ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD lyophilisate and suspension for suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 ml dose contains:

Active substances:

Lyophilisate:
Parainfluenza 3 virus, modified live strain RLB 103 $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$
Bovine Respiratory Syncytial Virus, modified live strain 375 $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$

Suspension:
Bovine Virus Diarrhoea Virus Type 1, inactivated strains 5960 (cytopathic) and 6309 (non-cytopathic), to induce a GMT seroneutralisation titre in guinea pigs of at least 3.0 log_2

$CCID_{50}$ = Cell Culture Infectious Dose 50%.

Adjuvant:

Alhydrogel 2%	0.8 ml (equivalent to 24.36 mg of aluminium hydroxide)

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Buffered lactose solution
Gelatin solution
Casein hydrolysate solution
Suspension:
HALS medium

Lyophilisate: slightly coloured freeze-dried pellet.
Suspension: slightly coloured turbid liquid which might contain a loose sediment. On shaking well, the sediment is easily resuspended.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For active immunisation of calves from 12 weeks of age to:

- reduce virus excretion and the clinical signs caused by bovine Pi3 virus,

- reduce virus excretion caused by BRSV infection and
- reduce virus excretion and the severity of the leucopenia induced by BVDV Type 1 infection.

Onset of immunity: 3 weeks.

Duration of immunity: 6 months (demonstrated by challenge studies) for BRSV and BVDV Type 1. Duration of immunity has not been established for bovine Pi3 virus.

Efficacy has not been demonstrated against BVDV Type 2 strains.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

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):	Hyperthermia[1] Injection site inflammation[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction, anaphylactic-type reaction[3]

[1]Transient and mild; can last for 2 days.
[2]Transient and minor; up to 0.5 cm which disappears within 15 days.
[3]In case of anaphylactic reaction, symptomatic treatment should be provided.

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 its local representative> 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 and lactation:

The safety and efficacy of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy and lactation.

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

Dose: 4 ml.

Route: intramuscular.

Reconstitution of the vaccine:

Reconstitute the vaccine by adding the suspension to the vial containing the lyophilisate.

When the lyophilisate and suspension are filled in equally sized vials, inject the entire suspension into the vial containing the lyophilisate.

When the lyophilisate is filled in a smaller vial size than the suspension, the reconstitution of the vaccine is carried out in 2 steps:

1. Inject 10 ml of the suspension on the lyophilised plug in the vial containing the lyophilisate.
2. Shake well and extract the reconstituted lyophilised fraction from the vial and mix with the remaining suspension in the liquid fraction vial.

Shake well before use.

Reconstituted product is a slightly coloured turbid liquid which might contain a loose sediment which is easily resuspended on shaking well.

Vaccination scheme:

Administer one dose (4 ml) of the reconstituted vaccine according to the following vaccination scheme:

Basic immunisation: two doses, each of 4 ml, 3-4 weeks apart from 12 weeks of age.

Booster vaccinations: if protection against BRSV and BVDV Type 1 is required, then animals should be revaccinated after 6 months.

Animals should be preferably vaccinated at least 3 weeks before a period of stress or high infection risk like re-grouping or transport of animals, or the start of autumn season. The duration of immunity of the Pi3 component is not known.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those mentioned in section 3.6 were observed after administration of an overdose of the vaccine.

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

To be completed nationally.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AH

To stimulate an active immunity against Pi3, BRSV and BVDV Type 1.

The vaccine has a broad cross-neutralising ability against various current European strains of BVDV Type 1 as measured *in vitro* by virus neutralisation test. Cross neutralisation at a lower level has also been demonstrated to BVDV Type 2 strains.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except suspension recommended for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 2 hours.

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

Type I glass vial containing 5 or 25 doses (20 or 100 ml) suspension, closed with chlorobutyl rubber stopper and sealed with aluminium cap.
Type I glass vial containing 5 or 25 doses of lyophilisate, closed with bromobutyl rubber stopper and sealed with aluminium cap.

Cardboard box with 1 vial of lyophilisate (5 doses) and 1 vial of suspension (20 ml).
Cardboard box with 1 vial of lyophilisate (25 doses) and 1 vial of suspension (100 ml).

Not all pack sizes may be marketed.

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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: *To be completed nationally.*

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

To be completed nationally.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

[BE, FR, CZ, DE, EE, ES, HU, IE, LU, LT, LV, NL, PL, PT, SI, SK, UK(NI)]: Veterinary medicinal product subject to prescription.
[IE]: Veterinary medicinal product not subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD lyophilisate and suspension for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4 ml dose contains:

Lyophilisate:
Modified live Bovine Pi3 virus, strain RLB 103 $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$
Modified live BRSV, strain 375 $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$

Suspension:
Inactivated BVDV Type 1, strains 5960 (cytopathic) and 6309 (non-cytopathic) ≥ 3.0 $\log_2$

3. PACKAGE SIZE

1 x 5 doses
1 x 25 doses

4. TARGET SPECIES

Cattle.

5. INDICATIONS

To be completed nationally.
<For products not subject to veterinary prescription.>

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

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

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL ON GLASS VIAL – LYOPHILISATE (5 and 25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Bovine Pi3 virus, BRSV

5 doses
25 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL ON GLASS VIAL – SUSPENSION (20 ml and 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

BVDV Type 1

5 doses (20 ml)
25 doses (100 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Rispoval 3 BRSV Pi3 BVD lyophilisate and suspension for suspension for injection for cattle

2. Composition

Each 4 ml dose contains:

Active substances:

Lyophilisate:

Parainfluenza 3 virus, modified live strain RLB 103	$10^{5.0}$ - $10^{8.6}$ $CCID_{50}$
Bovine Respiratory Syncytial Virus, modified live strain 375	$10^{5.0}$ - $10^{7.2}$ $CCID_{50}$

Suspension:

Bovine Virus Diarrhoea Virus Type 1, inactivated strains 5960 (cytopathic) and 6309 (non-cytopathic), to induce a GMT seroneutralisation titre in guinea pigs of at least 3.0 log_2

$CCID_{50}$ = Cell Culture Infectious Dose 50%.

Adjuvant:

Alhydrogel 2%	0.8 ml (equivalent to 24.36 mg of aluminium hydroxide)

Lyophilisate: slightly coloured freeze-dried pellet.
Suspension: slightly coloured turbid liquid which might contain a loose sediment. On shaking well, the sediment is easily resuspended.

3. Target species

Cattle.

4. Indications for use

For active immunisation of calves from 12 weeks of age to:

- reduce virus excretion and the clinical signs caused by bovine Pi3 virus,
- reduce virus excretion caused by BRSV infection and
- reduce virus excretion and the severity of the leucopenia induced by BVDV Type 1 infection.

Onset of immunity: 3 weeks.

Duration of immunity: 6 months (demonstrated by challenge studies) for BRSV and BVDV Type 1. Duration of immunity has not been established for bovine Pi3 virus.

Efficacy has not been demonstrated against BVDV Type 2 strains.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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 and lactation:
The safety and efficacy of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy and lactation.

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.

Overdose:
No adverse events other than those mentioned in section "Adverse events" were observed after administration of an overdose of the vaccine.

Special restrictions for use and special conditions for use:
To be completed nationally.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except suspension recommended for use with the veterinary medicinal product.

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Hyperthermia[1] Injection site inflammation[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction, anaphylactic-type reaction[3]

[1]Transient and mild; can last for 2 days.
[2]Transient and minor; up to 0.5 cm which disappears within 15 days.
[3]In case of anaphylactic reaction (severe allergic reaction), symptomatic treatment should be provided.

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 <or the local representative of 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

Dose: 4 ml.

Route: intramuscular.

Vaccination scheme:

Administer one dose (4 ml) of the reconstituted vaccine according to the following vaccination scheme:

Basic immunisation: two doses, each of 4 ml, 3-4 weeks apart from 12 weeks of age.

Booster vaccinations: if protection against BRSV and BVDV Type 1 is required, then animals should be revaccinated after 6 months.

Animals should be preferably vaccinated at least 3 weeks before a period of stress or high infection risk like re-grouping or transport of animals, or the start of autumn season. The duration of immunity of the Pi3 component is not known.

9. Advice on correct administration

Reconstitution of the vaccine:

Reconstitute the vaccine by adding the suspension to the vial containing the lyophilisate.

When the lyophilisate and suspension are filled in equally sized vials, inject the entire suspension into the vial containing the lyophilisate.

When the lyophilisate is filled in a smaller vial size than the suspension, the reconstitution of the vaccine is carried out in 2 steps:

1. Inject 10 ml of the suspension on the lyophilised plug in the vial containing the lyophilisate.
2. Shake well and extract the reconstituted lyophilised fraction from the vial and mix with the remaining suspension in the liquid fraction vial.

Shake well before use.

Reconstituted product is a slightly coloured turbid liquid which might contain a loose sediment which is easily resuspended on shaking well.

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 reconstitution according to directions: 2 hours.

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.

13. Classification of veterinary medicinal products

BE, FR, CZ, DE, EE, ES, HU, IE, LU, LT, LV, NL, PL, PT, SI, SK, UK(NI): Veterinary medicinal product subject to prescription.
IE: Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

Cardboard box with 1 vial of lyophilisate (5 doses) and 1 vial of suspension (20 ml).
Cardboard box with 1 vial of lyophilisate (25 doses) and 1 vial of suspension (100 ml).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

To be completed nationally.

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 reactions>:
To be completed nationally.

Manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

<Local representatives< and contact details to report suspected adverse reactions>:>
To be completed nationally (if needed).

17. Other information

To stimulate an active immunity against Pi3, BRSV and BVDV Type 1.

The vaccine has a broad cross-neutralising ability against various current European strains of BVDV Type 1 as measured *in vitro* by virus neutralisation test. Cross neutralisation at a lower level has also been demonstrated to BVDV Type 2 strains.