IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Nobivac Solvent

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Nobivac Solvent
Active substance(s)	Not applicable, the solvent does not contain active ingredients
Applicant	Intervet Ireland Ltd Magna Drive Magna Business Park Citywest Road Dublin 24
Date of Authorisation	3rd October 2003
Target species	Cats Dogs
Indication for use	Solvent for reconstitution of Nobivac DHP, Nobivac DHPPi, Nobivac Parvo-C, Nobivac Ducat and Nobivac Tricat Trio vaccines.
ATCvet code	QV07AB

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 Nobivac Solvent was assessed before the requirement to produce a public assessment report (implementation of Directive 2001/82/EC as amended by Directive 2004/82/EC in November 2005). Details of the quality, safety and efficacy of Nobivac Solvent which led to the initial authorisation are therefore not 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 AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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 considers that Nobivac Solvent, when used in combination with other vaccines demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory risk/benefit profile and therefore granted a marketing authorisation.

VI POST-AUTHORISATION ASSESSMENTS

This section contains information on significant changes made since November 2005 which are important for the quality, safety or efficacy of the product.

SCOPE
Addition of two new manufacturing sites for the blending and filling of Nobivac Solvent

The HPRA reference number for this change is CRN: 7000960.

SUMMARY OF CHANGE
Data were provided validating the blending of Nobivac Solvent at each of the proposed new manufacturing sites. Data were also provided demonstrating the consistency of the filling operation performed at each site. Based on these data, the two proposed manufacturing sites were considered suitable for blending and filling of Nobivac Solvent.

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

DATE OF APPROVAL

4th May 2006