ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BULTAVO 3 suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:
Inactivated bluetongue virus serotype 3 (strain Bio-93:BTV3) ..... ≥ 10 ELISA units*
*The amount of inactivated antigen was determined using an ELISA method.

Adjuvants:
Aluminium hydroxide ..... 2.25 – 2.75 mg
Quillaja saponin (Quil A) ..... 0.2 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Formaldehyde 35%	≤ 0.7 mg
Thiomersal	0.085 – 0.115 mg
Sodium chloride	
Water for injections	

White to pinkish liquid with sediment present.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and cattle.

3.2 Indications for use for each target species

Sheep:

Active immunisation to reduce viraemia and to prevent clinical signs and mortality caused by bluetongue virus serotype 3.

Onset of immunity: 3 weeks after the primary vaccination course.
Duration of immunity: not established.

Cattle:

Active immunisation against bluetongue virus serotype 3.

Onset of immunity: not established.
Duration of immunity: not established.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Basic immunisation should be started in time so that protection has fully developed by the beginning of the risk period for the animal (related to the appearance of the main vectors of the disease – biting midges).

High levels of maternal antibodies negatively affect the formation of post-vaccination antibodies, which may affect the level of antibodies after vaccination. These maternally derived antibodies usually disappear within 3 months of age in lambs and within 2.5 months of age in cattle.

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.

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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sheep and cattle:

Undetermined frequency:	Injection site swelling Elevated temperature

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian. Reports should be sent, preferably via a veterinarian, to the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation and fertility:
The safety of the veterinary medicinal product has not been established during lactation.
The safety of the vaccine has not been established in breeding males. In these categories 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).

3.8 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.

3.9 Administration routes and dosage

Apply usual aseptic procedures.

Shake gently immediately before use. Avoid bubble formation, as this can be irritating at the site of injection. The entire content of the bottle should be used immediately after broaching and during the same procedure. Avoid multiple broaching of vials.

Before use the vaccine should be warmed to 15-25°C.

Administer one dose of 1 ml, subcutaneously in sheep, intramuscularly in cattle, according to the following vaccination scheme:

Primary vaccination

In sheep: one injection from 1 month of age in naive animals.

In cattle:
- 1st injection: from 1 month of age in naive animals.
- 2nd injection: 3 weeks after the first injection.

Revaccination

Not established.

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

The safety of an overdose has not been established.

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

The veterinary medicinal product has been allowed for emergency use. The efficacy of the vaccine has not been tested in cattle. Therefore, the vaccine should be used according to the benefit/risk assessment by the responsible veterinarian.

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product containing serotype 3 must first consult the relevant National competent authority on the current vaccination policies, as these activities may be prohibited nationally on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AA02 (sheep) and QI02AA08 (cattle)

To stimulate active immunity against bluetongue virus in the vaccinated animal.

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: 24 months.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

HDPE bottle containing 10 doses of 1 ml with chlorobutyl elastomer closure.
HDPE bottle containing 50 doses of 1 ml with chlorobutyl elastomer closure.

Pack sizes:
Box of 1 bottle of 10 doses (1 x 10 ml)
Box of 1 bottle of 50 doses (1 x 50 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

Non-authorized product.
Marketed by Boehringer Ingelheim Vetmedica GmbH.

Allowance for emergency use according to Art. 110 of Reg. (EU) 2019/6 or Part 3, Sch. 4, Para. 4 of the UK VMRs 2013.
Assessment based on customised requirements for documentation.

7. MARKETING AUTHORISATION NUMBER(S)

Not applicable (see section 6).

8. DATE OF FIRST AUTHORISATION

Not applicable.

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

<DD month YYYY>
<{DD/MM/YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 bottle of 10 ml
Box of 1 bottle of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BULTAVO 3 suspension for injection for sheep and cattle.

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose (1 ml):
Inactivated bluetongue virus serotype 3 see leaflet

3. PACKAGE SIZE

10 doses (10 ml)
50 doses (50 ml)

4. TARGET SPECIES

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Sheep: subcutaneous use.
Cattle: intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once broached, use within 10 hours.

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

Boehringer Ingelheim Vetmedica GmbH

14. AUTHORISATION NUMBERS

Art. 110 of Reg. (EU) 2019/6.
Part 3, Sch. 4, Para. 4 of UK VMRs 2013.

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 10 ml
Bottle of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BULTAVO 3

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml / dose:
BTV3

10 doses (10 ml)
50 doses (50 ml)

Sheep: SC
Cattle: IM

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

BULTAVO 3 suspension for injection for sheep and cattle

2. Composition

Each 1 ml dose contains:
Inactivated bluetongue virus serotype 3 (strain Bio-93:BTV3) ..... ≥ 10 ELISA units*
Aluminium hydroxide ..... 2.25 – 2.75 mg
Quillaja saponin (Quil A) ..... 0.2 mg
Formaldehyde 35% ..... ≤ 0.7 mg
Thiomersal ..... 0.85 – 1.15 mg
*The amount of inactivated antigen was determined using an ELISA method.

White to pinkish liquid with sediment present.

3. Target species

Sheep and cattle.

4. Indications for use

Sheep:
Active immunisation to reduce viraemia and to prevent clinical signs and mortality caused by bluetongue virus serotype 3.

Onset of immunity: 3 weeks after the primary vaccination course.
Duration of immunity: not established.

Cattle:
Active immunisation against bluetongue virus serotype 3.

Onset of immunity: not established.
Duration of immunity: not established.

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.
Basic immunisation should be started in time so that protection has fully developed by the beginning of the risk period for the animal (related to the appearance of the main vectors of the disease – biting midges).
High levels of maternal antibodies negatively affect the formation of post-vaccination antibodies, which may affect the level of antibodies after vaccination. These maternally derived antibodies usually disappear within 3 months in lambs and within 2.5 months of age in cattle.

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, lactation and fertility:
Can be used during pregnancy.
The safety of the veterinary medicinal product has not been established during lactation.
The safety of the vaccine has not been established in breeding males. In these categories 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).

Interactions 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 decided on a case by case basis.

Overdose:
The safety of an overdose has not been established.

Special restrictions for use and special conditions for use:
The veterinary medicinal product has been allowed for emergency use. The efficacy of the vaccine has not been tested in cattle. Therefore, the vaccine should be used according to the benefit/risk assessment by the responsible veterinarian.
Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product containing serotype 3 must first consult the relevant National competent authority on the current vaccination policies, as these activities may be prohibited nationally on the whole or part of its territory pursuant to national legislation.

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

7. Adverse events

Sheep and cattle:

- **Undetermined frequency**: Injection site swelling and elevated temperature.

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 should report any adverse events via your national reporting system: BE: adversedrugreactions_vet@fagg-afmps.be; DE: https://www.vet-uaw.de/; FR: https://pharmacovigilance-anmv.anses.fr/; NL: https://www.cbg-meb.nl/onderwerpen/bd-bijwerking-melden; UK: https://www.gov.uk/report-veterinary-medicine-problem.

8. Dosage for each species, routes and method of administration

Administer one dose of 1 ml, subcutaneously in sheep, intramuscularly in cattle, according to the following vaccination scheme:

Primary vaccination
In sheep: one injection from 1 month of age in naive animals.

In cattle:
- 1st injection: from 1 month of age in naive animals.
- 2nd injection: 3 weeks after the first injection.

Revaccination
Not established.

9. Advice on correct administration

Apply usual aseptic procedures.

Shake gently immediately before use. Avoid bubble formation, as this can be irritating at the site of injection. The entire content of the bottle should be used immediately after broaching and during the same procedure. Avoid multiple broaching of vials.

Before use the vaccine should be warmed to 15-25°C.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2ºC – 8ºC).
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 first opening the immediate packaging: 10 hours.

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 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

Allowance for emergency use according to Art. 110 of Reg. (EU) 2019/6 or Part 3, Sch. 4, Para. 4 of the UK VMRs 2013.

Box of 1 bottle of 10 doses (1 x 10 ml)
Box of 1 bottle of 50 doses (1 x 50 ml)

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<DD month YYYY>
<{DD/MM/YYYY}>

16. Contact details

Holder of the allowance for emergency use:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Bioveta a.s.,
Komenského 212/12 Ivanovice
na Hané, 683 23
Czech Republic

Local representatives and contact details:

België/Belgique/Belgien
Boehringer Ingelheim Animal Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
1050 Bruxelles/Brussel/Brüssel
Tél/Tel: + 32 2 773 34 56

Deutschland
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Tel: 0800 290 0 270

France
Boehringer Ingelheim Animal Health France, SCS
29, avenue Tony Garnier
69007 Lyon
Tél : +33 4 72 72 30 00

Nederland
Boehringer Ingelheim Animal Health Netherlands BV
Basisweg 10
1043 AP Amsterdam
Tel: +31 20 799 6950

United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
Tel: +44 1344 746957

United Kingdom (Northern Ireland)
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, Germany
Tel: +353 1 291 3985

17. Other information

The vaccine stimulates active immunity against bluetongue virus in the vaccinated animal.

For NL only: **Kanalisatie**: UDD