ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 1 Bovis suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substance:

Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1 RP* ≥ 1

*Relative Potency by a mice potency test compared to a reference vaccine that was shown efficacious in calves.

Adjuvants:

Aluminium hydroxide (Al^{3+})	4 mg
Saponin	0.4 mg

Excipient:

Thiomersal	0.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection. Off-white or pink liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For active immunisation of cattle from 2 and a half months of age for the prevention* of viraemia caused by Bluetongue Virus (BTV), serotype 1.
*(Cycling value (Ct) ≥ 36 by a validated RT- PCR method, indicating no presence of viral genome)

Onset of immunity: 15 days after completion of the primary vaccination course.
Duration of immunity: 12 months after completion of the primary vaccination course.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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 cattle. No information is available on the use of the vaccine in animals with maternally derived antibodies.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy animals.

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

None

4.6 Adverse reactions (frequency and seriousness)

After first vaccination a rectal temperature increase of up to 1.6 °C may occur very commonly the 3rd day after the injection. Rectal temperatures should then return to normal values.

After second and third vaccination a rectal temperature increase of up to 1.3 °C and 2.8 °C respectively may occur very commonly one day after the injection and then rectal temperatures return to normal values.

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. No data is available on safety in lactating animals. The use in lactating animals is therefore not recommended.

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

Intramuscular use.

Primary vaccination:
Administer one dose of 2 ml according to the following vaccination scheme:

1st injection: from 2.5 months of age.
2nd injection: after 3 weeks

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.

In order to avoid accidental contamination of the vaccine during use, it is recommended to use a multi-injection type vaccination system when larger dose presentations are used.

Revaccination:

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

After administration of a two-fold overdose, a rectal temperature increase up to 2.1 ºC may occur 1 day after the injection and then rectal temperatures return to normal values.

A slight to moderate increase of local reactions may commonly be observed after a 2-fold overdose lasting for a maximum of 56 days.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines – Bluetongue virus. ATCvet code: QI02AA08

To stimulate active immunity against Bluetongue Virus, serotype 1 in cattle.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Saponin
Thiomersal
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate dodecahydrate
Sodium chloride
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: 1 year.
Shelf life after first opening the immediate packaging: use immediately after broaching.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box with one type I glass vial of 20 ml (containing 10 doses) with a chlorobutyl rubber stopper and aluminium cap.
Cardboard box with one type II glass vial of either 100 ml (containing 50 doses) or 240 ml (containing 120 doses) with a chlorobutyl rubber stopper and aluminium cap.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/130/001
EU/2/11/130/002
EU/2/11/130/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05/08/2011
Date of last renewal: 18/04/2016

10. DATE OF REVISION OF THE TEXT

Detailed information on this product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

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

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

Name and address of the manufacturer of the biological active substance

Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

Name and address of the manufacturer responsible for batch release

Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND 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 the immunological veterinary medicinal products on the whole or part of their territory if it is established that:

a) The administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control 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.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of Bluetongue.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

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 are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE INSERT

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton 1 x 20ml, 1 x 100ml and 1 x 240ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 1 Bovis suspension for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:
Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1
Aluminium hydroxide, saponin and thiomersal.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

20 ml (10 doses)
100 ml (50 doses)
240 ml (120 doses)

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

12. SPECIFIC 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

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/130/001
EU/2/11/130/002
EU/2/11/130/003

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial label 100 ml and 240ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 1 Bovis suspension for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml
Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1
Aluminium hydroxide, saponin and thiomersal.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml (50 doses)
240 ml (120 doses)

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label 20ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 1 Bovis suspension for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose of 2 ml
Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1
Aluminium hydroxide, saponin and thiomersal.

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

20 ml (10 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Zulvac1 Bovis suspension for injection for cattle

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

Marketing authorisation holder
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 1 Bovis suspension for injection for cattle

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

Each 2 ml dose contains:

Active substance:

Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1 RP* ≥ 1

*Relative Potency by a mice potency test compared to a reference vaccine that was shown efficacious in cattle.

Adjuvants:

Aluminium hydroxide (Al^{3+})	4 mg
Saponin	0.4 mg

Excipient:

Thiomersal	0.2 mg

Off-white or pink liquid.

4. INDICATIONS(S)

For active immunisation of cattle from 2 and a half months of age for the prevention* of viraemia caused by Bluetongue Virus (BTV), serotypes 1.
*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 15 days after completion of the primary vaccination scheme.
Duration of immunity: 12 months after completion of the primary vaccination scheme.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

After first vaccination a rectal temperature increase of up to 1.6°C may occur very commonly the 3rd day after the injection. Rectal temperatures should then return to normal values.

After second and third vaccination a rectal temperature increase of up to 1.3°C and 2.8°C respectively may occur very commonly one day after the injection and then rectal temperatures return to normal values.

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

Cattle

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

Intramuscular use.

Primary vaccination:
Administer one dose of 2 ml according to the following vaccination scheme:
1st injection: from 2.5 months of age.
2nd injection: after 3 weeks

Revaccination:
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

In order to avoid accidental contamination of the vaccine during use, it is recommended to use a multi-injection type vaccination system when larger dose presentations are used.

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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reachof children.
Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.

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

12. SPECIAL WARNING(S)

Vaccinate only healthy animals.

No information is available on the use of the vaccine in animals 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 cattle.

Pregnancy:
Can be used during pregnancy.

Lactation:
No data is available on safety in lactating animals. The use in lactating animals is therefore not recommended.

Fertility:
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).

Interactions with other medical 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):
After administration of a two-fold overdose a rectal temperature increase up to 2.1ºC may occur 1 day after the injection and then rectal temperatures return to normal values.

A slight to moderate increase of local reactions may commonly be observed after a 2-fold overdose lasting for a maximum of 56 days.

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

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

Medicines should not be disposed of via wastewater or household waste. 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

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

Cardboard box with one type I glass vial of 20 ml (containing 10 doses) with a chlorobutyl rubber stopper and aluminium cap.
Cardboard box with one type II glass vial of either 100 ml (containing 50 doses) or 240 ml (containing 120 doses) with a chlorobutyl rubber stopper and aluminium cap.

Not all pack sizes may be marketed.