ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3 lyophilisate and solvent for suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 ml dose contains:

Active substances:

Lyophilisate
Bovine parainfluenza virus 3 (Pi3V), strain RLB 103, live $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$.
Bovine respiratory syncytial virus (BRSV), strain 375, live $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$.

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

Adjuvant:

Aluminium hydroxide gel	0.8 ml (equivalent to 24.36 mg of aluminium hydroxide).

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Lactose Monohydrate
Potassium hydrogen phosphate
Dipotassium phosphate
Monopotassium L-glutamate
Water, purified
Gelatin
Casein hydrolysate solution
HALS medium
Solvent:
HALS medium

Lyophilisate: slightly whitish to yellowish freeze-dried pellet.
Solvent: pinkish to orange-brown turbid liquid, which might contain 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 vaccination with Rispoval 2 only:
Active immunisation of cattle from 12 weeks of age to:
- reduce virus excretion caused by bovine Pi3V and
- reduce virus excretion caused by BRSV infection.

Onset of immunity: 3 weeks after the basic vaccination scheme.
Duration of immunity: 6 months after the basic vaccination scheme for BRSV. Duration of immunity has not been established for bovine Pi3V.

For active immunisation with Rispoval RS+Pi3 IntraNasal* as basic vaccination and Rispoval 2 as booster vaccination from 13 weeks of age to:
- reduce virus excretion caused by bovine Pi3V and BRSV infection and
- reduce clinical signs (cough, depression, dyspnea, increased respiratory rate, elevated rectal temperature) associated with BRSV infection.

Onset of immunity: 3 weeks after the booster vaccination.
Duration of immunity: 6 months for BRSV and 3 months for Pi3V after the booster vaccination.

* Where this veterinary medicinal product is authorised.

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 (e.g. 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 use.

Reconstitution of the vaccine:

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

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

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

1. Inject 10 ml of the solvent 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 solvent in the liquid fraction vial.

Shake well before use.

Reconstituted product: pink-orange turbid suspension with loose sediment.

Vaccination scheme:
For vaccination with Rispoval 2 only:
Basic vaccination: two doses 3-4 weeks apart from 12 weeks of age.
Re-vaccination: if continued protection against BRSV is required, then animals should be revaccinated after 6 months. The duration of immunity of the Pi3V component is not known.

For use as a booster vaccination after basic vaccination with Rispoval RS+Pi3 IntraNasal*:
A single dose of Rispoval 2 three months after the basic vaccination with Rispoval RS+Pi3 IntraNasal*.
If continued protection against BRSV is required, then animals should be revaccinated with a single dose after 6 months. If continued protection against Pi3V is required, then animals should be revaccinated with a single dose after 3 months.

* Where this veterinary medicinal product is authorised.

Animals should preferably be vaccinated at least 3 weeks before a period of stress or high infection risk such as re-grouping or transport of animals, or the start of autumn season.

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

Reactions after administration of an overdose of vaccine are not different from those after the single dose.

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: QI02AD07

To stimulate an active immunity against Pi3V and BRSV.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied 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: 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

Type I glass vial containing 5 or 25 doses (20 or 100 ml) of solvent, 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 glass vial of lyophilisate (5 doses) and 1 glass vial of solvent (20 ml).
Cardboard box with 1 glass vial of lyophilisate (25 doses) and 1 glass vial of solvent (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, CZ, DE, EE, ES, FR, HR, HU, LT, LU, LV, NL, 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 (5 OR 25 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3 lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4 ml dose contains:

Bovine parainfluenza virus 3 (Pi3V), strain RLB 103, live $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$.
Bovine respiratory syncytial virus (BRSV), strain 375, live $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$.

3. PACKAGE SIZE

5 doses
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 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

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 OR 25 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Live bovine Pi3V and BRSV

5 doses
25 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL ON GLASS VIAL – SOLVENT (20 OR 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3 solvent

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Rispoval 2 / BRSV + Pi3 lyophilisate and solvent for suspension for injection for cattle

2. Composition

Each 4 ml dose contains:

Active substances:

Lyophilisate
Bovine parainfluenza virus 3 (Pi3V), strain RLB 103, live $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$.
Bovine respiratory syncytial virus (BRSV), strain 375, live $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$.

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

Adjuvant:

Aluminium hydroxide gel	0.8 ml (equivalent to 24.36 mg of aluminium hydroxide).

Lyophilisate: slightly whitish to yellowish freeze-dried pellet.
Solvent: pinkish to orange-brown turbid liquid, which might contain loose sediment. On shaking well, the sediment is easily resuspended.

3. Target species

Cattle.

4. Indications for use

For vaccination with Rispoval 2 only:
Active immunisation of cattle from 12 weeks of age to:
- reduce virus excretion caused by bovine Pi3V and
- reduce virus excretion caused by BRSV infection.

Onset of immunity: 3 weeks after the basic vaccination scheme.
Duration of immunity: 6 months after the basic vaccination scheme for BRSV. Duration of immunity has not been established for bovine Pi3V.

For active immunisation with Rispoval RS+Pi3 IntraNasal* as basic vaccination and Rispoval 2 as booster vaccination from 13 weeks of age to:
- reduce virus excretion caused by bovine Pi3V and BRSV infection and
- reduce clinical signs (cough, depression, dyspnea, increased respiratory rate, elevated rectal temperature) associated with BRSV infection.

Onset of immunity: 3 weeks after the booster vaccination.
Duration of immunity: 6 months for BRSV and 3 months for Pi3V after the booster vaccination.

* Where this veterinary medicinal product is authorised.

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:
Reactions after administration of an overdose of vaccine are not different from those after the single dose.

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 solvent supplied 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 [e.g. anaphylactic-type reaction (severe allergic 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 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 use.

Vaccination scheme:
For vaccination with Rispoval 2 only:
Basic vaccination: two doses 3-4 weeks apart from 12 weeks of age.
Re-vaccination: if continued protection against BRSV is required, then animals should be revaccinated after 6 months. The duration of immunity of the Pi3V component is not known.

For use as a booster vaccination after basic vaccination with Rispoval RS+Pi3 IntraNasal*:
A single dose of Rispoval 2 three months after the basic vaccination with Rispoval RS+Pi3 IntraNasal*.
If continued protection against BRSV is required, then animals should be revaccinated with a single dose after 6 months. If continued protection against Pi3V is required, then animals should be revaccinated with a single dose after 3 months.

* Where this veterinary medicinal product is authorised.

Animals should preferably be vaccinated at least 3 weeks before a period of stress or high infection risk such as re-grouping or transport of animals, or the start of autumn season.

9. Advice on correct administration

Reconstitution of the vaccine:

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

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

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

1. Inject 10 ml of the solvent 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 solvent in the liquid fraction vial.

Shake well before use.

Reconstituted product: pink-orange turbid suspension with loose sediment.

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: 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

BE, CZ, DE, EE, ES, FR, HR, HU, LT, LU, LV, NL, 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 glass vial of lyophilisate (5 doses) and 1 glass vial of solvent (20 ml). Both vials have rubber stopper and aluminium cap.
Cardboard box with 1 glass vial of lyophilisate (25 doses) and 1 glass vial of solvent (100 ml). Both vials have rubber stopper and aluminium cap.

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 Pi3V and BRSV.