IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

VANGUARD CPV-L

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Vanguard CPV-L Solution for injection
Active substance(s)	Attenuated canine parvovirus (strain NL-35-D) Inactivated *Leptospira canicola* Inactivated *Leptospira icterohaemorrhagiae*
Marketing Authorisation Holder	Zoetis Belgium S.A 2nd Floor Building 10 Cherrywood Business Park Loughlinstown Co Dublin
Legal basis of application	Review application in accordance with Directive 90/677/EC.
Date of authorisation	11th October 2004
Target species	Dogs
Indication for use	Active immunisation of dogs to prevent mortality and clinical signs including leucopenia and reduce viral shedding caused by canine parvovirus (types 2a, 2b and 2c) and to reduce infection caused by *Leptospira canicola*and *Leptospira icterohaemorrhagiae*.
ATC Vet Code	QI07AI05
Method of sale and supply	Prescription only medicine

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 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 the product was assessed before there was a requirement to produce a public assessment report due to implementation of Directive 2001/82/EC as amended by Directive 2004/82/EC in November 2005. Details on the quality, safety and efficacy of the product which led to the initial authorisation are not therefore included in the report.

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 ASSESSMENT

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the data submitted in the original application, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indication(s) as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet are updated on a continuous basis to include new information on the quality, safety and efficacy of the veterinary medicinal product.

The current SPC is available on the HPRA's website.

This section contains information on significant changes made after approval which are important for the quality, safety or efficacy of the product.

Safety/Efficacy Changes

Summary of change	**Approval date**
Type II variation to change the dosing recommendations for the initial course of vaccination for Vanguard CPV-L in puppies and to include additional information regarding the CPV duration of immunity (DOI) following the recommended vaccination regimen. The variation proposed to change the youngest age at which puppies received the final dose of the basic vaccination from 12 weeks to 10 weeks of age. Data were provided to support this change. Additional information was also included to support the following changes to the SPC: **SPC Section 4.5: Special precautions for use in animals**: inclusion of information on the potential for a higher MDA interference when puppies receive the final dose at 10 weeks than when the puppies receive the final dose at 12 weeks. **SPC Section 4.9: Amounts to be administered and administration route**: inclusion of information on the duration of immunity of the CPV component of the vaccine following administration of the recommended vaccination regimen. The Package leaflet was updated accordingly. HPRA case reference number 7004714	July 2008
Type II variation to change the claims for the CPV component to include protection against infection with canine parvovirus types 2a, 2b and 2c. This variation included information to support a change to the	August 2009

claim for protection against CPV infection to include prevention of mortality and clinical signs including leucopenia and reduce viral shedding caused by canine parvovirus (types 2a, 2b and 2c). The Packaging texts have been updated to reflect this change. HPRA case reference number 7004944	