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	323.5 mg)

Excipients:

Qualitative composition of excipients and 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

Treatment of systemic, respiratory, urinary and local infections. Specific indications include pasteurellosis, pneumonia, atrophic rhinitis, erysipelas, arthritis, omphalitis and supportive therapy of intramammary infections.

3.3. Contraindications

Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipients.
Do not use in cases of suspected renal or hepatic damage.

3.4. Special warnings

Cross resistance has been shown between oxytetracycline and other tetracyclines. Use of the product should be carefully considered when susceptibility testing has shown resistance to tetracyclines because its effectiveness may be reduced.

3.5. Special precautions for use

Special precautions for safe use in the target species:
If administered simultaneously with other treatments, use a separate injection site.
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.
Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

The feeding of waste milk containing residues of oxytetracycline to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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

The veterinary medicinal product should not be used in neonates or dehydrated animals.

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

- This veterinary medicinal product contains dimethylacetamide, which has been shown to have the potential to affect the development of unborn children. Pregnant women and women of child-bearing age should not administer the veterinary medicinal product.
- This veterinary medicinal product may cause sensitisation.
- People with known hypersensitivity to tetracyclines, such as oxytetracycline, should avoid contact with the veterinary medicinal product.
- This veterinary medicinal product may cause skin and eye irritation.
- Avoid contact of the skin and eyes with the veterinary medicinal 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

Cattle, sheep and pigs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction, including anaphylaxis.[1]
Undetermined frequency (cannot be estimated from the available data):	Injection site reaction[2].

[1] Sometimes fatal.
[2] Mild and transitory.

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

If administered simultaneously with other treatments, the injections should be given at different sites.
Oxytetracycline should not be administered simultaneously with bactericidal antimicrobials, such as penicillins and cephalosporins.
Divalent or trivalent cations (Mg, Fe, Al, Ca) can chelate tetracyclines.

3.9. Administration routes and dosage

Intramuscular use.

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

Piglets (based on age): 1 day: 0.2 ml
7 days: 0.3 ml
14 days: 0.4 ml
21 days: 0.5 ml'

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

The maximum injection volume per injection site is 15 ml (for cattle), 10 ml (for pigs) and 5 ml (for sheep).

The rubber stopper of the vial may be safely punctured up to 50 times.

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

The most common clinical signs are gastro-intestinal disorders.
In the case of administration of twice the therapeutic dose in cattle a severe local reaction can occur.

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

Cattle:
Meat and offal: 35 days
Milk: 168 hours

Sheep:
Meat and offal: 35 days
Milk: 216 hours

Pigs:
Meat and offal: 28 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01AA06

4.2. Pharmacodynamics

Oxytetracycline is a broad spectrum antibiotic effective against both Gram positive and Gram negative bacteria with a bacteriostatic effect. Oxytetracycline binds to 70S and 80S ribosomes blocking the attachment of aminoacyl-transfer RNA to the ribosomal messenger RNA thereby blocking the ability of bacteria to produce proteins. This prevents the bacteria from growing and multiplying.
A wide range of Gram positive and Gram negative bacteria are susceptible to oxytetracycline, including *Bordetella bronchiseptica*, *Trueperella pyogenes*,

Erysipelothrix rhusiopathiae, *Pasteurella* spp, *Staphylococcus* spp and *Streptococcus* spp.
Other: *Mycoplasma* spp. *r*icketias, protozoa and *Chlamydia* spp.

4.3. Pharmacokinetics

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 3.3, 5.0 and 6.92 µg/ml, at 3.9; 8.0 and 3.6 hours after administration in pigs, cattle and sheep, respectively. At this dose, levels above 0.5 µg/ml can be maintained for up to 4 days in pigs, 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 4,2, 5.8 and 6 µg/ml respectively at 4,3; 4.0 and 5.2 hours after administration.
At this dose, therapeutic levels above 0.5 µg/ml can be maintained for up to 5-6 days in pigs, up to 4-5 days in cattle and 5-6 days in sheep.

Environmental properties:
Oxytetracycline is persistent in soil.

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, 250 ml and box containing 12 or 10 vials

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	323.5 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: 168 hours

Sheep:
Meat and offal: 35 days
Milk: 216 hours

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	323.5 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: 168 hours

Sheep:
Meat and offal: 35 days
Milk: 216 hours

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	323.5 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

Treatment of systemic, respiratory, urinary and local infections. Specific indications include pasteurellosis, pneumonia, atrophic rhinitis, erysipelas, arthritis, omphalitis and supportive therapy of intramammary infections.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, to other tetracyclines or to any of the excipients.
Do not use in cases of suspected renal or hepatic damage.

6. Special warnings

Special warnings:
Cross resistance has been shown between oxytetracycline and other tetracyclines. Use of the product should be carefully considered when susceptibility testing has shown resistance to tetracyclines because its effectiveness may be reduced.

Special precautions for safe use in the target species:
If administered simultaneously with other treatments, use a separate injection site.
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.
Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

The feeding of waste milk containing residues of oxytetracycline to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
The veterinary medicinal product should not be used in neonates or dehydrated animals.

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 veterinary medicinal product.
- This veterinary medicinal product may cause sensitisation.
- People with known hypersensitivity to tetracyclines, such as oxytetracycline, should avoid contact with the veterinary medicinal product.
- This veterinary medicinal product may cause skin and eye irritation.
- Avoid contact of the skin and eyes with the veterinary medicinal 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:
If administered simultaneously with other treatments, should be given at different sites.
Oxytetracycline should not be administered simultaneously with bactericidal antimicrobials, such as penicillins and cephalosporins.
Divalent or trivalent cations (Mg, Fe, Al, Ca) can chelate tetracyclines.

Overdose:
The most common clinical signs are are gastro-intestinal disorders.
In the case of administration of twice the therapeutic dose in cattle a severe local reaction can occur.

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.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions, Including anaphylaxis[1]
Undetermined frequency (cannot be estimated from the available data):	Injection site reaction. [2]

[1] Sometimes fatal.
[2] Mild and transitory.

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 recommended dosage for this veterinary medicinal product is 30 mg oxytetracycline/ kg bodyweight (equivalent to 1ml of the veterinary medicinal product/10 kg of bodyweight) for a single deep intramuscular injection for a duration of action of 5 to 6 days.
Piglets (based on age): 1 day: 0.2 ml
7 days: 0.3 ml
14 days: 0.4 ml
21 days: 0.5 ml
To ensure a correct dosage body weight should be determined as accurately as possible.
The maximum injection volume per injection site is 15 ml (for cattle), 10 ml (for pigs) and 5 ml (for sheep).

The rubber stopper of the vial may be safely punctured up to 50 times.

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: 168 hours

Sheep:
Meat and offal: 35 days
Milk: 216 hours

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.

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

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.

17. Other information:

Oxytetracycline is persistent in soil.