ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BTVPUR suspension for injection for sheep and cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances *:
Inactivated bluetongue virus .....≥ strain specific pass level (log10 pixels) **
(*) maximum of two different inactivated bluetongue virus serotypes

(**)Strain-specific pass levels	(**) Antigen content (VP2 protein) by immuno-assay
BTV1	1.9 log10 pixels/mL
BTV2	1.82 log10 pixels/mL
BTV4	1.86 log10 pixels/mL
BTV8	2.12 log10 pixels/mL

A confirmatory final potency test by seroneutralisation in rats is conducted when a batch is released.

Adjuvants:
Al^{3+} (as hydroxide) 2.7 mg
Saponin 30 HU**
(**) Haemolytic units

For the full list of excipients, see section 6.1.

The type of strain(s) (two strains at most) included in the final product will be selected based on the epidemiological situation at the time of manufacturing and will be stated on the label.

3. PHARMACEUTICAL FORM

Suspension for injection
Appearance: homogeneous milky white .

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle

4.2 Indications for use, specifying the target species

Active immunisation of sheep to prevent viraemia* and to reduce clinical signs caused by bluetongue virus serotypes 1, 2, 4 and/or 8 (combination of maximum 2 serotypes).
Active immunisation of cattle to prevent viraemia* caused by bluetongue virus serotypes 1, 2, 4 and/or 8, and to reduce clinical signs caused by bluetongue virus serotypes 1, 4 and/or 8 (combination of maximum 2 serotypes).
*below the level of detection by the validated RT-PCR method at 3.68 $\log_{10}$ RNA copies/ml, indicating no infectious virus transmission.

Onset of immunity has been demonstrated 3 weeks (or 5 weeks in sheep for BTV2) after the primary vaccination course for BTV-1, BTV-2 (cattle), BTV-4 and BTV-8 serotypes.
The duration of immunity for cattle and sheep is 1 year after primary vaccination course.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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

None

4.6 Adverse reactions (frequency and seriousness)

In very rare cases it has been observed a small local swelling at the injection site (at most 32 cm^2 in cattle and 24 cm^2 in sheep) which becomes residual 35 days later ($\leq$ 1 cm^2).

In very rare cases a transient increase in body temperature, normally not exceeding an average of 1.1ºC, may occur within 24 hours after vaccination.

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 and lactation.

The safety and the efficacy of the vaccine have 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).

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

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 vial broaching.

Administer one dose of 1 ml subcutaneously according to the following vaccination scheme:

- **Primary vaccination**

In sheep:
- Firstinjection: from 1 month of age in naive animals (or from 2.5 months of age in young animals born to immune sheep).
- Second injection: after 3-4 weeks.
  For a monovalent vaccine containing an inactivated Bluetongue Virus serotype 2 or 4, or for a bivalent vaccine containing both serotypes 2 and 4 together, one injection is sufficient.

In cattle:
- First injection: from 1 month of age in naive animals (or from 2.5 months of age in young animals born to immune cattle).
- Second injection: after 3-4 weeks.

- **Revaccination**

Annual.

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

Very rare and transient apathy can be observed after the administration of a double-dose of the vaccine. No other adverse reactions except those mentioned in section 4.6 were observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: bluetongue virus vaccine, ATC vet code QI04AA02 (sheep) and QI02AA08 (cattle).

The vaccine contains inactivated Bluetongue Virus with aluminium hydroxide and saponin adjuvants. It induces an active and specific immunity against bluetongue virus in the vaccinated animal.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silicon antifoam
Phosphate buffer
Glycine buffer
Aluminium hydroxide
Saponin

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of monovalent or bivalent formulation with Bluetongue Virus serotypes 1, 8 (100 ml, 50 ml and 10 ml bottles) and/or 2, 4 (100 ml and 50 ml bottles): 2 years.
Shelf life of monovalent or bivalent formulation with Bluetongue Virus serotypes 2 and/or 4 (10 ml bottles): 18 months.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Polypropylene bottle of 50 or 100 ml with butyl elastomer closure.
Box of 1 bottle of 100 doses (1 x 100 ml)
Box of 10 bottles of 100 doses (10 x 100 ml)
Box of 1 bottle of 50 doses (1 x 50 ml)
Box of 10 bottles of 50 doses (10 x 50 ml)

Type I glass bottle of 10 ml with butyl elastomer closure.
Box of 1 bottle of 10 doses (1 x 10 ml)

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 local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/113/001-050

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17/12/2010
Date of last renewal: 08/09/2015

10. DATE OF REVISION OF THE TEXT

Detailed information of 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 of BTVPUR containing serotypes 1, 2, 4 and 8 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.