by immersion: 9 weeks after second dose at a water temperature between 19 – 21 ºC (1197-1323 degree days).
- Intraperitoneal administration: 6 weeks after vaccination at a water temperature between 19 – 21 ºC (798-882 degree days).

Duration of immunity: not established.

6. CONTRAINDICATIONS

Contraindications

None.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

Vaccinate healthy animals only.

Starvate 24h before vaccination.

Fish shall not be stressed during 48 hours before vaccination and 15 days thereafter.

Culture water temperature during vaccination shall be equal to or slightly lower than the optimal culture temperature for the species.

It is necessary to maintain the oxygen level at saturation (by strong aeration) during the vaccination process, and monitor the oxygen level in the vaccinal suspension

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

Fertility:

Do not use in breading animals.

Interactions with other medicinal products and other forms of interaction:

No information is available of 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.

Special restrictions for use and special conditions for use:

Overdose:

No clinical signs have been observed after the administration of a 2-fold vaccine dose.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

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 on this label, 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 or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Administration route: dipping and intraperitoneal use.

Recommended vaccination scheme:

Turbot: vaccination by short dipping or prolonged dipping. Vaccinate for the first time when fish weight is between 0.5 g- 2 g. Administer a second dose after 4 weeks.

Sea bass:
- Vaccination by short dipping or prolonged dipping. Vaccinate for the first time when fish weight is between 0.5 g and 2 g. Administer a second dose after 6 weeks.
- Administration by intraperitoneal injection in one dose of 0.1 ml, when fish weight is at least 15 g.

Vaccination by short dipping: Prepare a 1:10 (vaccine: water) dilution of the vaccine. Introduce in each 60-second immersion up to 0.5 5 Kg of fish per litre of diluted vaccine. The diluted vaccine can be reused for up to a maximum of 100 kg of fish per litre of vaccine.

Vaccination by prolonged dipping: add the vaccine to the culture tank considering the dilution factor 1:500 (vaccine: water). Previously, the water level will be lowered to a minimum. The vaccination period will last one hour. Thereafter the original water volume of the tank and its recirculation will be restored. Do not vaccinate more than 100 kg of fish per litre of vaccine.

Intraperitoneal injection: Fish must be anaesthetised prior to vaccination by using an authorized aesthetic for fish.

The usage of vaccination guns with 23G needles is recommended. The needle should penetrate the abdominal wall minimum by 1 1 mm, to deposit the entire dose in the abdominal cavity.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Shake well before use.

11. WITHDRAWAL PERIODS

Withdrawal periods

Zero-degree days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and research of children.
Store and transport refrigerated (2 - 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. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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 how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation numbers:

Pack sizes

1 000 ml bottle.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona), SPAIN
TEL: +34 972 43 06 60

Local representatives and contact details to report suspected adverse reactions:

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

18. OTHER INFORMATION

Other information

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after the first opening of the immediate packaging: use immediately.

21. BATCH NUMBER

Lot {number}