ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathozone 250 mg Intramammary Suspension for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml dose contains:

Active substance:

Cefoperazone	250
(as the sodium salt)	258.9

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
All-rac-α-Tocopherol (E307)	4.6 mg
Glycerol monostearate	
Sorbitan stearate	
Arachis oil, Refined	

White to off-white oily intramammary suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (lactating dairy cows).

3.2 Indications for use for each target species

The product is indicated for the treatment of clinical mastitis in lactating cows.

Clinical mastitis caused by a wide range of organisms including the following pathogens have been shown to respond to treatment with cefoperazone.

- *Streptococcus dysgalactiae*
- *Streptococcus uberis*
- *Streptococcus agalactiae*
- *Staphylococcus aureus (including penicillinase producing strains)*
- *Escherichia coli*
- *Trueperella pyogenes*
- *Pseudomonas aeruginosa*
- *Micrococcus* spp.
- *Klebsiella* spp.

3.3 Contraindications

Do not use in cases of hypersensitivity to cephalosporins or to any of the excipients.
Do not use in cases of severe disturbance of kidney function.

3.4 Special warnings

It is not envisaged for this product to be administrated to species other than lactating cattle.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on susceptibility testing of bacteria isolated from the affected quarter(s). If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about the susceptibility of target bacteria. Official, national, and regional antimicrobial policies should be taken into account when the product is used. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefoperazone, and may decrease the effectiveness of treatment with other cephalosporins, due to the potential for cross resistance.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice-versa. Allergic reaction to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms, such as a skin rash, you should seek medical advice and show the doctor this warning or the package leaflet. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent medical attention. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (lactating dairy cows):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Unclassified adverse event

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
By definition the product has been developed for use in lactating cows and has been shown to be safe in that regard.
In reproductive studies no adverse findings have been seen which might make the product unsafe in pregnant animals.

3.8 Interaction with other medicinal products and other forms of interaction

Cefoperazone is not compatible with aminoglycoside antibiotic such as streptomycin, neomycin and gentamicin. The simultaneous administration of possibly nephrotoxic drugs may prolong the elimination of cefoperazone.
There is a rare possibility of cross reaction with other beta-lactam antibiotics.

3.9 Administration routes and dosage

For intramammary use. Single administration. The contents of one syringe should be injected into the infected quarter immediately after milking. Before injection the teat should be thoroughly cleaned and disinfected.

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

Overdosing is unlikely to be a problem as the contents of a full syringe have been administered.

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

Meat and offal:	2 days.
Milk:	72 hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ51DD12

4.2 Pharmacodynamics

Cefoperazone is a third generation, semi-synthetic cephalosporin antibiotic with a broad spectrum of bactericidal activity covering both Gram-positive and Gram-negative organisms:
- *Streptococcus* dysgalactiae
- *Streptococcus* uberis
- *Streptococcus* agalactiae
- *Staphylococcus aureus* (including penicillinase producing strains)
- *Escherichia coli*
- *Trueperella pyogenes*
- *Pseudomonas aeruginosa*
- *Micrococcus* spp.
- *Klebsiella* spp

It acts by inhibition of bacterial cell wall synthesis.

4.3 Pharmacokinetics

Systemic drug absorption of cefaperazone has been found to be negligible in healthy animals, whereas it tends to be higher in infected animals, probably due to the damage to epithelial cell junctions caused by subclinical infections.

The detected urine concentrations indicate that cefoperazone is absorbed from the udder and is at least partly excreted by the kidneys. In tissue residue studies, no residues were detected in samples of muscle, liver, kidney, fat, heart or supramammary lymph node.

The highest concentrations of cefoperazone in milk are detected at the first milking (12 hours) after administration. From five days after administration, cefoperazone is not detectable in the milk. Milk yield does not influence the percentage of cefoperazone excreted in the milk.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

This veterinary medicinal product is not physico-chemically compatible with drugs of the aminoglycoside group.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

12 ml white opaque low density polyethylene syringe (containing 10 ml intramammary suspension) fitted with a protective cap of red low density polyethylene. Cartons contain four or ten syringes.

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

To be completed nationally

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.
To be completed nationally.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}
To be completed nationally after conclusion of the procedure.

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).