ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac SBV suspension for injection for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	**Amount per 2 ml dose (cattle)**	**Amount per 1 ml dose (sheep)**
Inactivated Schmallenberg virus, strain BH80/11-4	RP* ≥ 1	RP* ≥ 1
Adjuvants:		
Aluminium hydroxide	385.2 mg (4 mg Al^{3+})	192.6 mg (2 mg Al^{3+})
Quil-A (*Quillaja saponaria* saponin extract)	0.4 mg	0.2 mg
Excipient:		
Thiomersal	0.2 mg	0.1 mg

*Relative potency (mice potency test) compared to a reference vaccine that was shown efficacious in the target animal species.

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 and sheep.

4.2 Indications for use, specifying the target species

Cattle:
For active immunisation of cattle from 3.5 months of age to reduce viraemia* associated with infection by Schmallenberg virus.

Onset of immunity: 2 weeks after completion of the primary vaccination course.
Duration of immunity: 1 year after completion of the primary vaccination course.

Sheep:
For active immunisation of sheep from 3.5 months of age to reduce viraemia* associated with infection by Schmallenberg virus.

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

Vaccination of breeding sheep before pregnancy according to the recommended schedule described in section 4.9 results in reduction of viraemia* and transplacental infection associated with infection by Schmallenberg virus during the first trimester of pregnancy.

*Below the level of detection by the validated RT-PCR method at 3.6 $\log_{10}$ RNA copies/ml of plasma for cattle and at 3.4 $\log_{10}$ RNA copies/ml of plasma for sheep.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

No information is available on the use of the vaccine in seropositive animals including those with maternally-derived antibodies.

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
In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Cattle:
A transient increase in rectal temperature, not exceeding 1.5 ºC, was very commonly observed during the first 48 hours after vaccination. Local reactions at the injection site in the form of small intramuscular granulomas up to 0.7 cm in diameter which resolve in a maximum of 10 days, also very commonly appeared in the safety studies conducted.

Sheep:
A transient increase in rectal temperature, not exceeding 1.5 ºC, was very commonly observed during the first 24 hours after vaccination. Local reactions at the injection site in the form of diffuse swellings or subcutaneous granulomas of up to a maximum diameter of 8 cm also very commonly appeared in the safety studies conducted. The reactions were observed for at least 47 days in the form of diffuse swelling of less than 2 cm diameter.

Pregnant ewe:
A transient increase in rectal temperature, not exceeding 0.8 ºC, was very commonly observed during the first 4 hours after vaccination. Local reactions at the injection site in the form of diffuse swellings or subcutaneous granulomas of up to a maximum diameter of 8 cm also very commonly appeared in the safety studies conducted. The reactions were observed for at least 97 days in the form of small granulomas of less than 0.5 cm in diameter.

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

Pregnancy:
Sheep: Safety data are available to demonstrate the safety of the vaccine when administered to pregnant sheep. Can be used at 2 months of pregnancy and onwards.

Cattle: The safety and efficacy of the vaccine have not been established in pregnant cattle.

Lactation:
The safety and the efficacy of the vaccine have not been established in lactating animals.

Fertility:
The safety and the efficacy of the vaccine have not been established in breeding males.

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

Shake the vial before use.

Cattle:
Intramuscular use (in the neck).
Primary vaccination:
- For cattle from 3.5 months of age: administer two doses of 2 ml three weeks apart.

Booster vaccination:
- Administer two doses of 2 ml three weeks apart, every twelve months.

Sheep:
Subcutaneous use (in the axillar region behind the elbow).
Primary vaccination:
- For sheep from 3.5 months of age: administer one dose of 1 ml.
- For female sheep at breeding age: administer one dose of 1 ml at least 14 days prior to breeding.

Booster vaccination:
- For non-breeding sheep: administer one dose of 1 ml, every 6 months.
- For female breeding sheep: administer one dose of 1 ml at least 14 days prior to every breeding.

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

Not applicable.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for bovidae, inactivated viral vaccines for cattle.
ATC vet code: QI02AA.

To stimulate active immunity against Schmallenberg virus in cattle and sheep.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Quil-A (*Quillaja saponaria* saponin extract)
Thiomersal
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box with 1 high density polyethylene (HDPE) vial with chlorobutyl stopper and aluminium seal, containing 50 ml of vaccine.

Cattle: Cardboard box with 1 vial of 50 ml (25 doses).
Sheep: Cardboard box with 1 vial of 50 ml (50 doses).

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/2/14/178/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06/02/2015.
Date of last renewal: 15/01/2020.

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

Not applicable.

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

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

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. de Camprodón, s/n°
Finca La Riba
Vall de Bianya
Gerona, 17813
SPAIN

Name and address of the manufacturer responsible for batch release

Zoetis Manufacturing & Research Spain, S.L.
Ctra. de Camprodón, s/n°
Finca La Riba
Vall de Bianya
Gerona, 17813
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 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.

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 MAH shall complete the following measures (from EMEA/V/C/002781/II/006):

The results of the product control tests of the first batch of Zulvac SBV manufactured with the new master seed virus (and corresponding working seed virus) shall be provided.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac SBV suspension for injection for cattle and sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:	**Amount per 2 ml dose (cattle)**	**Amount per 1 ml dose (sheep)**
Inactivated Schmallenberg virus, strain BH80/11-4	RP ≥ 1	RP ≥ 1

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: intramuscular use.
Sheep: subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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.
Do not freeze. Protect from light.

12. SPECIAL 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/2/14/178/001

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL (50 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac SBV suspension for injection for cattle and sheep

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated Schmallenberg virus (RP ≥ 1/dose)

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

IM (cattle)
SC (sheep)

5. WITHDRAWAL PERIOD(S)

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:
Zulvac SBV suspension for injection for cattle and sheep

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. de Camprodón, s/n°
Finca La Riba
Vall de Bianya
Gerona, 17813
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac SBV suspension for injection for cattle and sheep

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

Active substance:	**Amount per 2 ml dose (cattle)**	**Amount per 1 ml dose (sheep)**
Inactivated Schmallenberg virus, strain BH80/11-4	RP* ≥ 1	RP* ≥ 1
Adjuvants:		
Aluminium hydroxide	385.2 mg (4 mg Al^{3+})	192.6 mg (2 mg Al^{3+})
Quil-A (*Quillaja saponaria* saponin extract)	0.4 mg	0.2 mg
Excipient:		
Thiomersal	0.2 mg	0.1 mg

*Relative potency (mice potency test) compared to a reference vaccine that was shown efficacious in the target animal species.

Off-white or pink liquid.

4. INDICATION(S)

Cattle:
For active immunisation of cattle from 3.5 months of age to reduce viraemia* associated with infection by Schmallenberg virus.

Onset of immunity: 2 weeks after completion of the primary vaccination course.

Duration of immunity: 1 year after completion of the primary vaccination course.

Sheep:
For active immunisation of sheep from 3.5 months of age to reduce viraemia* associated with infection by Schmallenberg virus.

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

Vaccination of breeding sheep before pregnancy according to the recommended schedule described in section 8 results in reduction of viraemia* and transplacental infection associated with infection by Schmallenberg virus during the first trimester of pregnancy.

*Below the level of detection by the validated RT-PCR method at 3.6 $\log_{10}$ RNA copies/ml of plasma for cattle and at 3.4 $\log_{10}$ RNA copies/ml of plasma for sheep.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Cattle:
A transient increase in rectal temperature, not exceeding 1.5 °C, was very commonly observed during the first 48 hours after vaccination. Local reactions at the injection site in the form of small intramuscular granulomas up to 0.7 cm in diameter which resolve in a maximum of 10 days, also very commonly appeared in the safety studies conducted.

Sheep:
A transient increase in rectal temperature, not exceeding 1.5 ºC, was very commonly observed during the first 24 hours after vaccination. Local reactions at the injection site in the form of diffuse swellings or subcutaneous granulomas of up to a maximum diameter of 8 cm also very commonly appeared in the safety studies conducted. The reactions were observed for at least 47 days in the form of diffuse swelling of less than 2 cm diameter.

Pregnant ewe:
A transient increase in rectal temperature, not exceeding 0.8 ºC, was very commonly observed during the first 4 hours after vaccination. Local reactions at the injection site in the form of diffuse swellings or subcutaneous granulomas of up to a maximum diameter of 8 cm also very commonly appeared in the safety studies conducted. The reactions were observed for at least 97 days in the form of small granulomas of less than 0.5 cm in diameter.

The frequency of adverse reactions is defined using the following convention:
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- 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 and sheep.

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

Cattle:
Intramuscular use (in the neck).

Primary vaccination:
- For cattle from 3.5 months of age: administer two doses of 2 ml three weeks apart.

Booster vaccination:
- Administer two doses of 2 ml three weeks apart, every twelve months.

Sheep:
Subcutaneous use (in the axillar region behind the elbow).

Primary vaccination:
- For sheep from 3.5 months of age: administer one dose of 1 ml.
- For female sheep at breeding age: administer one dose of 1 ml at least 14 days prior to breeding.

Booster vaccination:
- For non-breeding sheep: administer one dose of 1 ml, every 6 months.
- For female breeding sheep: administer one dose of 1 ml at least 14 days prior to every breeding.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial before use.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C). 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 container: use immediately.

12. SPECIAL WARNING(S)

Vaccinate healthy animals only.

Special warnings for each target species:
No information is available on the use of the vaccine in seropositive animals including those with maternally-derived antibodies.

Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:
Sheep: Safety data are available to demonstrate the safety of the vaccine when administered to pregnant sheep. Can be used at 2 months of pregnancy and onwards.

Cattle: The safety and efficacy of the vaccine has not been established in pregnant cattle.

Lactation:
The safety and the efficacy of the vaccine have not been established in lactating animals.

Fertility:
The safety and the efficacy of the vaccine have not been established in breeding males.

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.

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 to 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

Zulvac SBV is available in a cardboard box with 1 high density polyethylene (HDPE) vial with chlorobutyl stopper and aluminium seal, containing 50 ml of vaccine.

Cattle: Cardboard box with 1 vial of 50 ml (25 doses).
Sheep: Cardboard box with 1 vial of 50 ml (50 doses).