IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Eurican DHPPi lyophilisate for suspension for injection

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Eurican DHPPi Lyophilisate for suspension
Active substance(s)	Canine distemper virus Canine parvovirus Canine adenovirus 2 Canine parainfluenza type 2 virus
Marketing Authorisation Holder	Boehringer Ingelheim Vetmedica GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany
Legal basis of application	Review application in accordance with Directive 90/677/EC.
Date of Authorisation	28th October 2005
Target species	Dogs and puppies
Indication for use	Dogs and puppies from 8 weeks of age
ATCvet code	QI07AD04

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.

I. SCIENTIFIC OVERVIEW

The initial application for Eurican DHPPi 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

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 Eurican DHPPi 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 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.

Summary of change **HPRA case reference number 7001764**	**Approval date**
Minor changes to the vial and carton labels to facilitate used of the same presentations in both Ireland and the UK. Note country specific package inserts will still be used hence there is no change to the approved Irish package insert. Variation Type: 'Changes to the labels and leaflets not connected with the SPC'.	February 2007

Summary of change **HPRA case reference number 7024203**	**Approval date**
Type II variation C.I.4. "Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data". Changes to the SPC and packaging texts to make them consistent with those agreed for Eurican DAPPi Lyophilisate and Solvent for Suspension for Injection during MRPFR/V/0306/001/MR. Note: Declaration provided confirming that the starting materials, manufacturing process, control tests and specifications of Eurican DHPPi registered and commercialised in Ireland under VPA 10857/036/001 are identical to those of the lyophilisate portion of the Eurican DAPPi Lyophilisate and Solvent for Suspension for Injection vaccine approved as part of FR/V/0306/001/MRi.e. the lyophilised fractions of Eurican DHPPi and Eurican DAPPi are the same vaccine.	December 2016
