ANNEX I

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

Proteq West Nile suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

**Active substance:**
West Nile recombinant canarypox virus (vCP2017) ................................................. 6.0 to 7.8 log10 CCID*50
* Cell culture infectious dose 50 %

**Adjuvant:**
Carbomer ......................................................................................................................................... 4 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Homogeneous opalescent suspension.

4. CLINICAL PARTICULARS

4.1 Target species
Horses

4.2 Indications for use, specifying the target species
Active immunisation of horses from 5 months of age against West Nile disease by reducing the number of viraemic horses. If clinical signs are present, their duration and severity are reduced.

Onset of immunity: 4 weeks after the first dose of the primary vaccination course. In order to achieve full protection, the full vaccination course of two doses must be given.

Duration of immunity: 1 year after a full primary vaccination course of two injections.

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

Vaccinate only healthy animals.
The safety of the vaccine has been demonstrated in foals from 5 months of age. However, the vaccine has also been shown to be safe in a field study including animals of 2 months of age.
Vaccination may interfere with existing sero-epidemiological surveys. However, since the IgM response following vaccination is infrequent, a positive IgM-ELISA test result is a strong indicator of natural infection with West Nile Virus. If infection is suspected as a result of a positive IgM response, additional testing would need to be conducted to conclusively determine whether the animal was infected or vaccinated.

**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)

A transient swelling (max. diameter 5 cm) which resolves within 4 days may appear commonly at the injection site.

Pain and local hyperthermia can occur in rare cases.

A slight increase in temperature (max. 1.5 °C) may occur in rare cases for 1 day, exceptionally 2 days.

Apathy, usually resolving within two days, and reduced appetite may be observed in rare cases the day after vaccination.

A hypersensitivity reaction may occur in rare cases, which may require appropriate symptomatic treatment.

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).

### 4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

### 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

For intramuscular use.

Shake the vaccine gently before use.

Administer one dose of 1 ml, by intramuscular injection, preferably in the neck region, according to the following schedule:
- Primary vaccination course: first injection from 5 months of age, second injection 4-6 weeks later,
- Revaccination: a sufficient degree of protection should be achieved after an annual booster injection with a single dose although this schedule has not been fully validated.
4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions other than those already mentioned in section 4.6 have been observed after the administration of more than 10 doses.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for equidae, other immunologicals.
ATC vet code: QI05AX.

To stimulate active immunity against West Nile virus.

The vaccine strain vCP2017 is a recombinant canarypox virus expressing the preM/E genes of West Nile virus. After inoculation, the virus does not multiply in the horse but expresses the protective proteins. As a consequence, these proteins induce protective immunity against equine West Nile disease.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 27 months.
Use immediately after opening.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Type I glass vial, with a butyl elastomer closure, sealed with an aluminium cap.
Box of 1, 2, 5 or 10 vial(s) of 1 dose.
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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/129/001-004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05/08/2011
Date of last renewal: 17/05/2016

10 DATE OF REVISION OF THE TEXT

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

The manufacture, import, possession, sale, supply and/or use of Proteq West Nile may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use Proteq West Nile must consult the relevant Member State’s competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.
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
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l’Aviation
69800 Saint Priest
France

Name and address of the manufacturer responsible for batch release
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l’Aviation
69800 Saint Priest
France

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 programme 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 the product is intended to confer immunity is largely absent from the territory in question.

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 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

#### OUTER CARTON

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proteq West Nile suspension for injection

### 2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

**Active substance:**
West Nile (vCP2017) .................................................. 6.0 to 7.8 log10 CCID₅₀

**Adjuvant:**
Carbomer ................................................................. 4 mg

### 3. PHARMACEUTICAL FORM

Suspension for injection

### 4. PACKAGE SIZE

1 x 1 dose
2 x 1 dose
5 x 1 dose
10 x 1 dose

### 5. TARGET SPECIES

Horses

### 6. INDICATION(S)

### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
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

10. EXPIRY DATE

EXP {month/year}
Use immediately after opening

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

Read the package leaflet before use

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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/129/001 1 x 1 dose
EU/2/11/129/002 2 x 1 dose
EU/2/11/129/003 5 x 1 dose
EU/2/11/129/004 10 x 1 dose

17. MANUFACTURER’S BATCH NUMBER

Lot {number}
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proteq West Nile

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read the package leaflet before use

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal: Zero days

6. BATCH NUMBER

Lot {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 AUTHORIZAION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proteq West Nile suspension for injection for horses

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Homogeneous opalescent suspension for injection
Each dose of 1 ml contains:

**Active substance:**
West Nile recombinant canarypox virus (vCP2017) ........................................ 6.0 to 7.8 log10 CCID*50
* Cell culture infectious dose 50%

**Adjuvant:**
Carbomer ............................................................................................................................................... 4 mg

4. INDICATIONS

Active immunisation of horses from 5 months of age against West Nile disease by reducing the number of viraemic horses. If clinical signs are present, their duration and severity are reduced.
Onset of immunity: 4 weeks after the first dose of the primary vaccination course. In order to achieve full protection, the full vaccination course of two doses must be given.
Duration of immunity: 1 year after a full primary vaccination course of two injections.

5. CONTRAINDICATION

None.
6. ADVERSE REACTIONS

A transient swelling (max. diameter 5 cm) which resolves within 4 days may appear commonly at the injection site. Pain and local hyperthermia can occur in rare cases. A slight increase in temperature (max. 1.5 °C) may occur in rare cases for 1 day, exceptionally 2 days. Apathy, usually resolving within two days, and reduced appetite may be observed in rare cases the day after vaccination. A hypersensitivity reaction may occur in rare cases, which may require appropriate symptomatic treatment.

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 serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

Administer one dose of 1 ml, by intramuscular injection, preferably in the neck region, according to the following schedule:
- Primary vaccination course: first injection from 5 months of age, second injection 4-6 weeks later,
- Revaccination: a sufficient degree of protection should be achieved after an annual booster injection with a single dose although this schedule has not been fully validated.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vaccine gently before use.

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.

Use immediately after opening.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
12. SPECIAL WARNINGS

Special precautions for use in animals:
Vaccinate only healthy animals.
Vaccination may interfere with existing sero-epidemiological surveys. However, since the IgM response following vaccination is infrequent, a positive IgM-ELISA test result is a strong indicator of natural infection with West Nile Virus. If infection is suspected as a result of a positive IgM response, additional testing would need to be conducted to conclusively determine whether the animal was infected or vaccinated.

Special warnings for each target species:
The safety of the vaccine has been demonstrated in foals from 5 months of age. However the vaccine has also been shown to be safe in a field study including animals of 2 months of age.

Pregnancy and lactation:
This vaccine can be used during pregnancy and lactation.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions other than those already mentioned in the section “Adverse Reactions” have been observed after the administration of more than 10 doses.

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

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.

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.

The manufacture, import, possession, sale, supply and/or use of Proteq West Nile may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use Proteq West Nile must consult the relevant Member State’s competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

To stimulate active immunity against West Nile virus.

The vaccine strain vCP2017 is a recombinant canarypox virus expressing the preM/E genes of West Nile virus. After inoculation, the virus does not multiply in the horse but expresses the protective proteins. As a consequence, these proteins induce protective immunity against equine West Nile disease.

Box of 1, 2, 5 or 10 vial(s) of 1 dose.
Not all pack sizes may be marketed.