ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS
1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FILAVAC VHD K C+V suspension for injection for rabbits (FR, DK, ES, FI, IT, LU, NL, NO, PT).

FILAVAC RHD suspension for injection for rabbits (1-dose).
FILAVAC RHD suspension and diluent for suspension for injection for rabbits (50-dose and 200-dose presentations) (SE).

FILAVAC VHD K C+V suspension for injection for rabbits (1-dose).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

0.5 ml dose of vaccine for single-dose presentation or 0.2 ml for the 50-dose and 200-dose presentations contains:

Rabbit Haemorrhagic Disease Virus strain LP.SV.2012 (variant strain 2010, RHDV2), inactivated…………………………………………………………………….min 1 PD90% *

Rabbit Haemorrhagic Disease Virus strainIM507.SC.2011 (classical strain, RHDV1), inactivated…………………………………………………………………….min 1 PD90% *

Adjuvant:
Aluminium hydroxide (Al^{3+}) ………………………………………………………0.35 mg

(*)Protective dose at least 90% of the vaccinated animals.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Reddish homogeneous suspension before and after dilution (FR, DK, ES, FI, IT, LU, NL, NO, PT).

Suspension for injection for rabbits (1-dose).
Suspension and diluent for suspension for injection for rabbits (50-dose and 200-dose presentations).
Reddish homogeneous suspension before and after dilution (SE).

Suspension for injection (1-dose).
Concentrate and solvent for suspension for injection (50-dose and 200-dose presentations).
Reddish homogeneous suspension before and after dilution (BE, UK, DE).

4. CLINICAL PARTICULARS

4.1. Target species

Rabbits.
4.2. **Indications for use, specifying the target species**

For active immunisation of rabbits (fattening and future breeders) from 10 weeks of age, to reduce mortality due to rabbit haemorrhagic disease caused by classical (RHDV1) and type 2 (RHDV2) virus strains.

Onset of immunity: 7 days.
Duration of immunity: 12 months.

4.3. **Contraindications**

None.

4.4. **Special warning**

No information is available on the use of the vaccine in seropositive animals, including animals with maternally derived antibodies. Thus, in situations where a high level of antibodies is expected, the vaccination scheme must be adjusted accordingly.

The efficacy of the vaccine in animals younger than 10 weeks of age has not been demonstrated.

No information is available on the safety and efficacy in pet rabbits.

4.5. **Special precautions for use**

- **Special precautions for use in animals**

Vaccinate only healthy rabbits.

- **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.

4.6. **Adverse reactions (frequency and seriousness)**

Very common: a temporary increase in body temperature of up to 1.6°C can be observed one day after vaccination.

Common: Immunization is followed by a limited local reaction (subcutaneous nodule up to 3 mm in diameter) which may be palpable and observable for at least 52 days.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals occurring adverse reactions during the course of one treatment);
- common (more than 1 but less than 10 animals in 100 animals);
- uncommon (more than 1 but less than 10 animals in 1,000 animals);
- rare (more than 1 but less than 10 animals in 10,000 animals);
- very rare (less than 1 animal in 10,000 animals, including isolated reports).
4.7. Use during pregnancy and lactation

Pregnancy:
The available study (field trial) has not shown abortion in pregnant animals. Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
The influence of the vaccination on the fertility of rabbits has not been investigated.

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

One dose per subcutaneous injection to each animal with a volume of 0.5 ml for the single-dose presentation or 0.2 ml for the 50-dose and 200-dose presentations.

First vaccination from the 10th week of age.
Re-vaccination: annual

Dilution of the vaccine for 50-dose and 200-dose presentations:
Applying usual aseptic conditions.
Take the diluent in a sterile syringe with a sterile needle and inject the diluent into the vial of vaccine.
Shake gently before and occasionally during administration to maintain a homogeneous suspension.

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

No adverse reactions other than those referenced in section 4.6 have been observed after administration of a double dose of vaccine.

4.11. Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals, inactivated viral vaccine for rabbits, Rabbit Haemorrhagic Disease Virus (RHDV)
ATCvet code: QI08AA01
To stimulate active immunity against Rabbit Haemorrhagic Disease Virus (RHDV) caused by RHDV1 (classical form) and RHDV2 (variant form).
6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Single-dose presentation:
Aluminium hydroxide
Sodium disulfite
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Sodium hydroxide
Water for injections

Multi-dose presentation:
Aluminium hydroxide
Sodium disulfite
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Sodium hydroxide
Water for injections

Diluent:
Water for injections

6.2. Incompatibilities

Do not mix with any other veterinary medicinal product, except the diluent supplied for use with the multi-dose veterinary medicinal product.

6.3. Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 14 months.
Shelf-life after dilution according to directions (only for multi-dose presentation): 2 hours.

6.4. Special precautions for storage

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

6.5. Nature and composition of immediate packaging

Type I glass bottles closed with nitrile rubber stoppers and aluminium caps.

Single-dose: vial with 0.5 mL vaccine.
50 doses: vial with 7.5 ml vaccine and vial with 2.5 ml diluent.
200 doses: vial with 30 ml vaccine and vial with 10 ml diluent.

Secondary packaging: cardboard box.
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**

FILAVIE
20, LA CORBIERE
49450 ROUSSAY
FRANCE

8. **MARKETING AUTHORISATION NUMBER(S)**

To be completed nationally

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: DD/MM/YYYY

10. **DATE OF REVISION OF THE TEXT**

DD/MM/YYYY
ANNEX III

LABELLING AND PACKAGE LEAFLET
A. LABELLING
PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FILAVAC VHD K C+V suspension for injection for rabbits (FR, DK, ES, FI, IT, LU, NL, NO, PT).

FILAVAC RHD suspension for injection for rabbits (1-dose).
FILAVAC RHD suspension and diluent for suspension for injection for rabbits (50-dose and 200-dose presentations) (SE).

FILAVAC VHD K C+V suspension for injection for rabbits (1-dose).

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Rabbit Haemorrhagic Disease Virus strain LP.SV.2012 (variant strain 2010, RHDV2),
Inactivated…………………………………………………………………………………………..min 1 PD90% *

Rabbit Haemorrhagic Disease Virus strain IM507.SC.2011 (classical strain RHDV1),
Inactivated…………………………………………………………………………………………..min 1 PD90% *

(*)Protective dose at least 90% of the vaccinated animals

3. PHARMACEUTICAL FORM

Suspension for injection (FR, DK, ES, FI, IT, LU, NL, NO, PT).

Suspension for injection for rabbits (1-dose).
Suspension and diluent for suspension for injection for rabbits (50-dose and 200-dose presentations) (SE).

Suspension for injection (1-dose).
Concentrate and solvent for suspension for injection (50-dose and 200-dose presentations) (BE, UK, DE).

4. PACKAGE SIZE

Single-dose: vial with 0.5 mL vaccine.
50 doses: vial with 7.5 ml vaccine and vial with 2.5 ml diluent.
200 doses: vial with 30 ml vaccine and vial with 10 ml diluent.

5. TARGET SPECIES

Rabbits.

6. INDICATION(S)
7. **METHOD AND ROUTE(S) OF ADMINISTRATION**

Subcutaneous use.
Read the package leaflet before use.

8. **WITHDRAWAL PERIOD**

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 diluted use within 2 hours (only for multi-dose presentations).

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 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**

FILAVIE
20, LA CORBIERE
49450 ROUSSAY
FRANCE

16. **MARKETING AUTHORISATION NUMBER(S)**

To be completed nationally
17. MANUFACTURER'S BATCH NUMBER

Batch (number)
**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**VACCINE VIAL LABEL (1, 50 and 200 doses)**

<table>
<thead>
<tr>
<th>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>FILAVAC VHD K C+V suspension for injection for rabbits (FR, DK, ES, FI, IT, LU, NL, NO, PT).</td>
</tr>
<tr>
<td>FILAVAC RHD suspension for injection for rabbits (1-dose).</td>
</tr>
<tr>
<td>FILAVAC RHD suspension and diluent for suspension for injection for rabbits (50-dose and 200-dose presentations) (SE).</td>
</tr>
<tr>
<td>FILAVAC VHD K C+V suspension for injection for rabbits (1-dose).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. QUANTITY OF THE ACTIVE SUBSTANCE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 dose: vaccine (0.5 mL)</td>
</tr>
<tr>
<td>50 doses: vaccine (7.5 mL)</td>
</tr>
<tr>
<td>200 doses: vaccine (30 mL)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 dose: vaccine (0.5 mL)</td>
</tr>
<tr>
<td>50 doses: vaccine (7.5 mL)</td>
</tr>
<tr>
<td>200 doses: vaccine (30 mL)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>4. ROUTE(S) OF ADMINISTRATION</th>
</tr>
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<tbody>
<tr>
<td>SC.</td>
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<tr>
<th>5. WITHDRAWAL PERIOD</th>
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<table>
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<tr>
<th>6. BATCH NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch {number}</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>7. EXPIRY DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXP {month/year}</td>
</tr>
<tr>
<td>Once diluted use within 2 hours (only for multi-dose presentations).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8. THE WORDS “FOR ANIMAL TREATMENT ONLY”</th>
</tr>
</thead>
<tbody>
<tr>
<td>For animal treatment only.</td>
</tr>
</tbody>
</table>
### MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

#### DILUENT VIAL LABEL (50 and 200 doses)

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

FILAVAC VHD K C+V suspension for injection for rabbits  
Solvent (FR, BE, DE, DK, ES, FI, LU, NL, NO, PT, UK, IT)

FILAVAC RHD suspension for injection for rabbits  
Solvent (SE)

2. **QUANTITY OF THE ACTIVE SUBSTANCE(S)**

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

   50 doses: diluent (2.5 mL)  
   200 doses: diluent (10 mL)

4. **ROUTE(S) OF ADMINISTRATION**

5. **WITHDRAWAL PERIOD**

6. **BATCH NUMBER**

Batch {number}

7. **EXPIRY DATE**

EXP {month/year}

8. **THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.
B. PACKAGE LEAFLET
1. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

FILAVIE – 20, LA CORBIERE – 49450 ROUSSAY – FRANCE

2. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

FILAVAC VHD K C+V suspension for injection for rabbits (FR, DK, ES, FI, IT, LU, NL, NO, PT).

FILAVAC RHD suspension for injection for rabbits (1-dose).

FILAVAC RHD suspension and diluent for suspension for injection for rabbits (50-dose and 200-dose presentations) (SE).

FILAVAC VHD K C+V suspension for injection for rabbits (1-dose).


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

0.5 ml dose of vaccine for single-dose presentation or 0.2 ml for the 50-dose and 200-dose presentations contains:

- Rabbit Haemorrhagic Disease Virus strain LP.SV.2012 (variant strain 2010, RHDV2), Inactivated………………………………………………………………………………min 1 PD90% *
- Rabbit Haemorrhagic Disease Virus strain IMS07.SC.2011 (classical strain RHDV1), Inactivated……………………………………………………………………min 1 PD90% *

(*)Protective dose at least 90% of the vaccinated animals

Adjuvant:
Aluminium hydroxide (Al³⁺): …………………………………………………………………………………0.35 mg

Suspension for injection.
Reddish homogeneous suspension before and after dilution (FR, DK, ES, FI, IT, LU, NL, NO, PT).

Suspension for injection for rabbits (1-dose).
Suspension and diluent for suspension for injection for rabbits (50-dose and 200-dose presentations).
Reddish homogeneous suspension before and after dilution (SE).

Suspension for injection (1-dose).
Concentrate and solvent for suspension for injection (50-dose and 200-dose presentations).
Reddish homogeneous suspension before and after dilution (BE, UK, DE).

4. **INDICATIONS**

For active immunisation of rabbits (fattening and future breeders) from 10 weeks of age, to reduce mortality due to rabbit haemorrhagic disease caused by classical (RHDV1) and type 2 (RHDV2) virus strains.

Onset of immunity: 7 days.
Duration of immunity: 12 months.

5. **CONTRAINDICATIONS**

None.

6. **ADVERSE REACTIONS**

Very common: a temporary increase in body temperature of up to 1.6°C can be observed one day after vaccination.

Common: Immunization is followed by a limited local reaction (subcutaneous nodule up to 3 mm in diameter) which may be palpable and observable for at least 52 days.

The frequency of adverse reactions is defined using the following convention:

-very common (more than 1 in 10 animals occurring adverse reactions during the course of one treatment);

-common (more than 1 but less than 10 animals in 100 animals);

-uncommon (more than 1 but less than 10 animals in 1,000 animals);

-rare (more than 1 but less than 10 animals in 10,000 animals);

-very rare (less than 1 animal in 10,000 animals, including isolated reports).
7. **TARGET SPECIES**

Rabbits.

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

Subcutaneous use.
One dose per subcutaneous injection to each animal with a volume of 0.5 ml for the single-dose presentation or 0.2 ml for the 50-dose and 200-dose presentations.

First vaccination from the 10th week of age.
Re-vaccination: annual

9. **ADVICE ON CORRECT ADMINISTRATION**

Shake well before use.
Reddish homogeneous suspension (1-dose).
Reddish homogeneous suspension before and after dilution (50-dose and 200-dose).

Apply usual aseptic conditions.
Take the diluent in a sterile syringe with a sterile needle and inject the diluent into the vial of vaccine.

10. **WITHDRAWAL PERIOD**

Zero days.

11. **SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.
Store and transport refrigerated (2°C - 8°C).
Protect from light.
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf-life of the veterinary medicinal product as packaged for sale: 14 months.
Shelf-life after dilution according to directions (only for multi-dose presentation): 2 hours.

12. **SPECIAL WARNING(S)**

Special warnings for each target species:

No information is available on the use of the vaccine in seropositive animals, including animals with maternally derived antibodies. Thus, if situations where a high level of antibodies is expected, the vaccination scheme must be adjusted accordingly. The efficacy of the vaccine in animals younger than 10 weeks of age has not been demonstrated. No information is available on the safety and efficacy in pet rabbits.

Special precautions for use in animals:

Vaccinate only healthy rabbits.

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.
This product contains aluminium hydroxide. An accidental injection to the person giving the injection may result in a local inflammatory reaction, with pain more or less severe at the point of inoculation (in particular if injection into a finger).
Accidental injection to human may result in bacterial infection.

As soon as possible after the accidental injection, you must:
- Clean and disinfect at the point of injection.
- Put ice at the zone of injection.
- Seek prompt medical advice and take the package (vial, label and leaflet) insert with you.

**Pregnancy:**
The available study (field trial) has not shown abortion in pregnant animals.
Use only according to the benefit-risk assessment by the responsible veterinarian.

**Fertility:**
The influence of the vaccination on the fertility of rabbits has not been investigated.
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 adverse reactions other than those referenced in section 6 have been observed after administration of a double dose of vaccine.

Incompatibilities:

Do not mix with any other veterinary medicinal product, except the diluent supplied for use with the multi-dose veterinary medicinal product.

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

DD/MM/YYYY

15. OTHER INFORMATION

Single-dose: vial with 0.5 mL vaccine.
50-dose: vial with 7.5 ml vaccine and vial with 2.5 ml diluent.
200-dose: vial with 30 ml vaccine and vial with 10 ml diluent.

Not all pack sizes may be marketed.

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

FILAVIE – 20, LA CORBIERE – 49450 ROUSSAY – FRANCE
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E-MAIL: contact.filavie@filavie.com