ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labimycin LA 300 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Oxytetracycline	300 mg
(as Oxytetracycline dihydrate	323.18 mg)

Excipients:

ualitative composition of excipients nd other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium formaldehyde sulfoxylate	4 mg
Magnesium oxide, light	
Ethanolamine	
Dimethylacetamide	
Water for injections	

A clear dark amber solution free from visible particles.

3. CLINICAL INFORMATION

3.1. Target species

Cattle, sheep and pigs.

3.2. Indications for use, for each target species

This veterinary medicinal product is indicated for the control and treatment of a wide range of common systemic, respiratory, urinary and local infections.

Cattle: Treatment of respiratory infections caused by strains of *Histophilus somni*, *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis*.
Treatment of metritis caused by strains of *Arcanobacterium pyogenes*.
Treatment of navel/joint infections caused by strains of *Dichelobacter nodosus Fusobacterium necrophorum and Prevotella melaninogenicus*.

Sheep:
Treatment of respiratory infections caused by strains of *Mannheimia haemolytica* and *Pasteurella*.

Treatment of genital infections caused by strains of *Arcanobacterium pyogenes*, *Chlamydophila spp* and *Dermatophilus congolensis*.
Treatment of navel/joint infections caused by strains of *Dichelobacter nodosus Fusobacterium necrophorum and Prevotella melaninogenicus*.

Pigs:
For the treatment of respiratory infections caused by strains of *Bordetella bronchiseptica* and *Pasteurella*.
For the treatment of Erysipelas caused by strains of *Erysipelothrix rhusiopathiae*.
For the treatment of Atrophic rhinitis caused by strains of *Bordetella bronchiseptica* and *Pasteurella multocida*.

Other infections:
Treatment of mastitis caused by strains of *Staphylococcus aureus, Streptococcus agalactiae* and *Escherichia coli*.
Treatment of enzootic abortus caused by strains of *Chlamydia abortus* and *Chlamydia psittaci*.
Treatment of genital infections and Poliartritis caused by strains of *Chlamydia abortus* and *Mycoplasma spp*.

3.3. Contraindications

Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipient(s).

3.4. Special warnings

They have not been described.

3.5. Special precautions for use

Special precautions for safe use in the target species:
Do not dilute this veterinary medicinal product.
If administered simultaneously with other treatments, use a separate injection site.
Before any infectious process, bacteriological confirmation of the diagnosis and a sensitivity test of the bacteria causing the process is recommended.
"Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level."

"Use of the product should be in accordance with official, national and regional antimicrobial policies."

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

- The excipient dimethylacetamide may damage unborn children; therefore, women of child bearing age must be very careful to avoid exposure via spillage onto the skin or accidental self-injection when administering the product. If you

are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product.This product may cause sensitisation.
- People with known hypersensitivity to tetracyclines, such as oxytetracycline, should avoid contact with the product.
- This product may cause skin and eye irritation.
- Avoid contact of the skin and eyes with the product. In case of accidental spillage onto skin or eyes, rinse the affected area with large amounts of water.
- Take care to avoid accidental injection. In case of self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use

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

3.6. Adverse events

Target species: Cattle, sheep and pigs.

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site reactions [1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions, including anaphylaxis (sometimes fatal)

[1] Injection site reactions are transitory in nature

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 the last section of the package leaflet for respective contact details.

3.7. Use during pregnancy, lactation or lay

Pregnancy and lactation:
The use is not recommended during pregnancy. The use of tetracyclines during the period of tooth and bone development, including the last part of gestation, can lead (due to their potent calcium chelating capacity) to discoloration and inhibition of bone growth.

3.8. Interaction with other medicinal products and other forms of interaction

Do not administer together with bactericidal antibiotics. If administered simultaneously with other treatments, should be given at different sites.

3.9. Administration routes and dosage

Intramuscular use.

The rubber stopper of the vial may be safely punctured up to 50 times. The general recommended dosage for a prolonged duration of activity of 5 to 6 days is a single deep intramuscular injection of 30 mg oxytetracycline/ kg bodyweight (equivalent to 1ml of the veterinary medicinal product/10 kg of bodyweight).

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Maximum recommended dose at one site:

Cattle:	15 ml
Sheep:	5 ml
Pigs:	10 ml
Piglets	1 day: 0.2ml 7 days: 0.3 ml 14 days: 0.4 ml 21 days: 0.5 ml Over 21 days: 1ml/10 kg

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

Its most common effects are gastrointestinal disorders.
A double therapeutic dose in cattle can cause a severe local reaction.

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

Administration by a veterinarian surgeon or under their direct responsibility.

3.12. Withdrawal periods

Cattle:
Meat and offal: 35 days
Milk: 7 days

Sheep:
Meat and offal: 35 days
Milk: 9 days

Pigs:
Meat and offal: 28 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01AA06

4.2. Pharmacodynamic

This veterinary medicinal product contains oxytetracycline, a broad-spectrum, semi-synthetic antibiotic. The mechanism of action depends on its penetration into the cytoplasm of microorganisms through their cell wall, where it prevents the incorporation of amino acids into peptide chains, thus inhibiting protein synthesis at the ribosome level. Inhibition of protein synthesis significantly reduces the rate at which affected organisms develop and multiply.
Oxytetracycline inhibits protein synthesis in sensitive microorganisms.
A wide range of Gram positive and Gram negative bacteria are sensitive to oxytetracycline, including:
-Gram positive Bacteria: *Arcanobacterium pyogenes*, *Dermatophilus congolensis*, *Staphylococcus spp., Streptococcus spp.*
- Gram negative Bacteria: *Dichelobacter nodosus, E. coli, Fusobacterium necrophorum, parasuis, Histophilus somni, Mannehimia haemolytica, Pasteurella multocida, Prevotella melaninogenicus.*
-Other: *Chlamydia spp., Mycoplasma sppResults* of susceptibility tests published by the CLSI (2013).

The mechanisms of acquired resistance include: (i) energy-dependent efflux of antibiotic (membrane efflux proteins), or (ii) altered target whereby the ribosome is protected from binding of tetracyclines. A third mechanism whereby the drug is attacked by enzymes liberated by the bacteria is possible. The genes mediating resistance may be carried on plasmids or transposons. Resistance to one tetracycline will generally produce cross-resistance to the others in the group.

4.3. Pharmacokinetic

With this veterinary medicinal product, a prolonged action is achieved, resulting in sustained antibacterial activity. After a single intramuscular injection of this veterinary medicinal product at a dose of 20 mg / kg, maximum plasma oxytetracycline concentrations of 5.0 and 6.92 µg / ml, at 8.0 and 3.6 hours after administration in cattle and sheep, respectively. At this dose, levels above 0.5 µg / ml can be maintained for up to 3 days in cattle and up to 3 (2.75) days in sheep. When this veterinary medicinal product is administered at a dose of 30 mg / kg, the maximum concentrations of oxytetracycline that are reached in the plasma of cattle and sheep are 5.8 and 6 µg / ml respectively at 4.0 and 5.2 hours after administration.
At this dose, therapeutic levels above 0.5 µg / ml can be maintained for up to 4-5 days in cattle and 5-6 days in sheep.

5. PHARMACEUTICAL PARTICULARS

5.1. Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2. Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months

Shelf-life after first opening the immediate packaging: 28 days

5.3. Special precautions for storage

Store below 25ºC
Keep the vial in the outer carton in order to protect from light.

5.4. Nature and composition of immediate packaging

Amber glass vials type I closed with bromobutyl rubber stoppers Ph. Eur. type I and aluminium caps.
Pack sizes
Box containing 1 vial of 50 ml
Box containing 1 vial of 100 ml
Box containing 1 vial of 250 ml
Box containing 12 vials of 50ml
Box containing 10 vials of 100ml
Box containing 10 vials of 250ml
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

Labiana Life Sciences, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:DD/MM/YYYY

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.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Box with vial(s) of 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labimycin LA 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Oxytetracycline	300 mg
(as Oxytetracycline dihydrate	323.18 mg)

3. PACKAGE SIZE

1 x 50 ml
1 x 100 ml
1 x 250 ml
12 x 50 ml
10 x 100 ml
10 x 250 ml

4. TARGET SPECIES

Cattle, sheep and pigs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal: 35 days
Milk: 7 days

Sheep:
Meat and offal: 35 days
Milk: 9 days

Pigs:
Meat and offal: 28 days

8. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.
Use by: ….

9. SPECIAL STORAGE PRECAUTIONS

Store below 25ºC
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

Labiana Life Sciences, S.A.

14. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

15. BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

50 ml, 100 ml and 250 ml Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labimycin LA 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Oxytetracycline	300 mg
(as Oxytetracycline dihydrate	323.18 mg)

3. TARGET SPECIES

Cattle, sheep and pigs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
Meat and offal: 35 days
Milk: 7 days

Sheep:
Meat and offal: 35 days
Milk: 9 days

Pigs:
Meat and offal: 28 days

6. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.
Use by: ….

7. SPECIAL STORAGE PRECAUTIONS

Store below 25ºC
Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A.

9. BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Labimycin LA 300 mg/ml solution for injection

2. Composition

Each ml contains:
Active substance:

Oxytetracycline	300 mg
(as Oxytetracycline dihydrate	323.18 mg)

Excipients:

Sodium formaldehyde sulfoxylate	4 mg

A clear dark amber solution free from visible particles

3. Target species

Cattle, sheep and pigs.

4. Indications for use

This veterinary medicinal product is indicated for the control and treatment of a wide range of common systemic, respiratory, urinary and local infections.

Cattle: Treatment of respiratory infections caused by strains of *Histophilus somni*, *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis*.
Treatment of metritis caused by strains of *Arcanobacterium pyogenes*.
Treatment of navel/joint infections caused by strains of *Dichelobacter nodosus Fusobacterium necrophorum and Prevotella melaninogenicus*.

Sheep:
Treatment of respiratory infections caused by strains of *Mannheimia haemolytica* and *Pasteurella*.
Treatment of genital infections caused by strains of *Arcanobacterium pyogenes*, *Chlamydophila spp* and *Dermatophilus congolensis*.
Treatment of navel/joint infections caused by strains of *Dichelobacter nodosus Fusobacterium necrophorum and Prevotella melaninogenicus*.

Pigs:
For the treatment of respiratory infections caused by strains of *Bordetella bronchiseptica* and *Pasteurella*.
For the treatment of Erysipelas caused by strains of *Erysipelothrix rhusiopathiae*.
For the treatment of Atrophic rhinitis caused by strains of *Bordetella bronchiseptica* and *Pasteurella multocida*.

Other infections:
Treatment of mastitis caused by strains of *Staphylococcus aureus, Streptococcus agalactiae* and *Escherichia coli*.

Treatment of enzootic abortus caused by strains of *Chlamydia abortus* and *Chlamydia psittaci*.
Treatment of genital infections and Poliartritis caused by strains of *Chlamydia abortus* and *Mycoplasma spp*.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipient(s)

6. Special warnings

Special precautions for safe use in the target species:
Do not dilute this veterinary medicinal product.
If administered simultaneously with other treatments, use a separate injection site.
Before any infectious process, bacteriological confirmation of the diagnosis and a sensitivity test of the bacteria causing the process is recommended.
"Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level."

"Use of the product should be in accordance with official, national and regional antimicrobial policies."

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

- The excipient dimethylacetamide may damage unborn children; therefore, women of childbearing age must be very careful to avoid exposure via spillage onto the skin or accidental self-injection when administering the product. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product.
- This product may cause sensitisation.
- People with known hypersensitivity to tetracyclines, such as oxytetracycline, should avoid contact with the product.
- This product may cause skin and eye irritation.
- Avoid contact of the skin and eyes with the product. In case of accidental spillage onto skin or eyes, rinse the affected area with large amounts of water.
- Take care to avoid accidental injection. In case of self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use

Pregnancy and lactation:
The use is not recommended during pregnancy. The use of tetracyclines during the period of tooth and bone development, including the last part of gestation, can lead (due to their potent calcium chelating capacity) to discoloration and inhibition of bone growth."

Interaction with other medicinal products and other forms of interaction:

Do not administer together with bactericidal antibiotics. If administered simultaneously with other treatments, should be given at different sites.

Overdose:
Its most common effects are gastrointestinal disorders.
A double therapeutic dose in cattle can cause a severe local reaction.

Special restrictions for use and special conditions for use:
Administration by a veterinarian surgeon or under their direct responsibility

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Target species: Cattle, sheep and pigs.

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site reactions [1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions, including anaphylaxis (sometimes fatal)

*Injection site reactions are transitory in nature

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

Intramuscular use.
The general recommended dosage for a prolonged duration of activity of 5 to 6 days is a single deep intramuscular injection of 30 mg oxytetracycline/ kg bodyweight,(equivalent to 1 ml of the veterinary medicinal product/10 kg of bodyweight)

Maximum recommended dose at one site:

Cattle:	15 ml
Sheep:	5 ml
Pigs:	10 ml
Piglets	1 day: 0.2ml
	7 days: 0.3 ml
	14 days: 0.4 ml
	21 days: 0.5 ml
	Over 21 days: 1ml/10 kg

9. Advise on correct administration

The rubber stopper of the vial may be safely punctured up to 50 times.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

10. Withdrawal periods

Cattle:
Meat and offal: 35 days
Milk: 7 days

Sheep:
Meat and offal: 35 days
Milk: 9 days

Pigs:
Meat and offal: 28 days

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25ºC
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 carton and vial after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of in 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

Package sizes:
Box containing 1 vial of 50 ml
Box containing 1 vial of 100 ml
Box containing 1 vial of 250 ml

Box containing 12 vials of 50 ml
Box containing 10 vials of 100 ml
Box containing 10 vials of 250 ml

Not all pack sizes may be marketed.

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.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Labiana Life Sciences S.A. - Venus 26 - 08228 Terrassa (Barcelona) - Spain.

Local representatives:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.