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 substances:	**Each dose of 2 ml (cattle) contains**	**Each dose of 1 ml (sheep) contains**
Schmallenberg virus, strain BH80/11-4, inactivated.	RP* ≥ 1	RP* ≥ 1

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

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**	
	Each dose of 2 ml (cattle) contains	**Each dose of 1 ml (sheep) contains**
Thiomersal	0.2 mg	0.1 mg
Potassium chloride		
Potassium dihydrogen phosphate		
Disodium phosphate dihydrate		
Sodium chloride		
Water for injections		

Off-white or pink suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each 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 scheme.
Duration of immunity: 1 year after completion of the primary vaccination scheme.

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 3.9 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

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

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

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site granuloma[2]

[1]Transient, up to 1.5 °C, for up to 2 days.
[2]Intramuscular, up to 0.7 cm diameter, for up to 10 days.

Sheep:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2] Injection site granuloma[2]

[1]Transient, up to 1.5 °C, for up to 24 hours.
[2]Diffuse swelling or subcutaneous granulomas up to 8 cm diameter. The reactions may be observed for at least 47 days in the form of diffuse swelling of less than 2 cm diameter.

Pregnant ewe:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2] Injection site granuloma[2]

[1]Transient, up to 0.8 °C, for up to 4 hours.
[2]Diffuse swelling or subcutaneous granulomas up to 8 cm diameter. The reactions may be observed for at least 97 days in the form of small granulomas of less than 0.5 cm in diameter.

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 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:
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.

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

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 year.

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.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : QI02AA

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

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: 1 year.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 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).

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/178/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 06/02/2015.

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

OBLIGATION TO CONDUCT POST-AUTHORISATION MEASURES

The MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
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.	After production of the first batch with the new master seed virus.

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.

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances:	**Each dose of 2 ml (cattle) contains**	**Each dose of 1 ml (sheep) contains**
Schmallenberg virus, strain BH80/11-4, inactivated.	RP ≥ 1	RP ≥ 1

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

Cattle and sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: intramuscular use.
Sheep: subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/14/178/001

15. 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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated Schmallenberg virus

50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zulvac SBV suspension for injection for cattle and sheep

2. Composition

Active substances:	**Each dose of 2 ml (cattle) contains**	**Each dose of 1 ml (sheep) contains**
Schmallenberg virus, strain BH80/11-4, inactivated.	RP* ≥ 1	RP* ≥ 1

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

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
Excipients:		
Thiomersal	0.2 mg	0.1 mg

Off-white or pink suspension.

3. Target species

Cattle and sheep.

4. Indications for use

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

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. Special warnings

Special warnings:
Vaccinate healthy animals only.
No information is available on the use of the vaccine in seropositive animals including those with maternally derived antibodies.

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: 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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):
Elevated temperature[1]
Injection site granuloma[2]

[1]Transient, up to 1.5 °C, for up to 2 days.
[2]Intramuscular, up to 0.7 cm diameter, for up to 10 days.

Sheep:

Very common (>1 animal / 10 animals treated):
Elevated temperature[1]
Injection site swelling[2]
Injection site granuloma[2]

[1]Transient, up to 1.5 °C, for up to 24 hours.

[2]Diffuse swelling or subcutaneous granulomas up to 8 cm diameter. The reactions may be observed for at least 47 days in the form of diffuse swelling of less than 2 cm diameter.

Pregnant ewe:

Very common (>1 animal / 10 animals treated):
Elevated temperature[1]
Injection site swelling[2]
Injection site granuloma[2]

[1]Transient, up to 0.8 °C, for up to 4 hours.
[2]Diffuse swelling or subcutaneous granulomas up to 8 cm diameter. The reactions may be observed for at least 97 days in the form of small granulomas of less than 0.5 cm in diameter.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes 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 year.

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 periods

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 and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/14/178/001

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).

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

België/Belgique/Belgien
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Manufacturer responsible for batch release:
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Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

17. Other information

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