ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Protivity lyophilisate and solvent for suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substance:
Lyophilisate:
Mycoplasma bovis strain N2805-1, live (attenuated) 0.22×10^7 to 15.50×10^7 CFU*
* Colony Forming Units.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Lyophilisate:	
Lactose monohydrate	
Potassium dihydrogen phosphate	
Dipotassium hydrogen phosphate trihydrate	
Monopotassium L-glutamate	
Gelatin	
Casein Hydrolysate	
Basal Medium Eagle	
Magnesium chloride hexahydrate	
Phenol red	
Sodium hydrogen carbonate	
Water for injections	
Solvent:	
Water for injections	2 ml

Lyophilisate: slightly coloured (whitish to cream) freeze-dried pellet.
Solvent: clear and colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For active immunisation of calves from 1 week of age to reduce clinical signs and lung lesions caused by *Mycoplasma bovis* infection.

Onset of immunity: 12 days after the basic vaccination scheme.
Duration of immunity: has not been established.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The potential impact of maternally derived antibodies on efficacy of vaccination has not been established.

The product is a live attenuated vaccine. Antimicrobials active against *Mycoplasma* spp. should not be given 15 days before or after vaccination or during the two-dose basic vaccination scheme as they could interfere with vaccine efficacy. Within these time frames, and in the situation where a clinical condition requires the prescription of antimicrobials, preference should be given to those with no anti-*Mycoplasma* spp. activity.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The safety of the veterinary medicinal product has not been established in breeding bulls.

The live attenuated *Mycoplasma bovis* vaccine strain may disseminate into synovial fluid, lymph node, middle ear, conjunctiva, tonsil and lung tissue after vaccination.

In a laboratory study conducted using a dose 7-fold higher than the maximum bacterial content, nasal shedding was observed for at least 9 days post-vaccination in an animal vaccinated through intramuscular and subcutaneous routes. However, the vaccine strain did not spread to in-contact control animals.

Distinguishing between field strains and the vaccine strain of *M. bovis* can be performed by whole genome sequencing tests. Additional information to differentiate the vaccine strain from field strains is available upon request from the marketing authorisation holder.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

No special precautions to be taken by the person administering the veterinary medicinal product to animals are necessary as *M. bovis* is not considered to present a risk to healthy humans. However, in case of development of adverse reactions following 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):	injection site swelling [1]
Common (1 to 10 animals / 100 animals treated):	injection site pain[2] injection site warmth[2] injection site nodule[3]
Uncommon (1 to 10 animals / 1,000 animals treated):	lameness

[1]More than 5 cm in diameter observed on the day of vaccine administration and resolving spontaneously within 3 days.
[2]On the day of vaccine administration.
[3]Less than 0.8 cm^3 in volume observed from 10 days after vaccination and lasting between 1 to 5 days.

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 also section "Contact details" of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established 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

Vaccinate cattle by the subcutaneous route in the neck.

Reconstitute the lyophilisate with the solvent to obtain a suspension for injection.

After reconstitution, the suspension should be pinkish to orange-brown turbid in color.

Basic vaccination scheme:
Two doses, each of 2 ml, should be administered 3 weeks apart to calves from 1 week of age. The second dose should preferably be administered on the alternate side of the neck.

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

No other adverse events than those mentioned in section 3.6 "Adverse events" were observed after administration of a 10-fold overdose of the vaccine. Swelling at the injection site may have a diameter of more than 5 cm and will spontaneously resolve in 4 days. The volume of the observed nodule may be up to 3 cm^3, can be observed from 5 days post vaccination and may last until 16 days after administration of a 10-fold 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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AE05

The vaccine induces an active immunity against *Mycoplasma bovis* in young calves.

Duration of immunity has not been established. The basic vaccination scheme induces a serological response. Within a laboratory study conducted, a single dose administration approximately 14 weeks after the basic vaccination scheme induced an anamnestic immune response in vaccinated animals.

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).
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Type I hydrolytic glass vials containing 10 doses of lyophilisate or 20 ml of solvent.

Lyophilisate: bromobutyl rubber stoppers and aluminium caps.
Solvent: chlorobutyl rubber stoppers and aluminium caps.

Cardboard box containing 1 vial with 10 doses of lyophilisate and 1 vial with 20 ml solvent.

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

{Name} *To be completed nationally.*

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}. *To be completed nationally.*

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

{DD/MM/YYYY} *To be completed nationally.*

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Protivity lyophilisate and solvent for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Mycoplasma bovis strain N2805-1, live (attenuated) 0.22×10^7 to 15.50×10^7 CFU

3. PACKAGE SIZE

10 doses

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous 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.
Keep the vial in the outer carton in order to 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

{Name or company name or logo name of the marketing authorisation holder} *To be completed nationally.*

14. MARKETING AUTHORISATION NUMBERS

Number allocated by the Member State. To be completed nationally.

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL ON GLASS VIAL – LYOPHILISATE (10 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Protivity lyophilisate

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

M. bovis

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 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Protivity solvent

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

Protivity lyophilisate and solvent for suspension for injection for cattle

2. Composition

Each dose of 2 ml contains:

Active substance:
Lyophilisate:
Mycoplasma bovis strain N2805-1, live (attenuated) 0.22×10^7 to 15.50×10^7 CFU*
* Colony Forming Units.

Excipient:
Solvent:
Water for injections 2 ml

Lyophilisate: slightly coloured (whitish to cream) freeze-dried pellet.
Solvent: clear and colourless liquid.

3. Target species

Cattle.

4. Indications for use

For active immunisation of calves from 1 week of age to reduce clinical signs and lung lesions caused by *Mycoplasma bovis* infection.

Onset of immunity: 12 days after the basic vaccination scheme.
Duration of immunity: has not been established.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

The potential impact of maternally derived antibodies on efficacy of vaccination has not been established.

The product is a live attenuated vaccine. Antimicrobials active against *Mycoplasma* spp. should not be given 15 days before or after vaccination or during the two-dose basic vaccination scheme as they could interfere with vaccine efficacy. Within these time frames, and in the situation where a clinical condition requires the prescription of antimicrobials, preference should be given to those with no anti-*Mycoplasma* spp. activity.

Special precautions for safe use in the target species:
The safety of the veterinary medicinal product has not been established in breeding bulls.

The live attenuated *Mycoplasma bovis* vaccine strain may disseminate into synovial fluid, lymph node, middle ear, conjunctiva, tonsil and lung tissue after vaccination.

In a laboratory study conducted using a dose 7-fold higher than the maximum bacterial content, nasal shedding was observed for at least 9 days post-vaccination in an animal vaccinated through intramuscular and subcutaneous routes. However, the vaccine strain did not spread to in-contact control animals.

Distinguishing between field strains and the vaccine strain of *M. bovis* can be performed by whole genome sequencing tests. Additional information to differentiate the vaccine strain from field strains is available upon request from the marketing authorisation holder.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
No special precautions to be taken by the person administering the veterinary medicinal product to animals are necessary as *M. bovis* is not considered to present a risk to healthy humans. However, in case of development of adverse reactions following 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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established 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 other adverse events than those mentioned in section “Adverse events” were observed after administration of a 10-fold overdose of the vaccine. Swelling at the injection site may have a diameter of more than 5 cm and will spontaneously resolve in 4 days. The volume of the observed nodule may be up to 3 cm^3, can be observed from 5 days post vaccination and may last until 16 days after administration of a 10-fold overdose of the vaccine.

Special restrictions for use and special conditions for use:
Not applicable.

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):
injection site swelling [1]
Common (1 to 10 animals / 100 animals treated):
injection site pain[2] injection site warmth[2] injection site nodule[3]
Uncommon (1 to 10 animals / 1,000 animals treated):
lameness

[1]More than 5 cm in diameter observed on the day of vaccine administration and resolving spontaneously within 3 days.
[2]On the day of vaccine administration.
[3]Less than 0.8 cm^3 in volume observed from 10 days after vaccination and lasting between 1 to 5 days.

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: 2 ml.

Route: vaccinate cattle by the subcutaneous route in the neck.

Vaccination scheme:
Basic vaccination: two doses, each of 2 ml, should be administered 3 weeks apart to calves from 1 week of age. The second dose should preferably be administered on the alternate side of the neck.

9. Advice on correct administration

Reconstitute the lyophilisate with the solvent to obtain a suspension for injection.

After reconstitution, the suspension should be pinkish to orange-brown turbid in color.

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).

Keep the vial in the outer carton in order to 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 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers. To be completed nationally.

Type I hydrolytic glass vials containing 10 doses of lyophilisate or 20 ml of solvent.

Lyophilisate: bromobutyl rubber stoppers and aluminium caps.
Solvent: chlorobutyl rubber stoppers and aluminium caps.

Cardboard box containing 1 vial with 10 doses of lyophilisate and 1 vial with 20 ml solvent.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY} *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 representative <and contact details to report suspected adverse reactions>:>
To be completed nationally (if needed).

17. Other information

The vaccine induces an active immunity against *Mycoplasma bovis* in young calves.

Duration of immunity has not been established. The basic vaccination scheme induces a serological response. Within a laboratory study conducted, a single dose administration approximately 14 weeks after the basic vaccination scheme induced an anamnestic immune response in vaccinated animals.