

IPAR



**Publicly Available Assessment Report for a
Veterinary Medicinal Product**

Vanguard CPV

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Vanguard CPV Solution for injection
Active substance	Attenuated canine parvovirus (strain NL-35-D)
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	28 th May 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).
ATCvet code	QI07AD01

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 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 original data submitted, the HPRA considered that the product 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 SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA website.

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

Safety/Efficacy Changes

Summary of change	Approval date
<p>Type II variation to change the dosing recommendations for the initial course of vaccination for Vanguard CPV in puppies and to include additional information regarding the duration of immunity (DOI) following the recommended vaccination regimen.</p> <p>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.</p> <p>Additional information was also included to support the following SPC changes:</p> <p>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.</p> <p>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.</p> <p>The Package leaflet was updated accordingly.</p> <p>HPRA case reference number 7004714</p>	July 2008
<p>Type II variation to change the claims for the CPV component to include protection against infection with canine parvovirus types 2a, 2b and 2c.</p> <p>This variation included information supporting a change to the 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.</p> <p>HPRA case reference number 7004944</p>	August 2009
<p>Type II variation to change the claims for the CPV component to amend the onset of immunity (against CPV type 2b) to 7 days following administration of a single dose to dogs from 9 weeks of age.</p> <p>This variation included information to support a change to the</p>	August 2010

claim for onset of immunity for the canine parvovirus component of the vaccine. The data provided supported the claim that the onset of immunity against the CPV component occurs 7 days after a single dose of the vaccine, when administered to dogs from 9 weeks of age. The protection was demonstrated against CPV type 2b challenge.

The package leaflet was updated to reflect this change.

HPRA case reference number 7007027