IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Nobivac Parvo C

PRODUCT SUMMARY

EU Procedure number	IE/V/0160/001/MR
Name, strength and pharmaceutical form	Nobivac Parvo C Live freeze-dried pellet for suspension for injection
Active substance(s)	Canine parvovirus
Marketing Authorisation Holder	Intervet Ireland Ltd., Magna Drive, Magna Business Park, Citywest Road, Dublin 24.
Legal basis of application	Review application in accordance with Directive 90/677/EC.
Date of Authorisation	05th March 2014
Target species	Dogs
Indication for use	For active immunisation of dogs to prevent clinical signs of disease and excretion of virulent canine parvovirus caused by canine parvovirus infection. Onset of immunity has been shown to occur from 1 week after dosing and last for up to 3 years.
ATCvet code	QI07AD01
Concerned Member States	NO

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.

Section VI of the report includes details of significant post-approval changes which have occurred since November 2005 which are considered 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 (EFFICACY)

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 risk/benefit 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.

Quality Changes

Summary of change	**Approval date**
Addition of the manufacturing site Novartis UK as an additional blending, filling and freeze-drying site for Nobivac Parvo C. The data presented confirm Novartis UK to be a satisfactory alternative site for blending, filling and freeze-drying of Nobivac Parvo C. IE/V/160/001/II/003	23rd November 2006
Update of a Certificate of Suitability for one of the gelatine sources used in the manufacture of Nobivac Parvo C. The information provided confirms that there is no change to the risk of transferring TSE agents associated with the update to the gelatine Certificate of Suitability. IE/V/161/001/IA/004	18th July 2007

Safety/Efficacy Changes

Summary of change	Approval date
Change the claim in relation to excretion of canine parvovirus (CPV) from 'to reduce viral excretion caused by CPV infection' to 'to prevent viral excretion caused by CPV infection'. Evaluation of data from a number of efficacy studies demonstrated that a claim of 'prevention of CPV viral excretion' can be supported for Nobivac Parvo C. On this basis, the change in claim from 'to reduce viral excretion caused by CPV infection' to 'to prevent viral excretion caused by CPV infection' was considered appropriate for this vaccine. IE/V/160/001/II/002	01st July 2006
Application for a compatible use claim for Nobivac Parvo C with the inactivated vaccines of the Nobivac series against canine leptospirosis. Change to SPC sections 4.6, 4.8, 4.9 and 6.2. Relevant studies have been performed which support the safety and efficacy of Nobivac Parvo C when reconstituted with the inactivated vaccines of the Nobivac series against canine leptospirosis caused by all or some of the following serovars: L. *interrogans* serogroup Canicola serovar Canicola, L. *interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni, L. *interrogans* serogroup Australis serovar Bratislava, and L. *kirschneri* serogroup Grippotyphosa serovar Bananal/Liangguang.. SPC section 4.8 for Nobivac Parvo C has been amended to include details of this simultaneous administration schedule and to describe the associated adverse reactions. For consistency purposes, the adverse reactions currently described in the Nobivac Parvo C SPC Section 4.6 for the simultaneous administration of Nobivac Parvo C reconstituted with the Nobivac vaccine series against rabies are also moved to Section 4.8 of the SPC. IE/V/0160/001/II/009	18th June 2014