ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioBos BTV 3 suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substance:
Bluetongue virus, serotype 3, strain Bio-93:BTV3, inactivated 10 - 320 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**
Thiomersal	0.085 – 0.115 mg
Formaldehyde	
Sodium chloride	
Potassium chloride	
Disodium hydrogen phosphate dodecahydrate	
Potassium dihydrogen phosphate	
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 caused by bluetongue virus (BTV) serotype 3.

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

Cattle:

Active immunisation to prevent viraemia and to prevent clinical signs caused by bluetongue virus (BTV) serotype 3.

Onset of immunity: 3 weeks after the primary vaccination course.
Duration of immunity: 6 months.

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, to either the marketing

authorisation holder <or its local representative> or via 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:
Can be used during pregnancy.

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

Fertility:
The safety of the vaccine has not been established in breeding males. 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).

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)

Not applicable.

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

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.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AA02

To stimulate active immunity against bluetongue virus serotype 3 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: 2 years.
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

Glass vial of hydrolytic class I containing 10 doses of 1 ml closed with chlorobutyl elastomer closure.
Glass vials of hydrolytic class II containing 50 doses or 100 doses of 1 ml closed with chlorobutyl elastomer closure.
HDPE vials containing 10 doses, 50 doses or 100 doses of 1 ml with chlorobutyl elastomer closure.

Pack sizes:
Plastic box with 10 wells:
Box of 10 vials of 10 doses (10 x 10 ml)

Carton box:
Box of 1 vial of 10 doses (1 x 10 ml)
Box of 1 vial of 50 doses (1 x 50 ml)
Box of 1 vial of 100 doses (1 x 100 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

Bioveta a.s.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

EXCEPTIONAL CIRCUMSTANCES:

Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation. Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union medicinal products database (https://medicines.health.europa.eu/veterinary).