ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumospectin 50 mg/ml +100 mg/ml solution for injection for cattle (calves), sheep, goat, pig, chicken, turkey, cats and dogs

FR: PNEUMOSPECTIN 50/100 MG/ML SOLUTION INJECTABLE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substances:
Lincomycin.....50 mg
(equivalent to 54.47 mg of lincomycin hydrochloride (dried substance))
Spectinomycin.....100 mg
(equivalent to 129.45 mg of spectinomycin sulphate (dried substance))

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	9 mg
Sodium hydroxide	
Hydrochloric acid	
Water for injections	

Clear and colourless solution or slightly yellowish

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves), sheep, goat, pig, chicken, turkey, cats and dogs.

3.2 Indications for use for each target species

Calves:
- Treatment of respiratory infections, arthritis and omphalitis.

Ovine and caprine:
- Treatment of respiratory infections and mycoplasmosis.

Porcine:
- Treatment of enteric adenomatosis (ileitis) caused by *Lawsonia intracellularis*,
- Treatment of hemorrhagic enteritis and colibacillosis,
- Treatment of mycoplasmosis,
- Treatment of infectious arthritis.

Chickens and turkeys:
- Treatment of mycoplasmosis associated or not to *Escherichia coli,*
- Treatment of aerosacculitis caused by *Escherichia coli,*
- Treatment of avian cholera caused by *Pasteurella multocida.*

Cats and dogs:
- Treatment of respiratory, intestinal, urinary, skin infections (including wounds and abscess) and arthritis caused by organisms including *Staphylococcus spp., Streptococcus spp., Bacteroides spp., Clostridium spp., Fusobacterium spp., Actinomyces spp, Mycoplasma spp.*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in rabbits, hamsters, guinea pigs, chinchillas or horses as this could result in severe gastro-intestinal disturbance.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogens. 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.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
This antimicrobial combination should only be used where diagnostic testing has indicated the need for simultaneous administration of each of the active substances.
Use of the veterinary medicinal product deviating from the instructions in the SPC may increase the risk of development and selection of resistant bacteria and decrease the effectiveness of treatment with macrolides due to the potential for cross-resistance.
Administer with care in animals with background of allergic signs.

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

Lincomycin and spectinomycin can cause hypersensitivity (allergy) after injection, inhalation, ingestion or spillage onto skin. Allergic reactions to these substances can be severe. People with known hypersensitivity to lincomycin and spectinomycin should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Avoid contact with skin and eyes. Wash any splashes off immediately with plenty of water. Wash hands after use.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (calves), sheep, goat, pig, chicken, turkey, cats and dogs:

Undetermined frequency (cannot be estimated from the available data):	Loose stools[1] Injection site reactions NOS

[1] It is normally transient and recovers within few days without treatment.

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

The safety of the product has not been assessed during pregnancy, lactation and in breeders. Use only after according to the risk-benefit assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer with macrolides.
Combination with anaesthetics may lead to possible neuromuscular blocking.

3.9 Administration routes and dosage

To be administered by intramuscular or subcutaneous injection.
To ensure a correct dosage, body weight should be determined as accurately as possible.

Calves:
5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal /10 kg bw) intramuscularly, twice daily for the first day followed by once daily for 3-5 days.

Ovine and caprine:
5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal /10 kg bw) intramuscularly, once daily for 3-5 days.

Porcine:
5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal /10 kg bw) intramuscularly, to be repeated, if necessary, 24 hours later and for 5 days maximum.

Chickens and turkeys:
10 mg of lincomycin and 20 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal /5 kg bw) by subcutaneous route, once daily for 3 days.

Dogs and cats:
10 mg of lincomycin and 20 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal /5 kg bw) intramuscularly. The treatment may be repeated at 12 to 24 hours intervals for 3 to 7 days according to clinical response.

Do not puncture the stopper more than 30 times. Otherwise, automatic syringe equipment, or a suitable draw-off needle, should be used to avoid excessive puncturing of the closure.

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

None known.

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

3.12 Withdrawal periods

Cattle (calves): meat and offal: 14 days.

Sheep and goat: meat and offal: 14 days.

Milk: not authorized for use in animals producing milk for human consumption and during lactation or dry period nor in future producers of milk for human consumption within 2 months before calving.

Porcine: meat and offal: 14 days

Chickens and turkeys: meat and offal: 14 days
Not for use in birds producing or intended to produce eggs for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01FF52

4.2 Pharmacodynamic

The combination lincomycin-spectinomycin is active against a wide range of Gram-positive and Gram-negative bacteria and mycoplasma. Lincomycin is especially active against Gram-positive bacteria (such as streptococcus and staphylococcus) and mycoplasma. Spectinomycin is more specifically active against Gram-negative (colibacillus, pasteurella, salmonella), mycoplasma and Gram-positive bacteria.
Resistance to lincomycin is frequently conferred by plasmid-borne factors (*erm* genes) coding for methylases modifying the ribosomal binding site and frequently leading to cross-resistance to other antimicrobials of the MLSb group. However, the most prevalent mechanism in mycoplasmas is the alteration of the binding site through mutational events (chromosomal resistance). Lincomycin resistance mediated by efflux pumps, or by inactivating enzymes, has also been described. There is often complete cross-resistance between lincomycin and clindamycin.

Chromosomal one-step mutation to high-level spectinomycin resistance develops in many enteric bacteria (such as E. coli). Plasmid-mediated resistance is less common. Strains with chromosomal resistance do not show cross-resistance with aminoglycosides.

4.3 Pharmacokinetic

Lincomycin is well distributed throughout the body and significantly metabolised.
Spectinomycin is also well distributed throughout the body and appears to be mainly excreted as the parent compound

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:2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

100 ml and 250 ml translucent polypropylene vials, with bromobutyl stopper and aluminium cap with FLIP-OFF seal.

Pack sizes:
- Cardboard box with 1 vial of 100 ml
- Cardboard box with 1 vial of 250 ml
- Cardboard box with 10 vials of 100 ml
- Cardboard box with 6 vials of 250 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

GLOBAL VET HEALTH S.L.

7. MARKETING AUTHORISATION NUMBER(S)

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 (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box for 100 ml and 250 ml vials.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumospectin 50 mg/ml +100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Lincomycin 50 mg (equivalent to 54.47 mg of lincomycin hydrochloride)
Spectinomycin 100 mg (equivalent to 129.45 mg of spectinomycin sulphate)

3. PACKAGE SIZE

100 ml
250 ml
10 x 100 ml
16 x 250 ml

4. TARGET SPECIES

Cattle (calves), sheep, goat, pig, chicken, turkey, cats and dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Solution for injection
To be administered by intramuscular or subcutaneous injection.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle (calves): meat and offal: 14 days.

Sheep and goat: meat and offal: 14 days.
Milk: not authorized for use in animals producing milk for human consumption and during lactation or dry period nor in future producers of milk for human consumption within 2 months before calving.

Porcine: meat and offal: 14 days

Chickens and turkeys: meat and offal: 14 days
Not for use in birds producing or intended to produce eggs for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.
Use by…

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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

GLOBAL VET HEALTH S.L.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for 100 ml and 250 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumospectin 50 mg/ml +100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Lincomycin 50 mg (equivalent to 54.47 mg of lincomycin hydrochloride)
Spectinomycin 100 mg (equivalent to 129.45 mg of spectinomycin sulphate)

3. TARGET SPECIES

Cattle (calves), sheep, goat, pig, chicken, turkey, cats and dogs.

4. ROUTES OF ADMINISTRATION

Solution for injection
To be administered by intramuscular or subcutaneous injection.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle (calves): meat and offal: 14 days.

Sheep and goat: meat and offal: 14 days.
Milk: not authorized for use in animals producing milk for human consumption and during lactation or dry period nor in future producers of milk for human consumption within 2 months before calving.

Porcine: meat and offal: 14 days

Chickens and turkeys: meat and offal: 14 days
Not for use in birds producing or intended to produce eggs for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Use by…

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

GLOBAL VET HEALTH S.L.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Pneumospectin 50 mg/ml +100 mg/ml solution for injection for cattle (calves), sheep, goat, pig, chicken, turkey, cats and dogs
FR: PNEUMOSPECTIN 50/100 MG/ML SOLUTION INJECTABLE

2. Composition

Each ml contains:

Active substances:
Lincomycin 50 mg
(equivalent to 54.47 mg of lincomycin hydrochloride (dried substance))
Spectinomycin 100 mg
(equivalent to 129.45 mg of spectinomycin sulphate (dried substance))

Excipients:

Benzyl alcohol (E1519) ..... 9 mg

Clear and colourless solution or slightly yellowish

3. Target species

Cattle (calves), sheep, goat, pig, chicken, turkey, cats and dogs.

4. Indications for use

Calves: Treatment of respiratory infections, arthritis and omphalitis.
Ovine and caprine: Treatment of respiratory infections and mycoplasmosis.
Porcine: Treatment of enteric adenomatosis (ileitis) caused by *Lawsonia intracellularis*. Treatment of hemorrhagic enteritis and colibacillosis. Treatment of mycoplasmosis. Treatment of infectious arthritis.
Chickens and turkeys: Treatment of mycoplasmosis associated or not to *Escherichia coli.* Treatment of aerosacculitis caused by *Escherichia coli.* Treatment of avian cholera caused by *Pasteurella multocida.*
Cats and dogs: Treatment of respiratory, intestinal, urinary, skin infections (including wounds and abscess) and arthritis caused by organisms including *Staphylococcus spp., Streptococcus spp., Bacteroides spp., Clostridium spp., Fusobacterium spp., Actinomyces spp, Mycoplasma spp.*

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in rabbits, hamsters, guinea pigs, chinchillas or horses as this could result in severe gastro-intestinal disturbance.

6. Special warnings

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogens. 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.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
This antimicrobial combination should only be used where diagnostic testing has indicated the need for simultaneous administration of each of the active substances.
Use of the veterinary medicinal product deviating from the instructions in the SPC may increase the risk of development and selection of resistant bacteria and decrease the effectiveness of treatment with macrolides due to the potential for cross-resistance. Administer with care in animals with background of allergic signs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Lincomycin and spectinomycin can cause hypersensitivity (allergy) after injection, inhalation, ingestion or spillage onto skin. Allergic reactions to these substances can be severe. People with known hypersensitivity to lincomycin and spectinomycin should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Avoid contact with skin and eyes. Wash any splashes off immediately with plenty of water. Wash hands after use.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Pregnancy and lactation:
The safety of the product has not been assessed during pregnancy, lactation and in breeders. Use only after according to the risk-benefit assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Do not administer with macrolides.
Combination with anaesthetics may lead to possible neuromuscular blocking.

Overdose:
None known.

Special restrictions for use and special conditions for use:

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

7. Adverse events

Cattle (calves), sheep, goat, pig, chicken, turkey, cats and dogs:

Undetermined frequency (cannot be estimated from the available data):
Loose stools. It is normally transient and recovers within few days without treatment. Injection site reactions NOS

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

To be administered by intramuscular or subcutaneous injection.

Calves:
5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of product/10 kg bw) intramuscularly, twice daily for the first day followed by once daily for 3-5 days.

Ovine and caprine:
5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of product/10 kg bw) intramuscularly, once daily for 3-5 days.

Porcine:
5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of product/10 kg bw) intramuscularly, to be repeated, if necessary, 24 hours later and for 5 days maximum.

Chickens and turkeys:
10 mg of lincomycin and 20 mg spectinomycin per kg bw (corresponding to 1 ml of product/5 kg bw) by subcutaneous route, once daily for 3 days.

Dogs and cats:
10 mg of lincomycin and 20 mg spectinomycin per kg bw (corresponding to 1 ml of product/5 kg bw) intramuscularly. The treatment may be repeated at 12 to 24 hours intervals for 3 to 7 days according to clinical response.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
Do not puncture the stopper more than 30 times. Otherwise, automatic syringe equipment, or a suitable draw-off needle, should be used to avoid excessive puncturing of the closure.

10. Withdrawal periods

Cattle (calves):meat and offal: 14 days.

Sheep and goat: meat and offal: 14 days.
Milk: not authorized for use in animals producing milk for human consumption and during lactation or dry period nor in future producers of milk for human consumption within 2 months before calving.

Porcine: meat and offal: 14 days

Chickens and turkeys: meat and offal: 14 days
Not for use in birds producing or intended to produce eggs for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf-life after fist opening the immediate packaging: 28 days

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

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
- Cardboard box with 1 vial of 100 ml
- Cardboard box with 1 vial of 250 ml
- Cardboard box with 10 vials of 100 ml
- Cardboard box with 6 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 (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
GLOBAL VET HEALTH S.L.
c/ Capçanes nº 12 bajos.

Polígono Agro-Reus
43206 – REUS
TARRAGONA, SPAIN

Manufacturer responsible for batch release:
S.P. VETERINARIA, S.A.
Ctra. Reus a Vinyols, Km 4,1
43330 – RIUDOMS
TARRAGONA, SPAIN

Local representatives and contact details to report suspected adverse reactions:

France
{Nom}
<{Adresse}
FR-00000 {Localité}>
Tél: + {Numéro de téléphone}
<{E-mail}>

Italia
{Nome}
<{Indirizzo}
IT-00000 {Località}>
Tel: + {Numero di telefono}>
<{E-mail}>

Polska
{Nazwa/ Nazwisko:}
<{Adres:}
PL – 00 000{Miasto:}>
Tel.: + {Numer telefonu:}
<{E-mail}>

Portugal
{Nome}
<{Morada}
PT-0000–000 {Cidade}>
Tel: + {Número de telefone}
<{E-mail}>

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

17. Other information