ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZULVAC 8 Bovis suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml of the vaccine contains:

Active substance:
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02 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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Off-white or pink suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

Active immunisation of cattle from 3 months of age for the prevention* of 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: 25 days after administration of the second dose.
The duration of immunity is at least 1 year after the primary vaccination course.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Use in other domestic and wild ruminant species that are considered at risk of infection 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 however the vaccine has been shown safe and efficacious in seropositive cattle.

4.5 Special precautions for use

Special precautions for use in animals
Only use in healthy animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable

4.6 Adverse reactions (frequency and seriousness)

In one laboratory safety study, no adverse reactions were observed after the first injection of a single dose of vaccine to calves.
After the second injection of a single dose, a slight and transient but significant increase in the mean rectal temperature of 0.4ºC was very commonly recorded in the vaccinated calves during the first 24 hours. On day 2 after vaccination, rectal temperatures had returned to normal values. This clinical sign has been reported very rarely from the field.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

4.7 Use during pregnancy, lactation or lay

The vaccine can be used during pregnancy.

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 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:
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.

Primary vaccination:
Administer one dose of 2 ml according to the following vaccination scheme:
1st injection: from 3 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.

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

After administration of a double dose, a slight and transient but significant increase in the mean rectal temperature of 0.7ºC was recorded in the vaccinated calves during the first 24 hours. On day 2 after vaccination, rectal temperatures had returned to normal values. Local reactions of more than 2 cm are common after 2 fold overdose while reactions of up to 5 cm may occasionally occur after overdose administration, these resolve within a maximum of 57 days.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines – bluetongue virus vaccine.
ATC vet code: QI02AA08
To stimulate active immunity against bluetongue virus, serotype 8 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 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.

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

Type I glass bottle (10 doses) or type II glass bottle (50 doses) with butyl elastomer closure

Pack sizes
Pack of 1 bottle of 10 doses (20 ml).
Pack of 1 bottle of 50 doses (100 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 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/2/09/105/001
EU/2/09/105/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15/01/2010
Date of last renewal: 07/11/2014

10. DATE OF REVISION OF THE TEXT

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

The manufacture, import, possession, sale, supply and/or use of ZULVAC 8 BOVIS may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use ZULVAC 8 BOVIS must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

ANNEX II

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

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

Name and address of the manufacturer of the biological active substance(s):
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 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 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 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

The periodic safety update report (PSUR) cycle should be restarted for submission of 6 monthly reports (covering all authorised presentations of the product) for the next two years, followed by yearly reports for the subsequent two years and thereafter at 3 yearly intervals, unless otherwise required.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box 1 x 20ml / Carton box 1 x 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZULVAC 8 Bovis suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 2 ml contains:
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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 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.
The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in Member States on the Whole or part of its territory. See package leaflet for further information

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/2/09/105/001
EU/2/09/105/002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial label 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZULVAC 8 Bovis suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 2 ml contains:
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml (50 doses)

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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 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 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZULVAC 8 Bovis suspension for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose of 2 ml: Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02

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

20 ml (10 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

Withdrawal period: 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 FOR:
ZULVAC 8 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. Camprodon s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZULVAC 8 Bovis suspension for injection for cattle

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

One dose of 2 ml of vaccine contains:
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02 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

4. INDICATION(S)

Active immunisation of cattle from 3 months of age for the prevention* of 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: 25 days after administration of the second dose.
The duration of immunity is at least 1 year after the primary vaccination course.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In one laboratory safety study, no adverse reactions were observed after the first injection of a single dose of vaccine to calves.
After the second injection of a single dose, a slight and transient but significant increase in the mean rectal temperature of 0.4ºC was very commonly recorded in the vaccinated calves during the first 24 hours. On day 2 after vaccination, rectal temperatures had returned to normal values. This clinical sign has been reported very rarely from the field.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

Intramuscular use.
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.

Primary vaccination:
Administer one dose of 2 ml according to the following vaccination scheme:
1st injection: from 3 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.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze
Once broached use immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and on the label after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Use in other domestic and wild ruminant species that are considered at risk of infection 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 however the vaccine has been shown safe and efficacious in seropositive cattle.

Special precautions for use in animals:
Only use in healthy animals

Pregnancy:
Can be used during pregnancy.

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 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.

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

Overdose:
After administration of a double dose, a slight and transient but significant increase in the mean rectal temperature of 0.7 ºC was recorded in the vaccinated calves during the first 24 hours. On day 2 after vaccination, rectal temperatures had returned to normal values. Local reactions of more than 2 cm are common after 2 fold overdose while reactions of up to 5 cm may occasionally occur after overdose administration, these resolve within a maximum of 57 days.

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 product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Pack sizes
Pack of 1 bottle of 10 doses (20 ml).
Pack of 1 bottle of 50 doses (100 ml).
Not all pack sizes may be marketed.

The manufacture, import, possession, sale, supply and/or use of ZULVAC 8 Bovis may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use ZULVAC 8 Bovis must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

België/Belgique/Belgien
Zoetis Belgium SA
Tél/Tel.: +32 (0) 800 99 189

Република България
Zoetis Belgium SA
Тел: +359 2 4775791

Česká republika
Zoetis Česká republika, s.r.o.
Tel: +420 257 101 111

Danmark
Zoetis Finland Oy
Tlf: +358 (0)9 4300 40

Deutschland
Zoetis Deutschland GmbH
Tel: +49 30 330063 0

Eesti
Oriola Vilnius UAB
Tel: +370 610 05088

Lietuva
Oriola Vilnius UAB
Tel: +370 610 05088

Luxembourg/Luxemburg
Zoetis Belgium SA
Tél/Tel.: +352 8002 4026

Magyarország
Zoetis Hungary Kft.
Tel: +361 224 5222

Malta
Agrimed Limited
Tel: +356 21 465 797

Nederland
Zoetis B.V.
Tel: +31 (0)10 714 0900

Norge
Zoetis Finland Oy
Tlf: +358 (0)9 4300 40

Ελλάδα
Zoetis Hellas S.A.
Τηλ.: +30 210 6791900

España
Zoetis Spain, S.L.
Tel: +34 91 4191900

France
Zoetis France
Tél: +33 (0)810 734 937

Hrvatska
Zoetis B.V., Podružnica Zagreb za promidžbu
Tel: +385 1 644 1460

Ireland
Zoetis Belgium SA
Tel: +353 (0) 1 256 9800

Ìsland
Zoetis Finland Oy
Sími: +358 (0)9 4300 40

Italia
Zoetis Italia S.r.l.
Tel: +39 06 3366 8133

Κύπρος
Zoetis Hellas S.A.
Τηλ.: +30 210 6791900

Latvija
Oriola Vilnius UAB
Tel: +370 610 05088

Österreich
Zoetis Österreich GmbH
Tel: +43 1 2701100 110

Polska
Zoetis Polska Sp. z o.o.
Tel: +48 22 2234800

Portugal
Zoetis Portugal, Lda.
Tel: + 351 21 042 72 00

România
Zoetis România S.R.L
Tel : +40 21 202 3083

Slovenija
Zoetis B.V., Podružnica Zagreb za promidžbu
Tel: +385 1 644 1460

Slovenská republika
Zoetis Česká republika, s.r.o.
Tel: +420 257 101 111

Suomi/Finland
Zoetis Finland Oy
Puh/Tel: +358 (0)9 4300 40

Sverige
Zoetis Finland Oy
Tel: +358 (0)9 4300 40

United Kingdom
Zoetis UK Limited
Tel: +44 (0) 845 300 8034