ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
{NATURE/TYPE} Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenoflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Enrofloxacin	50 mg
n-butanol	30 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100ml, 250ml

5. TARGET SPECIES

Cattle (calves), Pigs, Dogs and Cats

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous, subcutaneous or intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Calves:

Intravenous: Meat and offal: 5 days.

subcutaneous: Meat and offal: 12 days.

Not authorised for use in animals producing milk for human consumption.

Pigs:

Meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP

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

Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^0C. After first opening the immediate packaging: do not store above 25^0C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

BN:

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
{NATURE/TYPE} Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenoflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Enrofloxacin	50mg
n-butanol	30 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100ml, 250ml

5. TARGET SPECIES

Cattle (calves), Pigs, Dogs and Cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous, subcutaneous or intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Calves:

IV: Meat and offal: 5 days.

SC: Meat and offal: 12 days.

Not authorised for use in animals producing milk for human consumption.

Pigs:

Meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP

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

Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^0C.

After first opening the immediate packaging: do not store above 25^0C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Fenoflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats

Enrofloxacin

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

Manufacturer for the batch release:

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

and

Labiana Life Sciences, c/ Venus, 26. Can Parellada Industrial, 08228 Terrassa . Barcelona, Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenoflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats

Enrofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:

Enrofloxacin 50mg

Excipient:

n-butanol 30mg

A clear light yellow solution, free from particulate matter.

4. INDICATION(S)

Calves:

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*.

Pigs:

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae*.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli.*

Dogs:

Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by enrofloxacin susceptible strains of *Staphylococcus* spp*., Escherichia coli, Pasteurella* spp*., Klebsiella* spp*., Bordetella* spp*., Pseudomonas* spp*.* and *Proteus* spp*.*

Cats

Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by enrofloxacin susceptible strains of, e.g.: *Staphylococcus* spp*., Escherichia coli, Pasteurella* spp*., Klebsiella* spp*., Bordetella* spp*., Pseudomonas* spp*.* and *Proteus* spp*.*

5. CONTRAINDICATIONS

Do not use when resistance / cross resistance to (Fluoro)quinolones is known to occur. Do not use in the case of known hypersensitivity to fluoroquinolones or to any of the excipients.

Dogs under 1 year of age should not be treated with Enrofloxacin as damage to the articular cartilage may occur during the period of rapid growth, specifically in large breeds of dog. As a precaution very large breeds of dog should not be treated with Enrofloxacin until they are 18 months of age because of their longer growth period.

Enrofloxacin should be used with caution in epileptic animals or animals affected by renal dysfunction

Do not use in cats less than 8 weeks of age.

Do not use for prophylaxis.

Do not use in growing horses because of possible deleterious damage on articular cartilage.

6. ADVERSE REACTIONS

During the period of rapid growth, enrofloxacin may affect articular cartilage.

Local tissue reactions may occasionally occur at the injection site. Normal sterile precautions should be taken.

In cattle and dogs, gastrointestinal disturbances may occasionally occur.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (calves), Pigs, Dogs, Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intravenous, subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.

Calves:

5 mg of enrofloxacin/kg body weight (bw), corresponding to 1 ml/10 kg bw, once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis:* 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.
The product can be administered by slow intravenous or subcutaneous administration.
Not more than 10 ml should be administered at one subcutaneous injection site.
Pigs
2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/10 kg bw, once daily by intramuscular injection for 3 days.
Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.
In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.
Dogs and Cats:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the SPC of the tablet product.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Calves:
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.
Pigs:
Meat and offal: 13 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25^0C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after “EXP”. The expiry date refers to the last day of that month.
Shelf-life after first broaching the vial: 28 days
After first opening the immediate packaging: do not store above 25^0C.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special Precautions for use in animals

Do not exceed the recommended dosage.

Repeat injections should be made at different sites.

Retinotoxic effects including blindness can occur in cats when the recommended dose is exceeded.

Occasionally skin reactions have been seen after administration to kennelled greyhounds.

Enrofloxacin should be used with caution in epileptic animals or animals affected by renal dysfunction.

In cattle and dogs, gastrointestinal disturbances may occasionally occur.

Official and local antimicrobial policies should be taken into account when the product is used.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Whenever possible, fluoroquinolones should only be used based on susceptibility testing.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

Use during pregnancy and lactation.

There is no restriction on the use of this product during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Combination of enrofloxacin with cloramphenicol, macrolide antibiotics or tetracyclines may produce antagonistic effects.

Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline.

Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

Incompatibilities.

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

Overdose:

In dogs and cats, lack of appetite and nausea may occur following overdose.

Overdose may result in CNS and renal dysfunction. In dogs, 10-fold over dosage results in neurological symptoms such as ataxia, tremor, nystagmus or convulsions. These symptoms are reversible on cessation of treatment.

No signs of over dosage were observed in pigs following administration of the product at five times the recommended therapeutic dose.

In target animal studies, cats have been shown to suffer ocular damage after receiving doses of more than 15mg/kg once daily for 21 consecutive days. Doses of 30mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50mg/kg given once daily for 21 consecutive days, blindness can occur.
In accidental overdose, there is no antidote and treatment should be symptomatic.

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

The product is an alkaline solution. Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Wear gloves. Wash any splashes from skin and eyes immediately with water.
Do not eat, drink or smoke whilst using the product.
Care should be taken to avoid accidental self-injection. In case of accidental injection, seek medical advice immediately and show the package leaflet or the label to the physician.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes: 100ml and 250ml.

No of containers in a carton:
1 x 100 ml, 5 x 100 ml, 10 x 100 ml, 12 x 100 ml, 15 x 100 ml, 20 x 100 ml
1 x 250 ml, 5 x 250 ml, 10 x 250 ml, 12 x 250 ml, 15 x 250 ml, 20 x 250 ml.

Not all pack sizes may be marketed.