ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Artervac emulsion for injection for horses and ponies

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substance:
Equine arteritis virus, strain Bucyrus, inactivated 1.0 – 1.8 RP*

*Relative potency compared to a reference vaccine

Adjuvants:

Squalane	0.2% (v/v)
Pluronic L-121	0.1% (v/v)
Polysorbate 80	0.016% (v/v)

Excipients:

Qualitative composition of excipients and other constituents
Eagles Hepes (0.05 % LAH) Medium
Phosphate Buffered Saline

Red/rust coloured emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Horses and ponies.

3.2 Indications for use for each target species

For the active immunisation of horses and ponies against equine arteritis in order to reduce clinical signs and shedding of virus in nasal secretion after infection.

Onset of immunity: 3 weeks
Duration of immunity: 6 months

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
Vaccination does not prevent infection.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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.

Other precautions:
Vaccination does not have an effect on the shedding of EAV by previously infected carrier stallions. The effect of the veterinary medicinal product on the fertility of breeding stallions has not been investigated.

3.6 Adverse events

Horses and ponies:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1] Elevated temperature[2]
Common (1 to 10 animals / 100 animals treated):	Ocular discharge Nasal discharge Depression
Rare (1 to 10 animals / 10,000 animals treated):	Allergic reaction[3], Anaphylactic-type reaction[3], Localised allergic oedema (oedema of the legs, abdominal oedema, scrotal oedema)[3], Urticaria[3]

[1]Transient, usually lasting for 2 to 3 days. The swellings are usually less than 4 cm in diameter but in one horse a swelling of 20 cm lasting for 5 days was recorded. All swellings resolved.
[2]Minor transient (1 to 5 days) increase in body temperature (<40°C).
[3]If such reactions occur, adrenaline should be administered intramuscularly.

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

Pregnancy:
Do not use (during the whole or part of the pregnancy).

3.8 Interaction with other medicinal products and other forms of interaction

Animals that have received immunosuppressive drugs (e.g. glucocorticoids) should not be vaccinated until an interval of at least 4 weeks has elapsed.

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.

3.9 Administration routes and dosage

Shake well before use.

1 ml dose per horse to be administered by intramuscular injection.

Primary course:
A single dose should be administered two times with an interval of 3-6 weeks from an age of nine months onwards.

Booster vaccination:
Booster vaccinations are recommended every 6 months.

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

Administration of a twofold overdose has no influence on the systemic reactions to vaccination as described in section 3.6 "Adverse events". Local swellings (< 4 cm in size) were observed in 80% of horses administered two doses of vaccine, these swellings were observed for one day only.

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

To be completed nationally.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI05AA07

The vaccine induces an active immunity against equine arteritis virus, strain Bucyrus in horses and ponies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Sterile single-use Type I glass syringes containing one dose each and closed with bromobutyl rubber tips.
Syringes are supplied in a cardboard box of 1, 2 and 10 units.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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:
To be completed nationally.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE 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

Carton Box 1 x 1 Dose, 2 x 1 Dose, 10 x 1 Dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Artervac emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains:

Equine arteritis virus, strain Bucyrus, inactivated	1.0-1.8 RP

3. PACKAGE SIZE

1 x 1 single-dose syringe
2 x 1 single-dose syringe
10 x 1 single-dose syringe

4. TARGET SPECIES

Horses and ponies.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

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}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Artervac

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Equine arteritis virus, inactivated

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equip Artervac emulsion for injection for horses and ponies

2. Composition

Each 1 ml dose contains:

Active substance:

Equine arteritis virus, strain Bucyrus, inactivated 1.0 – 1.8 RP*

*Relative potency compared to a reference vaccine

Adjuvants:

Squalane	0.2% (v/v)
Pluronic L-121	0.1% (v/v)
Polysorbate 80	0.016% (v/v)

Red/rust coloured emulsion.

3. Target species

Horses and ponies.

4. Indications for use

For the active immunisation of horses and ponies against equine arteritis in order to reduce clinical signs and shedding of virus in nasal secretion after infection.

Onset of immunity: 3 weeks
Duration of immunity: 6 months

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
Vaccination does not prevent infection.

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.

Other precautions:
Vaccination does not have an effect on the shedding of EAV by previously infected carrier stallions. The effect of the veterinary medicinal product on the fertility of breeding stallions has not been investigated.

Pregnancy:
Do not use (during the whole or part of the pregnancy).

Interaction with other medicinal products and other forms of interaction:
Animals that have received immunosuppressive drugs (e.g. glucocorticoids) should not be vaccinated until an interval of at least 4 weeks has elapsed.
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:
Administration of a twofold overdose has no influence on the systemic reactions to vaccination as described in section 7 "Adverse events". Local swellings (< 4 cm in size) were observed in 80% of horses administered two doses of vaccine, these swellings were observed for one day only.

Special restrictions for use and special conditions for use:
To be completed nationally.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Horses and ponies:

Very common (>1 animal / 10 animals treated):
Injection site swelling[1], Elevated temperature[2]
Common (1 to 10 animals / 100 animals treated):
Ocular discharge Nasal discharge Depression
Rare (1 to 10 animals / 10,000 animals treated):
Allergic reaction[3], Anaphylactic-type reaction (severe allergic reaction)[3], Localised allergic oedema (swelling) (oedema of the legs, abdominal oedema, scrotal oedema)[3], Urticaria (hives)[3]

[1]Transient, local reactions usually lasting for 2 to 3 days. The swellings are usually less than 4 cm in diameter but in one horse a swelling of 20 cm lasting for 5 days was recorded. All swellings resolved.
[2]Minor transient (1 to 5 days) increase in body temperature (<40°C).
[3]If such reactions occur, adrenaline should be administered intramuscularly.

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

1 ml dose per horse to be administered by intramuscular injection.

Primary course:
A single dose should be administered two times with an interval of 3-6 weeks from an age of nine months onwards.

Booster vaccination:
Booster vaccinations are recommended every 6 months.

9. Advice on correct administration

Shake well before use.

10. Withdrawal periods

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 carton and the syringe after Exp. The expiry date refers to the last day of that month.

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.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

Syringes are supplied in a cardboard box of 1, 2 and 10 units.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

To be completed nationally.

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 reactions>:

To be completed nationally.

Manufacturer responsible for batch release:

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

<Local representative <and contact details to report suspected adverse reactions>:>
To be completed nationally.

<17. Other information>