ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioEquin FH, emulsion for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vaccine dose (1 ml) contains:

Active substances:
Inactivated equine influenza virus, strains:

A/Equi 2/Brno 08 (American type line Florida 2) H3N8	Min. 6.0 $\log_2$ HIT[1]
A/Equi 2/ Limerick 2010 (American type line Florida 1) H3N8	Min. 6.0 $\log_2$ HIT[1]
Inactivated equine herpesvirus type 1, (EHV-1)	Min. 2.1 $\log_{10}$ VNI[2]

1 The geometric mean of specific antibodies determined by haemagglutination inhibition test in the guinea pig serum
2 The virus neutralization index in the hamster serum

Adjuvant(s):
Oil adjuvant (Montanide ISA 35 VG) 0.25 ml

Excipient(s):
Thiomersal 0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
The vaccine is a white, oily liquid with easily shakeable sediment.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

For active immunization of horses to reduce the occurrence of respiratory infections and clinical signs caused by equine influenza virus and equine herpesvirus type 1(EHV-1).
For active immunization to reduce the occurrence of abortions in pregnant mares caused by equine herpesvirus type 1 (EHV-1) infection.

Onset of immunity has been demonstrated by virulent challenge for equine influenza strain A/Equi 2/Brno 08 and for strain A/Equi 2/ Limerick 2010.
Duration of immunity has been demonstrated by serology for both vaccine influenza strains.

Influenza
Onset of active immunity: 2 weeks after primary vaccination
Duration of active immunity: 6 months after revaccination

Herpesvirus type 1
Onset of active immunity: 2 weeks after primary vaccination

Duration of active immunity: 6 months after revaccination

4.3 Contraindications
None.

4.4 Special warnings for each target species
In order to reduce the infection pressure, all horses on a farm should be vaccinated. At least primary vaccination, with the following 14 days of rest necessary to create immunity, should be performed before transfers of horses to other herds or stables, or before races. Regular vaccination of all animals in a breeding facility, with observance of prescribed deadlines, is necessary to create and maintain immunity from equine herpesvirus and equine influenza virus infections. Primary vaccination, with the following 14 days of rest necessary to create immunity, is recommended during the quarantine period for all unvaccinated horses to be included in breeding. Sick horses with signs of a respiratory disease should be isolated from healthy animals.

4.5 Special precautions for use

Special precautions for use in animals
Only healthy animals should be vaccinated. It is recommended not to physically burden the horses for 2-3 days after vaccination.

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 label to the physician.

To the user:
This veterinary medicinal product contains an oily adjuvant based on non-mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)
Temporary temperature rise (max. 0,5 °C for 3 days) can be uncommonly observed in connection with the vaccination. Local reaction (hot and painful swelling at the injection site for max. 3 days) is rare.
The vaccine may very rare cause an anaphylactic reaction. In this case, symptomatic treatment is applied without delay.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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.
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

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

Vaccine dose - 1 ml.
The vaccine (1 ml) is applied deep intramuscularly by aseptic method
Before use, allow the vaccine to reach a temperature of 15-25°C and shake well.

Vaccination schedule:
Primary vaccination against equine influenza and herpesvirus:
The first vaccination at the age of 6 months; the second vaccination 4 weeks later.

Revaccination against equine influenza and herpesvirus:
The first revaccination (third dose) is administered 3 months after the primary vaccination and next revaccination is carried out every 6 months.

Vaccination of pregnant mares:
To reduce the incidence of abortions caused by equine herpesvirus infection one dose of the vaccine is administered to pregnant mares in the second month after mating and then in the fifth or sixth month and in the ninth month of pregnancy.

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

Not applicable.

4.11 Withdrawal periods

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines for horses
ATC vet code: QI05AA04

For active immunization against equine influenza and equine herpesvirus.

Application of active substances into the body of an animal causes an active immune response that is manifested by induction of local and systemic humoral immunity and the activity of cytotoxic T-lymphocytes.

Active immunity starts no later than 2 weeks after the primary vaccination performed according to the recommended vaccination schedule.
The immunity of foals and adult horses against equine herpesvirus and equine influenza virus lasts at least 6 months after the third vaccination and next revaccinations. The recommended vaccination schedule must be observed to ensure a long-term immunity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montanide ISA 35 VG
Thiomersal
Sodium chloride
Potassium chloride
Potassium dihydrogenphosphate
Disodium hydrogen phosphate dodecahydrate
Water for injection
Sodium hydroxide for pH adjustment

6.2 Major incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: 10 hours.

6.4 Special precautions for storage
Store in a refrigerator (2°C - 8°C).
Protect from light.
Store in a dry place.

6.5 Nature and composition of immediate packaging
The vaccine is shipped in glass vials of hydrolytic class I, hermetically closed with pierceable rubber stopper and with aluminium caps.
An approved package leaflet is enclosed to every package.
The vials with the vaccine are placed in cardboard cartons. Multiple packaged vials are placed in a PVC package.
Pack size: 2 x 1 dose, 5 x 1 dose, 10 x 1 dose
1 x 5 doses, 10 x 5 doses

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 product
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
Bioveta, a.s., Komenského 212/12, 683 23, Ivanovice na Hané,
Czech Republic
tel. 420 517 318 500
fax 420 517 318 653
e-mail comm@bioveta.cz

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY

10. DATE OF REVISION OF THE TEXT

MM/ YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{1x5 doses/ cardboard packaging; 2 x 1 dose, 5 x 1 dose, 10 x 1 dose, 10x 5 doses/ plastic box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioEquin FH, emulsion for injection for horses

2. STATEMENT OF ACTIVE SUBSTANCES

Composition of one dose (1 ml):

Active substances:
Inactivated equine influenza virus, strains:

A/Equi 2/Brno 08 (American type line Florida 2) H3N8	Min. 6.0 $\log_2$ HIT
A/Equi 2/ Limerick 2010 (American type line Florida 1) H3N8	Min. 6.0 $\log_2$ HIT
Inactivated equine herpesvirus type 1, (EHV-1)	Min. 2.1 $\log_{10}$ VNI

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

2 x 1 dose/ 5 x 1 dose/ 10 x 1 dose/ 1x 5 doses/ 10x 5 doses

5. TARGET SPECIES

Horses.

6. INDICATION(S)

Read the package leaflet before use.

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

Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP: {month/year}
Once opened use by 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Protect from light.
Store in a dry place.

12. SPECIFIC 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.

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

Bioveta, a.s., Komenského 212/12, 683 23 Ivanovice na Hané, Czech Republic

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

17. MANUFACTURER´S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{1 dose/ 5 doses / label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioEquin FH, emulsion for injection for horses

2. QUANTITY OF THE ACTIVE SUBSTANCES

Read the package leaflet before use.

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

1 ml / 5 ml

4. ROUTE OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP: {month/year}
Once opened use by 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
BioEquin FH, emulsion for injection for horses

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

Marketing authorisation holder and manufacturer responsible for batch release:

Bioveta, a. s.
Komenského 212/12
683 23 Ivanovice na Hané,
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT
BioEquin FH, emulsion for injection for horses

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)
One dose (1 ml) of the vaccine contains:
Active substances:
Inactivated equine influenza virus, strains:

A/Equi 2 Brno 08 (American type line Florida 2) H3N8	Min. 6.0 $\log_2$ HIT[1]
A/Equi 2 Limerick 2010 (American type line Florida 1) H3N8	Min. 6.0 $\log_2$ HIT[1]
Inactivated equine herpesvirus type 1, (EHV-1)	Min. 2.1 $\log_{10}$ VNI[2]

1 geometrical average of specific antibodies determined by haemagglutination inhibition test in serum of guinea pigs
2 Virus neutralization index determined in serum of hamsters

Adjuvant(s):

Oil adjuvant (Montanide ISA 35 VG)	0.25 ml

Excipient(s):

Thiomersal	0.1 mg

The vaccine is a white, oily liquid with easily shakeable sediment.

4. INDICATION(S)
For active immunization of horses to reduce the incidence of respiratory infections and clinical signs caused by equine influenza virus and equine herpesvirus type 1 (EHV-1).
For active immunization to reduce the occurrence of abortions in pregnant mares caused by equine herpesvirus type 1 (EHV-1) infection.

Onset of immunity has been demonstrated by virulent challenge for equine influenza strain A/Equi 2/Brno 08, and for strain A/Equi 2/ Limerick 2010.
Duration of immunity has been demonstrated by serology for both vaccine influenza strains.

Influenza
Onset of active immunity: 2 weeks after primary vaccination
Duration of active immunity: 6 months after revaccination

Herpesvirus type 1

Onset of active immunity: 2 weeks after primary vaccination
Duration of active immunity: 6 months after revaccination

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Temporary temperature rise (max. 0,5 °C for 3 days) can be uncommonly observed in connection with the vaccination. Local reaction (hot and painful swelling at the injection site for max. 3 days) is rare. The vaccine may very rare cause an anaphylactic reaction. In this case, symptomatic treatment is applied without delay.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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. Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Horses

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

The vaccination dose – 1 ml

The vaccine (1 ml) is applied deeply intramuscularly by aseptic method.

Primary vaccination against influenza and equine herpesvirus:
1st vaccination at the age of 6 months; 2nd vaccination after 4 weeks;

Revaccination against influenza and equine herpesvirus:
The first revaccination (third dose) should be administered 3 months after primary vaccination and each following revaccination is applied every six months.
Vaccination pregnant mares:
To reduce the incidence of abortion caused by equine herpesvirus infection is administered 1 dose of the vaccine in pregnant mares in the second month after admission and at 5 to 6th and the 9th month of pregnancy.

9. ADVICE ON CORRECT ADMINISTRATION

Before use, allow the vaccine to reach a temperature of 15-25 ° C and the content of the vial shake well.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).
Protect from light.
Store in a dry place.

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

Shelf-life after first opening the container: 10 hours

12. SPECIAL WARNING(S)

Special warnings for each target species:
In order to reduce the infection pressure, all horses on a farm should be vaccinated. At least primary vaccination, with the following 14 days of rest necessary to create immunity, should be performed before transfers of horses to other herds or stables, or before races. Regular vaccination of all animals in a breeding facility, with observance of prescribed deadlines, is necessary to create and maintain immunity from equine herpesvirus and equine influenza virus infections. Primary vaccination, with the following 14 days of rest necessary to create immunity, is recommended during the quarantine period for all unvaccinated horses to be included in breeding. Sick horses with signs of a respiratory disease should be isolated from healthy animals.

Special precautions for use in animals:
Only healthy animals should be vaccinated. It is recommended not to physically burden the horses for 2-3 days after vaccination.

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 label to the physician.

To the user:
This veterinary medicinal product contains an oily adjuvant based on non-mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy:
Can be used during pregnancy.

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

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.

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

15. OTHER INFORMATION

For active immunization against equine influenza and equine herpesvirus.

Application of active substances into the body of an animal causes an active immune response that is manifested by induction of local and systemic humoral immunity and the activity of cytotoxic T-lymphocytes.

Active immunity starts no later than 14 days after the primary vaccination performed according to the recommended vaccination schedule.
The immunity of foals and adult horses against equine herpesvirus and equine influenza virus lasts at least 6 months after the third vaccination and next revaccinations. The recommended vaccination schedule must be observed to ensure a long-term immunity.

For animal treatment only - to be supplied only on veterinary prescription.

Pack size: 2 x 1, 5 x 1 dose, 10 x 1 dose,
1 x 5 doses, 10 x 5 doses.

Not all pack sizes may be marketed.