ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Blue-8 suspension for injection for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine contains:

Active substance:
Bluetongue virus inactivated, serotype 8: $10^{6.5}$ $CCID_{50}$*
(* equivalent to titre prior to inactivation)

Adjuvants:
Aluminium hydroxide 6 mg
Purified saponin (Quil A) 0.05 mg

Excipient:
Thiomersal 0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
White or pinkish-white.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle.

4.2 Indications for use, specifying the target species

Sheep
For the active immunisation of sheep from 2.5 months of age to prevent viraemia* and to reduce clinical signs caused by bluetongue virus serotype 8.
*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 20 days after the second dose.
Duration of immunity: 1 year after the second dose.

Cattle
For the active immunisation of cattle from 2.5 months of age to prevent viraemia* caused by bluetongue virus serotype 8.
*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 31 days after the second dose.
Duration of immunity: 1 year after the second dose.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Occasionally, the presence of maternally derived antibodies in ovines of minimum recommended age might interfere with the protection induced by the vaccine.

No information is available on the use of the vaccine in seropositive bovines, including those with maternally derived antibodies.

If used in other domestic and wild ruminant species that are considered at risk of infection, its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of animals prior to mass vaccination. The level of efficacy for other species may differ from that observed in sheep and cattle.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

An average increase in body temperature varying between 0.5 and 1.0 ºC is a common reaction observed in sheep and cattle. It lasted not longer than 24 to 48 hours. Transient fever was observed in rare cases. Temporary local reactions can occur very rarely at the injection site in the form of a nodule of 0.5 to 1 cm in sheep and of 0.5 to 3 cm in cattle which disappears within 14 days, at the latest and which may be painful. Loss of appetite can occur in very rare cases. Hypersensitivity reactions are very rarely observed.

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

Pregnancy:
Can be used during pregnancy.

Lactation:
There is no negative impact on the milk yield using the vaccine in lactating ewes and cows.

Fertility:
The safety and efficacy of the vaccine has not been established in breeding males (sheep and cattle). In this category of animals the vaccine should be used only according to the benefit-risk assessment by the responsible veterinarian and/or National competent authorities on the current vaccination policies against bluetongue virus (BTV).

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

Subcutaneous use.

Shake well before use. Avoid multiple vial broaching. Avoid introduction of contamination.

Primary vaccination:

Sheep from 2.5 months of age:
Administer two doses of 2 ml subcutaneously with a 3 week interval.

Cattle from 2.5 months of age:
Administer two doses of 4 ml subcutaneously with a 3 week interval.

Revaccination:

1 dose per year.

Any revaccination scheme should be agreed by the competent authority or by the responsible veterinarian, taking into account the local epidemiological situation.

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

Occasionally a slight increase of the temperature (0.5 ºC – 1.0 ºC) is observed for 24–48 hours after the administration of a double dose of the vaccine. Painless swellings occur occasionally with a size up to 2 cm in sheep and up to 4.5 cm in cattle after a double dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Bovidae/Ovidae, inactivated bluetongue virus vaccines.
ATCvet codes: Cattle: QI02AA08 / Sheep: QI04AA02

Bovilis Blue-8 stimulates active immunity against bluetongue virus, serotype 8.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Purified saponin (Quil A)
Thiomersal
Phosphate buffered saline (sodium chloride, disodium phosphate and potassium 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: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.

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

High density polyethylene (HDPE) bottles of 52 ml, 100 ml or 252 ml with bromobutyl stoppers and aluminium seals.

Package sizes:
Cardboard box with 1 bottle containing either 26 sheep doses or 13 cattle doses (52 ml).
Cardboard box with 1 bottle containing either 50 sheep doses or 25 cattle doses (100 ml).
Cardboard box with 1 bottle containing either 126 sheep doses or 63 cattle doses (252 ml).

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 products should be disposed of in accordance with the local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/213/001-003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21/11/2017

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

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.

ANNEX II

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

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

Name and address of the manufacturer of the biological active substance

CZ Veterinaria, S.A.
La Relva s/n,
36400 Porriño
SPAIN

Name and address of the manufacturer responsible for batch release

Intervet International BV
Wim de Körverstraat 35,
5831 AN Boxmeer
The NETHERLANDS

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR 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 and/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.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

PSUR submissions for Bovilis Blue-8 shall be synchronised and submitted at the same frequency as for Bluevac BTV8.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (52 ml, 100 ml and 252 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Blue-8 suspension for injection for cattle and sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Inactivated BTV8: $10^{6.5}$ $CCID_{50}$

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

52 ml
100 ml
252 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Shake well before 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}
Once broached, use within 10 hours.

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

Disposal: read package leaflet.

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

Intervet International BV
Wim de Körverstraat 35,
5831 AN Boxmeer
The NETHERLANDS

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/218/001
EU/2/17/218/002
EU/2/17/218/003

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml and 252 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Blue-8 suspension for injection for cattle and sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated BTV8: $10^{6.5}$ $CCID_{50}$/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
252 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

SC
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}

Once broached, use within 10 hours.

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

Disposal: read package leaflet.

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

Intervet International BV
NL-5831 AN Boxmeer

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 52 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Blue-8 suspension for injection for cattle and sheep

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated BTV8: $10^{6.5}$ $CCID_{50}$/ml

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

52 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bovilis Blue-8 suspension for injection for cattle and sheep

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

Intervet International BV
Wim de Körverstraat 35,
5831 AN Boxmeer
The NETHERLANDS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Blue-8 suspension for injection for cattle and sheep

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

Each ml of vaccine contains:

Bluetongue virus inactivated, serotype 8	$10^{6.5}$ $CCID_{50}$*
Aluminium hydroxide	6 mg
Purified saponin (Quil A)	0.05 mg
Thiomersal	0.1 mg

(* equivalent to titre prior to inactivation)

4. INDICATION(S)

Sheep
For the active immunisation of sheep from 2.5 months of age to prevent viraemia* and to reduce clinical signs caused by bluetongue virus serotype 8.
*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 20 days after the second dose.
Duration of immunity: 1 year after the second dose.

Cattle
For the active immunisation of cattle from 2.5 months of age to prevent viraemia* caused by bluetongue virus serotype 8.
*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 31 days after the second dose.
Duration of immunity: 1 year after the second dose.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

An average increase in body temperature varying between 0.5 and 1.0 ºC is a common reaction observed in sheep and cattle. It lasted not longer than 24 to 48 hours. Transient fever was observed in rare cases. Temporary local reactions can occur very rarely at the injection site in the form of a nodule

of 0.5 to 1 cm in sheep and of 0.5 to 3 cm in cattle which disappears within 14 days, at the latest and which may be painful. Loss of appetite can occur in very rare cases. Hypersensitivity reactions are very rarely observed.

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

7. TARGET SPECIES

Sheep and cattle.

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

Subcutaneous use.

Primary vaccination:

Sheep from 2.5 months of age:
Administer two doses of 2 ml subcutaneously with a 3 week interval.

Cattle from 2.5 months of age:
Administer two doses of 4 ml subcutaneously with a 3 week interval.

Revaccination:

1 dose per year.

Any revaccination scheme should be agreed by the competent authority or by the responsible veterinarian, taking into account the local epidemiological situation.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use. Avoid multiple vial broaching. Avoid introduction of contamination.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton.
Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Occasionally, the presence of maternally derived antibodies in ovines of minimum recommended age might interfere with the protection induced by the vaccine.

No information is available on the use of the vaccine in seropositive bovines, including those with maternally derived antibodies.

If used in other domestic and wild ruminant species that are considered at risk of infection, its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of animals prior to mass vaccination. The level of efficacy for other species may differ from that observed in sheep and cattle.

Pregnancy and lactation:
Can be used during pregnancy. There is no negative impact on the milk yield using the vaccine in lactating ewes and cows.

Fertility:
The safety and efficacy of the vaccine has not been established in breeding males (sheep and cattle). In this category of animals the vaccine should be used only according to the benefit-risk assessment by the responsible veterinarian and/or National competent authorities on the current vaccination policies against bluetongue virus (BTV).

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.

Overdose (symptoms, emergency procedures, antidotes):
Occasionally a slight increase of the temperature (0.5 ºC – 1.0 ºC) is observed for 24–48 hours after the administration of a double dose of the vaccine. Painless swellings occur occasionally with a size up to 2 cm in sheep and up to 4.5 cm in cattle after administration of a double dose.

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

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

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

Bovilis Blue-8 stimulates active immunity against bluetongue virus, serotype 8.

Package sizes:
Box with 1 bottle of 52 ml, 100 ml or 252 ml.

Not all pack sizes may be marketed.