ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAP lyophilisate and solvent for suspension for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose of vaccine contains:
Active substances:

	Minimum	**Maximum**
Attenuated canine distemper virus, strain BA5	$10^{4.0}$ $CCID_{50}$*	$10^{6.0}$ $CCID_{50}$*
Attenuated canine adenovirus type 2, strain DK13	$10^{2.5}$ $CCID_{50}$*	$10^{6.3}$ $CCID_{50}$*
Attenuated canine parvovirus type 2, strain CAG2	$10^{4.9}$ $CCID_{50}$*	$10^{7.1}$ $CCID_{50}$*

* $CCID_{50}$: 50 % cell culture infective dose

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Casein hydrolysate
Gelatin
Dextran 40
Dipotassium phosphate
Potassium dihydrogen phosphate
Potassium hydroxide
Sorbitol
Sucrose
Water for injections
Solvent:
Water for injections

Beige to pale yellow lyophilisate and colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

Active immunisation of dogs to:
- prevent mortality and clinical signs caused by canine distemper virus (CDV),
- prevent mortality and clinical signs caused by infectious canine hepatitis virus (CAV-1),
- reduce viral excretion during respiratory disease caused by canine adenovirus type 2 (CAV-2),
- prevent mortality, clinical signs and viral excretion caused by canine parvovirus (CPV)*.

Onset of immunity: 2 weeks after the second injection of the primary vaccination course.

Duration of immunity: at least one year after the second injection of the primary vaccination course and at least 2 years after the first annual booster.
Current available challenge and serological data show that protection for distemper virus, adenovirus and parvovirus* lasts for 2 years after primary vaccination course followed by a first annual booster.
Any decision to adapt the vaccination schedule of this veterinary medicinal product needs to be made on a case by case basis, taking into account the vaccination history of the dog and the epidemiological context.
*Protection has been demonstrated against canine parvovirus type 2a, 2b and 2c either by challenge (type 2b) or serology (type 2a and 2c).

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:
Apply usual aseptic procedures.
After vaccination, the live CAV-2 and CPV vaccine strains can transiently be shed without adverse consequence for in-contact animals.

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

Dogs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1], injection site pruritus, injection site pain. Lethargy[2]. Emesis[2].
Uncommon (1 to 10 animals / 1,000 animals treated):	Anorexia, polydipsia, hyperthermia. Diarrhoea. Muscle tremor. Muscle weakness. Injection site warmth, injection site lesions[3].
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction (facial oedema, anaphylactic shock, urticaria)[4].

[1] Slight (≤ 2 cm), immediately after injection. It usually regresses within 1-6 days.
[2] Transient.
[3] Cutaneous.

[4] Some of which are life-threatening. Appropriate symptomatic treatment should promptly be provided.

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

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered with Eurican LR, Eurican L, Eurican Lmulti or Eurican L4 vaccines (used as solvent) where available.
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Rabisin vaccine.
When administered with Boehringer Ingelheim's vaccines containing rabies, the minimum age for vaccination is 12 weeks of age.
When mixed with the Eurican LR vaccine a small and transient nodule (maximum size 1.5 cm) at the injection site may be induced due to the presence of aluminium hydroxide and a slight swelling (~4 cm) may occur after the injection at injection site, regressing generally within 1-4 days.
When mixed with the Eurican L4 vaccine a swelling (less than 6 cm) may very commonly occur at the injection site, disappearing within 8 days, anorexia may commonly occur and vocalisation, tachycardia and tachypnoea may uncommonly be observed. For Eurican L4, no safety data in pregnant bitches are available for the additional inactivated strain, Leptospira Australis.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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

Aseptically reconstitute the contents of the lyophilisate with either solvent for Eurican DAP/DAPPi or a compatible Boehringer Ingelheim vaccine (Eurican LR, Eurican L, Eurican Lmulti or Eurican L4) where available. Shake well before use. The entire contents of the reconstituted vial should be administered as a single dose.

The reconstituted content shall be an opalescent yellow to orange suspension.

Inject a 1 ml dose subcutaneously according to the following schedule:

Primary vaccination: Two injections separated by an interval of 4 weeks from 7 weeks of age.
When administered with Boehringer Ingelheim's vaccines containing rabies, the minimum age for vaccination is 12 weeks of age.

In cases where high levels of maternally derived antibodies are suspected by the veterinarian and the primary vaccination course was completed before 16 weeks of age, a third injection is recommended from 16 weeks of age, at least 3 weeks after the second injection.

Revaccination: Administer one dose 12 months after completion of the primary vaccination course. Dogs should be revaccinated with a single booster dose every two years after the first annual booster

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

No adverse effects other than those mentioned in section 3.6 were observed after administration of a 10-fold overdose of the lyophilisate.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AD02

Vaccine against canine distemper, canine adenovirus (CAV-1 and CAV-2) and parvovirus infections.

After administration, the vaccine induces an active immune response in dogs against distemper, adenoviroses (CAV-1 and CAV-2) and parvovirosis demonstrated by challenge and by the presence of antibodies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Do not mix with any other veterinary medicinal product except the solvent for Eurican DAP/DAPPi, supplied for use with the veterinary medicinal product, and except those mentioned in section 3.8 above.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life of the solvent as packaged for sale: 3 years.
Shelf-life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Immediate container: type I glass vials with chlorobutyl rubber stoppers, sealed with aluminium caps.

Outer container:
Plastic box of 10 vials of lyophilisate (1 dose) and 10 vials of solvent (1 ml).
Plastic box of 50 vials of lyophilisate (1 dose) and 50 vials of solvent (1 ml).

Plastic box of 10 vials of lyophilisate (1 dose).

Plastic box of 50 vials of lyophilisate (1 dose).

Plastic box of 10 vials of solvent (1 ml).
Plastic box of 50 vials of solvent (1 ml).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY} to be completed nationally

9. DATE OF THE LAST REVISION OF THE SUMMARY OF TE PRODUCT CHARACTERISTICS

To be completed nationally.

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 OUTER PACKAGE

Plastic box of 10 doses: 10 vials (glass) of 1 dose of lyophilisate and 10 vials (glass) of 1 ml of solvent
Plastic box of 50 doses: 50 vials (glass) of 1 dose of lyophilisate and 50 vials (glass) of 1 ml of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAP
lyophilisate and solvent for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose (1 ml):
Attenuated distemper virus ..... $10^{4.0-6.0}$ $CCID_{50}$
Attenuated canine adenovirus type 2 ..... $10^{2.5-6.3}$ $CCID_{50}$
Attenuated canine parvovirus type 2 ..... $10^{4.9-7.1}$ $CCID_{50}$

3. PACKAGE SIZE

10 doses: 10 x 1 dose lyophilisate + 10 x 1ml solvent.
50 doses: 50 x 1 dose lyophilisate + 50 x 1ml solvent.

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted: use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

10. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box of 10 vials (glass) of 1 dose of lyophilisate
Plastic box of 50 vials (glass) of 1 dose of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAP
lyophilisate for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose (1 ml):
Attenuated distemper virus ..... $10^{4.0-6.0}$ $CCID_{50}$
Attenuated canine adenovirus type 2 ..... $10^{2.5-6.3}$ $CCID_{50}$
Attenuated canine parvovirus type 2 ..... $10^{4.9-7.1}$ $CCID_{50}$

3. PACKAGE SIZE

10 doses: 10 x 1 dose
50 doses: 50 x 1 dose

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted: use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box of 10 vials (glass) of 1 ml of solvent
Plastic box of 50 vials (glass) of 1 ml of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Eurican DAP/DAPPi

2. STATEMENT OF ACTIVE SUBSTANCES

Water for injections 1 ml

3. PACKAGE SIZE

10 x 1 ml
50 x 1 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {dd/mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet supplied with the vaccine before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial: 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAP

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

DAP
1 d.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent vial: 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

solvent for Eurican DAP/DAPPi 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Eurican DAP lyophilisate and solvent for suspension for injection.

1. Name of the veterinary medicinal product

Eurican DAP lyophilisate and solvent for suspension for injection.

2. Composition

Each 1 ml dose contains:
Lyophilisate:

Active substance:

	Minimum	**Maximum**
Attenuated canine distemper virus, strain BA5	$10^{4.0}$ $CCID_{50}$*	$10^{6.0}$ $CCID_{50}$*
Attenuated canine adenovirus type 2, strain DK13	$10^{2.5}$ $CCID_{50}$*	$10^{6.3}$ $CCID_{50}$*
Attenuated canine parvovirus type 2, strain CAG2	$10^{4.9}$ $CCID_{50}$*	$10^{7.1}$ $CCID_{50}$*

* $CCID_{50}$: 50% cell culture infective dose

Solvent:
Water for injections 1 ml

Beige to pale yellow lyophilisate and colourless liquid.

3. Target species

Dogs

4. Indications for use

Active immunisation of dogs to:
- prevent mortality and clinical signs caused by canine distemper virus (CDV),
- prevent mortality and clinical signs caused by infectious canine hepatitis virus (CAV-1),
- reduce viral excretion during respiratory disease caused by canine adenovirus type 2 (CAV-2),
- prevent mortality, clinical signs and viral excretion caused by canine parvovirus (CPV),

Onset of immunity: 2 weeks after the second injection of the primary vaccination course.

Duration of immunity: at least one year after the second injection of the primary vaccination course and at least 2 years after the first annual booster.
Current available challenge and serological data show that protection for distemper virus, adenovirus and parvovirus* lasts for 2 years after primary vaccination course followed by a first annual booster.
Any decision to adapt the vaccination schedule of this veterinary medicinal product needs to be made on a case by case basis, taking into account the vaccination history of the dog and the epidemiological context.
*Protection has been demonstrated against canine parvovirus type 2a, 2b and 2c either by challenge (type 2b) or serology (type 2a and 2c).

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Apply usual aseptic procedures.
After vaccination, the live CAV-2 and CPV vaccine strains can transiently be shed without adverse consequence for in-contact animals.

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.

Pregnancy:
Can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered with Eurican LR, Eurican L, Eurican Lmulti or Eurican L4 vaccines (used as solvent) where available.
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Rabisin.
When administered with Boehringer Ingelheim's vaccines containing rabies, the minimum age for vaccination is 12 weeks of age.
When mixed with the Eurican LR vaccine a small and transient nodule (maximum size 1.5 cm) at the injection site may be induced due to the presence of aluminium hydroxide and a slight swelling (~4 cm) may occur after the injection at injection site, regressing generally within 1-4 days.
When mixed with the Eurican L4 vaccine a swelling (less than 6 cm) may very commonly occur at the injection site, disappearing within 8 days, anorexia may commonly occur and vocalisation, tachycardia and tachypnoea may uncommonly be observed. For Eurican L4, no safety data in pregnant bitches are available for the additional inactivated strain, Leptospira Australis.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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:
No adverse events other than those mentioned in section “adverse events” were observed after administration of a 10-fold overdose of the lyophilisate.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except the solvent for Eurican DAP/DAPPi, supplied for use with the veterinary medicinal product, and except those mentioned in subsection “Interaction” above.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
Injection site swelling[1], injection site pruritus, injection site pain. Lethargy[2]. Emesis[2].

Uncommon (1 to 10 animals / 1,000 animals treated):
Anorexia, polydipsia, hyperthermia. Diarrhoea. Muscle tremor. Muscle weakness. Injection site warmth, injection site lesions[3].

Rare (1 to 10 animals / 10,000 animals treated):
Hypersensitivity reaction (facial oedema, anaphylactic shock, urticaria)[4].

[1] Slight (≤ 2 cm), immediately after injection. It usually regresses within 1-6 days.
[2] Transient.
[3] Cutaneous.
[4] Some of which are life-threatening. Appropriate symptomatic treatment should promptly be provided.

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 or the local representative of the marketing authorisation holder 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

After reconstitution, inject a 1 ml dose subcutaneously according to the following schedule:

Primary vaccination: Two injections separated by an interval of 4 weeks from 7 weeks of age. When administered with Boehringer Ingelheim's vaccines containing rabies, the minimum age for vaccination is 12 weeks of age.

In cases where high levels of maternally derived antibodies are suspected by the veterinarian and the primary vaccination course was completed before 16 weeks of age, a third injection is recommended from 16 weeks of age, at least 3 weeks after the second injection.

Revaccination: Administer one dose 12 months after completion of the primary vaccination course. Dogs should be revaccinated with a single booster dose every two years after the first annual booster.

9. Advice on correct administration

Aseptically reconstitute the contents of the lyophilisate with either solvent for Eurican DAP/DAPPi or a compatible vaccine (Eurican LR, Eurican L, Eurican Lmulti or Eurican L4) where available. Shake well before use. The entire contents of the reconstituted vial should be administered as a single dose.

The reconstituted content shall be an opalescent yellow to orange suspension.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Lyophilisate and solvent:
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 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

Plastic box of 10 vials of lyophilisate (1 dose) and 10 vials of solvent (1 ml).
Plastic box of 50 vials of lyophilisate (1 dose) and 50 vials of solvent (1 ml).

Plastic box of 10 vials of lyophilisate (1 dose).
Plastic box of 50 vials of lyophilisate (1 dose).

Plastic box of 10 vials of solvent (1 ml).
Plastic box of 50 vials of solvent (1 ml).

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 contact details to report suspected adverse events:
To be completed nationally.

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS,
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest

France

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

17. Other information

To be completed nationally.