ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box with one (1) bottle of 100 or 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFFECT 25 mg/ml suspension for injection for cattle and pigs
Cefquinome

2. STATEMENT OF ACTIVE SUBSTANCES

Cefquinome (as sulfate) 25 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

For intramuscular use.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle:	meat and offal:	5 days;	milk: 24 hours
Pigs:	meat and offal:	3 days	

9. SPECIAL WARNINGS, IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions.
Read the package leaflet before use.

10. EXPIRY DATE

EXP *{month/year}*
Shelf-life after first opening of the immediate packaging: 28 days
Once broached, use by: ... ...

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

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

Dispose of waste material in accordance with local requirements.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

EMDOKA bvba
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 34534/4002

17. MANUFACTURER'S BATCH NUMBER

<Batch> *{number}*

[Blue-box information
Optional:

- *logo(s), name(s), address(es) and contact information of the Distributor(s) of the VMP in a Member State*
- *barcode, national code*
- *pictogram of target species]*

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box with 6 bottles of 100 or 250 ml and 12 bottles of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFFECT 25 mg/ml suspension for injection for cattle and pigs
Cefquinome

2. STATEMENT OF ACTIVE SUBSTANCES

Cefquinome (as sulfate) 25 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

6 x 100 ml
12 x 100 ml
6 x 250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

For intramuscular use.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle:	meat and offal:	5 days;	milk: 24 hours
Pigs:	meat and offal:	3 days	

9. SPECIAL WARNINGS, IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions.
Read the package leaflet before use.

10. EXPIRY DATE

EXP *{month/year}*
Shelf-life after first opening of the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

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

Dispose of waste material in accordance with local requirements.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

EMDOKA bvba
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 34534/4002

17. MANUFACTURER'S BATCH NUMBER

<Batch> *{number}*

[Blue-box information
Optional:

- *logo(s), name(s), address(es) and contact information of the Distributor(s) of the VMP in a Member State*
- *barcode, national code*
- *pictogram of target species]*

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Bottle of 100 or 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFFECT 25 mg/ml suspension for injection for cattle and pigs
Cefquinome

2. STATEMENT OF ACTIVE SUBSTANCES

Cefquinome (as sulfate) 25 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

For intramuscular use.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle:	meat and offal:	5 days;	milk: 24 hours
Pigs:	meat and offal:	3 days	

9. SPECIAL WARNINGS, IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions
Read the package leaflet before use.

10. EXPIRY DATE

EXP *{month/year}*
Shelf-life after first opening of the immediate packaging: 28 days
Once broached, use by: ... ...

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

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

[Not to be mentioned on the immediate package]

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

EMDOKA bvba
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 34534/4002

17. MANUFACTURER'S BATCH NUMBER

<Batch> *{number}*

[Blue-box information
Optional:

- *logo(s), name(s), address(es) and contact information of the Distributor(s) of the VMP in a Member State*
- *barcode, national code, ...]*

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Ceffect 25 mg/ml
suspension for injection for cattle and pigs

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

Marketing authorisation holder: Emdoka bvba, B-2321 Hoogstraten, Belgium.
Manufacturer responsible for batch release: Wirtschaftsgenossenschaft deutscher Tierärzte eG (WDT), 30827 Garbsen, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT:

CEFFECT 25 mg/ml suspension for injection for cattle and pigs
Cefquinome

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS:

Ceffect is a white to slightly yellowish suspension for injection containing 25 mg of cefquinome (as sulfate) per ml.

4. INDICATIONS:

For the treatment of bacterial infections in cattle and pigs caused by the Gram positive and Gram negative microorganisms sensitive to cefquinome.

Cattle:
Respiratory disease caused by *Pasteurella multocida* and *Mannheimia haemolytica.*
Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot).
Acute *E.coli* mastitis with signs of systemic involvement.

Calves:
E.coli septicaemia in calves.

Pigs:
For the treatment of bacterial infections of the lungs and respiratory tract caused by *Pasteurella multocida, Haemophilus parasuis, Actinobacillus pleuropneumoniae, Streptococcus suis* and other cefquinome-sensitive organisms.
Mastitis-Metritis-Agalactia syndrome (MMA) with involvement of *E.coli, Staphylococcus* spp.*, Streptococcus* spp. and other cefquinome sensitive organisms.

Piglets:
Reduction of mortality in cases of meningitis caused by *Streptococcus suis*.
For the treatment of:
Arthritis caused by *Streptococcus* spp.*, E. coli* and other cefquinome-sensitive organisms.
Epidermitis (mild or moderate lesions) caused by *Staphylococcus hyicus.*

5. CONTRAINDICATIONS:

Do not use in case of hypersensitivity to ß-lactam antibiotics, or to any of the excipients.

Do not administer to animals less than 1.25 kg body weight.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

6. ADVERSE REACTIONS:

Use of the veterinary medicinal product may result in localised tissue reaction. Tissue lesions are repaired 15 days after the last administration of the veterinary medicinal product.
Hypersensitivity reactions to cephalosporins occur rarely.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1.000 animals treated)
- rare (more than 1 but less than 10 animals in 10.000 animals treated)
- very rare (less than 1 animal in 10.000 animals treated, including isolated reports)

If you notice any side effects, even those not already listedin this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES:

Cattle and pigs

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION:

Species	Indication	Dosage	Frequency
Cattle	Respiratory disease caused by *Pasteurella multocida* and *M. haemolytica* Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 3 or 5 consecutive days
	Acute *E. coli* mastitis with signs of systemic involvement	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 2 consecutive days
Calves	*E. coli* septicaemia	2 mg cefquinome/kg bw (4 ml/50 kg bw)	Once daily for 3 or 5 consecutive days
Pigs	Respiratory disease	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 3 consecutive days
	MMA	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 2 consecutive days
Piglets	Meningitis Arthritis Epidermitis	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 5 consecutive days

All treatments to be given by intramuscular injection.

Studies have indicated the advisability of giving second and subsequent injections at a different injection site. The preferred injection site is in muscular tissue in the mid neck.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

Before use shake the bottle for a minute or until the product appears adequately resuspended.

9. ADVICE ON CORRECT ADMINISTRATION:
The veterinary medicinal product does not contain an antimicrobial preservative. Swab the septum before removing each dose.
Use a dry sterile needle and syringe.
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes, for example when treating piglets. When treating groups of animals, use a draw-off needle.
The rubber stopper of the 100 ml vial may be safely punctured up to 25 times and the rubber stopper of the 250 ml vial may be safely punctured up to 50 times. The user should choose the most appropriate vial size according to the target species and body weight category of animals to be treated.

10. WITHDRAWAL PERIODS:

Cattle:	meat and offal:	5 days
	milk:	24 hours
Pigs:	meat and offal:	3 days

11. SPECIAL STORAGE PRECAUTIONS:
Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
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 first opening the immediate packaging: 28 days. When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNINGS:
Special warnings for each target species:
None.

Special precautions for use in animals:
In case of occurrence of allergic reaction, the treatment should be withdrawn.
The use of cefquinome should be restricted to appropriate use according to the labelled indications in the target animal species.
Inappropriate use of the product may increase the prevalence of bacteria resistant to cefquinome and may decrease the effectiveness of treatment with other beta lactam antibiotics, due to the potential for cross resistance.

Use of the product may constitute a risk to public health due to spread of antimicrobial resistance.
The product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis) to first line treatment.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Increased use, including use of the product deviating from the instructions given in the SPC and this leaflet, may increase the prevalence of such resistance. Whenever possible, the product should only be used based on susceptibility testing.

The product is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programs. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

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

Cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. 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.
4. Care should be taken to avoid accidental injection and contact with the skin. Wash hands after use.

Pregnancy and lactation:

Laboratory studies in rat and rabbit have not produced any evidence of teratogenic, embryotoxic or maternotoxic effects. The safety of the product has not been assessed in cow and sow during pregnancy. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Due to an undesirable pharmacodynamic interaction, do not use cefquinome simultaneously with pharmaceuticals acting bacteriostatically.

Overdose (symptoms, emergency procedures, antidotes)

Overdoses of 20 mg/kg/day in cattle and 10 mg/kg/day in pigs and piglets have been well tolerated.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY:
Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:

15. OTHER INFORMATION:
Pack sizes: Carton with 1, 6 or 12 vials containing 100 ml or 1 or 6 vials containing 250 ml of suspension for injection.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
[optional: name, address, contact information (tel., e-mail address) and logo of the local (national) representative].

[To be completed in accordance with national requirements]

Approved: 10 May 2018