IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Pathocef 25 mg/ml Intramammary Suspension

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Pathocef 25 mg/ml Intramammary Suspension
Active substance(s)	Cefoperazone
Applicant	Zoetis Belgium S.A. 2nd Floor, Building 10 Cherrywood Business Park Loughlinstown Co Dublin Ireland
Date of authorisation	1st October 1988
Target species	Cattle
Indication for use	For intramammary administration to lactating cattle for the single dose treatment of clinical mastitis
ATCvet code	QJ51DA32

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The initial application for Pathocef 25 mg/ml Intramammary Suspension was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available. Please refer to section VI for significant post-approval changes which are important for the quality, safety and efficacy of the product.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See Section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that Pathocef 25 mg/ml Intramammary Suspension demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

VI. POST-AUTHORISATION ASSESSMENTS

The Applicant submitted an application to change the milk withdrawal period in cattle from 84 hours to 72 hours.

Safety/Efficacy Changes

Summary of change **(Application number)**	**Approval date**
Change to withdrawal period A new residue depletion study conducted in cows treated with the product justified the decrease in the cow milk withdrawal period to 72 hours. The application to vary the marketing authorisation can be approved. HPRA case reference number 7005378	October 2009
