ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabitec oral suspension for foxes and raccoon dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (1.7 ml) contains:

Active substance:
Attenuated live rabies vaccine virus, strain SPBN GASGAS: $10^{6.8}$ FFU* - $10^{8.1}$ FFU*
(* Focus Forming Units)

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

The suspension has a yellow colour in a frozen state and a reddish colour in the liquid state. The baits are rectangular, brownish coloured and have an intensive smell.

4. CLINICAL PARTICULARS

4.1 Target species

Foxes, raccoon dogs

4.2 Indications for use, specifying the target species

For the active immunization of foxes and raccoon dogs against rabies to prevent infection and mortality.

Duration of immunity: at least 12 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals:
Vaccine baits are not intended for vaccination of domestic animals.

Gastrointestinal signs (potentially due to the indigestible blister material) have been reported in dogs following accidental ingestion of the bait.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Handle the baits with care. It is recommended to wear disposable rubber gloves when handling and distributing baits. In case of contact of the vaccine fluid, immediately remove it by thoroughly rinsing with water and soap. Seek medical advice immediately and show the package leaflet or the label to the physician.

Proposed first aid measures immediately after direct human exposure to the vaccine fluid should follow the recommendations of the WHO as outlined in the "WHO Guide for Rabies Pre- and Post-Exposure Prophylaxis (PEP) in Humans".

Since this vaccine has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process, e.g. by wearing appropriate protective clothes.

4.6 Adverse reactions (frequency and seriousness)

No adverse reactions have been observed.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy.

The safety of the veterinary medicinal product has not been established during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Oral use.

The intake of single bait is sufficient to ensure active immunisation to prevent infection by rabies virus. The baits are distributed by land or by air within the framework of vaccination campaigns against rabies.

The vaccination area should be as large as possible (preferably larger than 5,000 km^2). The vaccination campaigns in rabies-free areas should be designed in such a way that the area covers a 50 km belt ahead of the rabies front. The distribution rate depends on the topography, on the population density of the target species and on the epizootiological situation. Therefore the recommendations / request of the duly designated competent authority are followed concerning distribution rate, vaccination area, distribution/baiting method and other local/areal conditions as specified by the competent authority. A higher distribution density is recommended in areas with a high population density of foxes/raccoon dogs. Aerial distribution of the baits by any suitable flight devices (such as airplane, helicopter, drones or similar) is recommended for open or sparsely populated areas, and manual distribution in areas with a high human population.
Aerial baiting is not recommended in the vicinity of water (lakes, rivers, water reservoirs) neither in densely populated areas. The vaccination should be preferably carried out biannually (e.g. in spring and autumn), for a number of consecutive years, for at least two years after the last confirmed case of rabies in the region; however vaccination should not be attempted when temperatures are expected to reach 25 °C or more, and never during the summer season. To protect regions which are free of rabies, baiting may be carried out to create a vaccination belt or in the form of spot vaccinations.

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

The administration of the vaccine at 10 times the recommended dose induced no undesirable effects.

4.11 Withdrawal period (s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for canidae, live viral vaccines.
ATCvet code: QI07BD.

Rabitec is a live modified rabies vaccine for oral administration to foxes and raccoon dogs. Immunized animals are protected against field rabies virus infection and do not transmit rabies. In contrast to its parental strain SAD B19, the Rabitec vaccine's active ingredient proved to be apathogenic for immunocompetent mice, the most sensitive species for rabies virus infection.

The active ingredient is a quadruple highly attenuated genetically modified rabies virus construct, derived from the SAD B19 vaccine strain. The genome carries mutations in the G-protein (glycoprotein) located at 2 independent loci of the genome (at amino acid positions 194 and 333 in G-protein), where all three nucleotides 'codon' were exchanged resulting in amino acid changes at both positions. In addition, the genome carries an exact duplicate of the modified immune-relevant G-protein (glycoprotein) gene, which results in the significant higher expression of the G protein gene. As each of these modifications on the genome were shown to further attenuate the SAD B19 virus strain, their multiple effect helps to avoid the reversion to the parental strain. Finally, the pseudogen located between the G – and L-gene has been deleted.

A differentiation of this vaccine virus from any other rabies virus strains is possible, including its parental strain, for example by PCR methods.

Rabitec is used for the induction of the protective immunity in foxes and raccoon dogs by the oral route characterised by the induction of rabies virus specific (neutralising) antibodies induced primarily by the G-protein (glycoprotein).

No field studies were conducted.

The efficacy of the vaccine was demonstrated in laboratory studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine:
Water for injections
Sucrose
Gelatin (porcine)
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Neomycin sulfate

Bait:
Fishmeal
Palm fat
Coconut fat
Paraffin

Oxytetracycline hydrochloride (may be added as biomarker if requested by authorities)

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years at/below -15 °C.
Stability after distribution in the environment was shown for 7 days at temperatures up to 25 °C.

6.4 Special precautions for storage

Store and transport frozen, below -15 °C.
Do not refreeze.
Baits should be distributed immediately after thawing. The thawed vaccine bait may be stored for 7 days between 2 °C– 8 °C before use; however baits for which the cooling chain was disrupted, because they were not stored in a refrigerator, should be destroyed.

6.5 Nature and composition of immediate packaging

The vaccine suspension is filled in polymer/aluminium blisters which are embedded in a bait matrix attractive for the target species. Baits are packed in plastic foil sleeves or bags in cardboard boxes of:

1 x 800 units
4 x 200 units
40 x 20 units

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

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/219/001-003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01/12/2017

10. DATE OF REVISION OF THE TEXT

20/07/2020

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.
Restricted to duly designated competent administrative authorities.

ANNEX II

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

Name and address of the manufacturers of the biological active substance

Ceva Tiergesundheit (Riems) GmbH
An der Wiek 7
17493 Greifswald - Insel Riems
Germany

Name and address of the manufacturer responsible for batch release

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Ceva Tiergesundheit (Riems) GmbH
An der Wiek 7
17493 Greifswald - Insel Riems
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programmes for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 800 baits (1 x 800 units, 4 x 200 units or 40 x 20 units**)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabitec oral suspension for foxes and raccoon dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Attenuated live rabies vaccine virus, strain SPBN GASGAS
$10^{6.8}$ FFU*/dose - $10^{8.1}$ FFU*/dose (* Focus Forming Units)

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

1 x 800 units
4 x 200 units
40 x 20 units

5. TARGET SPECIES

Foxes, raccoon dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Distribution of baits manually or by air.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

9. SPECIAL WARNING(S), IF NECESSARY

Handle the baits with care. It is recommended to wear disposable rubber gloves when handling and distributing baits. In case of contact of the vaccine fluid, immediately remove it by thoroughly rinsing

with water and soap. Seek medical advice immediately and show the package leaflet or the label to the physician.

10. EXPIRY DATE

EXP {month/year}
Baits should be distributed immediately after thawing.

11. SPECIAL STORAGE CONDITIONS

Store and transport frozen.
Do not refreeze.
As an exception, the thawed vaccine may be stored for up to 7 days at 2 °C - 8 °C before use.

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

Dispose of waste material in accordance with local requirements.

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. Restricted to duly designated competent authorities. The import, possession, sale, supply and/or use of this veterinary medicinal product is or may be prohibited in certain Member States on the whole or part of their territory, see package insert for further information.

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

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

16. MARKETING AUTHORISATION NUMBER

EU/2/17/219/001
EU/2/17/219/002
EU/2/17/219/003

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

PVC/Aluminium blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabitec

2. EXPIRY DATE

EXP: {month/year}

3. BATCH NUMBER

Lot: {number}

HAZARD WARNING

Rabies vaccine.

MINIMUM PARTICULARS TO APPEAR ON BAITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabitec

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale, France

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Lot: {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

HAZARD WARNING

Rabies vaccine. Do not touch!

QR code – https:\\www.ceva.de\service\rabitec

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Rabitec oral suspension, for foxes and raccoon dogs

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

Marketing authorisation holder:

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

Manufacturer responsible for batch release:

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Ceva Tiergesundheit (Riems) GmbH
An der Wiek 7
17493 Greifswald - Insel Riems
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabitec oral suspension for foxes and raccoon dogs

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

1 dose (1.7 ml) embedded in bait contains:

Active substance:
Attenuated live rabies vaccine virus, strain SPBN GASGAS: $10^{6.8}$ FFU* - $10^{8.1}$ FFU*
(* Focus Forming Units)

The suspension has a yellow colour in a frozen state and a reddish colour in the liquid state. The baits are rectangular, brown coloured and have an intensive smell.

4. INDICATION(S)

For the active immunization of foxes and raccoon dogs against rabies to prevent infection and mortality.

Duration of immunity: at least 12 months.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Not known.

If you notice any side effects, even those not listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Foxes, raccoon dogs

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

Oral use.

The intake of single bait is sufficient to ensure active immunisation to prevent infection by rabies virus. The baits are distributed by land or by air within the framework of vaccination campaigns against rabies.

The vaccination area should be as large as possible (preferably larger than 5,000 km^2). The vaccination campaigns in rabies-free areas should be designed in such a way that the area covers a 50 km belt ahead of the rabies front. The distribution rate depends on the topography, on the population density of the target species and on the epizootiological situation. Therefore the recommendations / request of the duly designated competent authority are followed concerning distribution rate, vaccination area, distribution/baiting method and other local/areal conditions as specified by the competent authority. A higher distribution density is recommended in areas with a high population density of foxes/raccoon dogs. Aerial distribution of the baits by any suitable flight devices (such as airplane, helicopter, drones or similar) is recommended for open or sparsely populated areas, and manual distribution in areas with a high human population.
Aerial baiting is not recommended in the vicinity of water (lakes, rivers, water reservoirs,) neither in densely populated areas. The vaccination should be preferably carried out biannually (e.g. in spring and autumn), for a number of consecutive years, for at least two years after the last confirmed case of rabies in the region, however vaccination should not be attempted when temperatures are expected to reach 25 °C or more, and never during the summer season. To protect regions which are free of rabies, baiting may be carried out to create a vaccination belt or in the form of spot vaccinations.

9. ADVICE ON CORRECT ADMINISTRATION

Baits should be distributed immediately after thawing.
Vaccination should not be attempted when temperatures are expected to reach 25 °C or more, and never during the summer season.

10. WITHDRAWAL PERIOD (S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport frozen, below -15 °C.
Do not refreeze.

The thawed vaccine may be stored for up to 7 days at 2 °C - 8 °C before use; however baits for which the cooling chain was disrupted, because they were not stored in a refrigerator, should be destroyed.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and cardboard after EXP.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Vaccine baits are not suitable for vaccination of domestic animals.

Gastrointestinal signs (potentially due to the indigestible blister material) have been reported in dogs following accidental ingestion of the bait.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Handle the baits with care. It is recommended to wear disposable rubber gloves when handling and distributing baits. In case of contact of the vaccine fluid, immediately remove it by thoroughly rinsing with water and soap. Seek medical advice immediately and show the package leaflet or the label to the physician.

Proposed first aid measures immediately after direct human exposure to the vaccine fluid should follow the recommendations of the WHO as outlined in the "WHO Guide for Rabies Pre- and Post-Exposure Prophylaxis (PEP) in Humans".

Since this vaccine has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.

Pregnancy and lactation:
Can be used during pregnancy.

The safety of the veterinary medicinal product has not been established during lactation.

Interaction with other medicinal products and other forms of interaction:
Not known.

Overdose (symptoms, emergency procedures, antidotes):
The administration of the vaccine at 10 times the recommended dose induced no undesirable effects.

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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. 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 is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Liquid vaccine contained in a polymer/aluminium blisters which are embedded in a bait matrix attractive for the target species.
Plastic foil sleeves or bags in cardboard boxes of:

1 x 800 units
4 x 200 units
40 x 20 units

Not all pack sizes may be marketed.