ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAVAC emulsion for injection for rabbits.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml contains:

Active substance:
Inactivated rabbit haemorrhagic disease type 2 virus (RHDV2), strainV-1037……≥70% cELISA40*
(*) ≥70 % of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

Adjuvant:
Mineral oil……104.125 mg

Excipients:
Thiomersal……0.05 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
Whitish emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Rabbits

4.2 Indications for use, specifying the target species

For active immunisation of rabbits from the age of 30 days to reduce mortality caused by the rabbit haemorrhagic disease type 2 virus (RHDV2).

Onset of immunity: 1 week.
Duration of immunity: *12 months demonstrated by challenge*

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.

4.4 Special warnings for each target species

The vaccine provides protection only against RHDV2, cross protection against classical RHDV has not been demonstrated.
Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
Vaccination is recommended where RHDV2 is epidemiologically relevant.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
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)

A transient temperature increase slightly above 40 ºC might very commonly occur between two or three days following vaccination. This slight temperature increase resolves spontaneously without treatment by day 5 post vaccination.

Nodules or swelling (< 2 cm) can be very commonly observed in the injection site, which may last 24 hours. These local reactions gradually reduce and disappear without need for treatment.

Lethargy and/or inappetence may be observed very rarely in the first 48 hours after injection, based on post-authorisation pharmacovigilance reporting.

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

Pregnancy:
Laboratory studies in doe rabbits in the last third of gestation have not been produced any evidence of a teratogenic, foetotoxic and maternotoxic effects.

Pregnant does should be handled with special care to avoid stress and risk of abortion

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

Subcutaneous use.
Administer 1 dose (0.5 ml) of the veterinary medicinal product to rabbits from the age of 30 days by subcutaneous injection in the lateral thoracic wall.

Revaccination: 12 months after vaccination.

Before use allow the vaccine to reach room temperature.
Shake well before administration.

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

No available data.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines for Leporidae, inactivated viral vaccine for rabbits.
ATCvet code: QI08AA

To stimulate active immunity against the rabbit haemorrhagic disease type 2 virus (RHDV2).
Vaccination of rabbits induced the production of hemagglutination inhibition antibodies that persisted for at least 12 months.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mineral oil
Thiomersal
Sorbitan mono-oleate
Polysorbate 80
Sodium chloride
Potassium chloride
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal products.

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: Use immediately.

6.4. Special precautions for storage

Store and transport refrigerated (2 ºC–8 ºC).
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Type I colourless glass vials with 0.5 ml (1 dose), 5 ml (10 doses) and 20 ml (40 doses).
The vials are closed with a rubber stopper and aluminium cap.

Pack sizes:
Cardboard box of 10 glass vials of 1 dose (0.5 ml).
Cardboard box of 1 glass vial of 10 doses (5 ml).
Cardboard box of 1 glass vial of 40 doses (20 ml).

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

Laboratorios Hipra S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN
Tel. +34 972 430660
Fax +34 972 430661
E-mail: hipra@hipra.com

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/199/001 (5 ml)
EU/2/16/199/002 (20 ml)
EU/2/16/199/003 (0.5 ml)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 September 2016

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}
Detailed information on this product is available on the website of the European Medicines Agency http://www.ema.europa.eu

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Laboratorios Hipra, S.A.
Carretera C-63, km 48.300,
Polígono Industrial El Rieral
17170 Amer
SPAIN

Name and address of the manufacturer responsible for batch release

Laboratorios Hipra, S.A.
Avda. La Selva, 135
17170 Amer
SPAIN

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAVAC emulsion for injection for rabbits.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated rabbit haemorrhagic disease type 2 virus (RHDV2), strain V-1037 …..≥70% cELISA40*
(*) ≥70 % of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

10 x 1 dose (0.5 ml).
1 x 10 doses (5 ml).
1 x 40 doses (20 ml).

5. TARGET SPECIES

Rabbits

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Shake well before administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the 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

Laboratorios Hipra S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/199/001(5 ml)
EU/2/16/199/002 (20 ml)
EU/2/16/199/003 (0.5 ml)

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label (1, 10 or 40 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAVAC emulsion for injection for rabbits

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated RHDV2, strain V-1037: …….≥70% cELISA40
≥70 % of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 x 1 dose (0.5 ml).
1 x 10 doses (5 ml).
1 x 40 doses (20 ml).

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch{number}

7. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

ERAVAC emulsion for injection for rabbits

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:
LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAVAC
Emulsion for injection for rabbits.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of 0.5 ml contains:

Active substance:
Inactivated rabbit haemorrhagic disease type 2 virus (RHDV2), strain V-1037: ……≥70% cELISA40*
(*) ≥70 % of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

Adjuvant:
Mineral oil: ……..104.125 mg
Excipients:
Thiomersal: ……..0.05 mg

Whitish emulsion.

4. INDICATION(S)

For active immunisation of rabbits from the age of 30 days to reduce mortality caused by the rabbit haemorrhagic disease type 2 virus (RHDV2).

Onset of immunity: 1 week
Duration of immunity: 12 months demonstrated by challenge

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.

6. ADVERSE REACTIONS

A transient temperature increase slightly above 40 ºC might very commonly occur between two or three days following vaccination. This slight temperature increase resolves spontaneously without treatment by day 5 post vaccination.

Nodules or swelling (< 2 cm) can be very commonly observed in the injection site, which may last 24 hours. These local reactions gradually reduce and disappear without need for treatment.

Lethargy and/or inappetence may be observed very rarely in the first 48 hours after injection, based on post-authorisation pharmacovigilance reporting.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions during the course of one treatment)
- 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).

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

Rabbits.

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

Subcutaneous use.

Administer 1 dose (0.5 ml) of the veterinary medicinal product to rabbits from the age of 30 days by subcutaneous injection in the lateral thoracic wall.
Revaccination: 12 months after vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

Before use allow the vaccine to reach room temperature.
Shake well before administration.

10. WITHDRAWAL PERIOD(S)

Zero 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: Use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The vaccine provides protection only against RHDV2, cross protection against classical RHDV has not been demonstrated.
Vaccinate healthy animals only.

Special precautions for use in animals:
Vaccination is recommended where RHDV2 is epidemiologically relevant.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 12hours 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:
Laboratory studies in pregnant doe in the last third of gestation have not been produced any evidence of a teratogenic, foetotoxic and maternotoxic effects.
Pregnant does should be handled with special care to avoid stress and risk of abortion

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):
No available data.

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

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon 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

Detailed information on this veterinary medicinal product us available on the website of the European Medicines Agency (http://www.ema.europa.eu)

15. OTHER INFORMATION

Cardboard box of 10 glass vial of 1 dose (0.5 ml).
Cardboard box of 1 glass vial of 10 doses (5 ml).
Cardboard box of 1 glass vial of 40 doses (20 ml).

Not all pack sizes may be marketed.

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

België/Belgique/Belgien HIPRA BENELUX NV Tél/Tel: +32 09 2964464	**Lietuva** LABORATORIOS HIPRA, S.A. Tel: +34 972 43 06 60
Република България LABORATORIOS HIPRA, S.A. Тел: +34 972 43 06 60	**Luxembourg/Luxemburg** HIPRA BENELUX NV Tél/Tel: +32 09 2964464
Česká republika HIPRA SLOVENSKO, s.r.o. Tel: +421 02 32 335 223	**Magyarország** LABORATORIOS HIPRA, S.A. Tel: +34 972 43 06 60
Danmark LABORATORIOS HIPRA, S.A. Tel: +34 972 43 06 60	**Malta** LABORATORIOS HIPRA, S.A. Tel: +34 972 43 06 60
Deutschland HIPRA DEUTSCHLAND GmbH Tel: +49 211 698236 – 0	**Nederland** HIPRA BENELUX NV Tel: +32 09 2964464
Eesti LABORATORIOS HIPRA, S.A. Tel: +34 972 43 06 60	**Norge** LABORATORIOS HIPRA, S.A. Tlf: +34 972 43 06 60
Ελλάδα HIPRA ΕΛΛΑΣ Α.Ε. Τηλ: +30 210 4978660	**Österreich** HIPRA DEUTSCHLAND GmbH Tel: +49 211 698236 – 0
España LABORATORIOS HIPRA, S.A. Tel: +34 972 43 06 60	**Polska** HIPRA POLSKA Sp.z.o.o. Tel: +48 22 642 33 06

France HIPRA FRANCE Tél: +33 02 51 80 77 91	**Portugal** ARBUSET, Produtos Farmacêuticos e Sanitários De Uso Animal, Lda Tel:+351 219 663 450
Hrvatska LABORATORIOS HIPRA, S.A. Tel: +34 972 43 06 60	**România** LABORATORIOS HIPRA, S.A. Tel: +34 972 43 06 60
Ireland HIPRA UK AND IRELAND, Ltd. Tel: +44-(0)11 5845 6486	**Slovenija** LABORATORIOS HIPRA, S.A. Tel: +34 972 43 06 60
Ísland LABORATORIOS HIPRA, S.A. Sími: +34 972 43 06 60	**Slovenská republika** HIPRA SLOVENSKO, s.r.o. Tel: +421 02 32 335 223
Italia Hipra Italia S.r.l. Tel: +39 030 7241821	**Suomi/Finland** LABORATORIOS HIPRA, S.A. Puh/Tel: +34 972 43 06 60
Κύπρος LABORATORIOS HIPRA, S.A. Τηλ: +34 972 43 06 60	**Sverige** LABORATORIOS HIPRA, S.A. Tel. +34 972 43 06 60
Latvija LABORATORIOS HIPRA, S.A. Tel. +34 972 43 06 60	**United Kingdom** HIPRA UK AND IRELAND, Ltd. Tel. +44-(0)11 5845 6486