IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Poulvac IBMM

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Poulvac IBMM
Active substance(s)	Infectious bronchitis virus strain 1263
Applicant	Zoetis Ireland Limited 25/28 North Wall Quay Dublin 1 Ireland
Legal basis of application	Review application in accordance with Directive 90/677/EC.
Date of Authorisation	05th March 2004
Target species	Chicken
Indication for use	For the vaccination of broilers and growing chicks for the prevention of respiratory signs caused by the Massachusetts serotype of infectious bronchitis.
ATCvet code	QI01AD07
Concerned Member States	N/A

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 Poulvac IBMM 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 Rispoval Pasteurella 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.

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**
This variation served to align the SPC's and product literature in IE and the UK. As a result of this alignment, some changes to indications, warnings etc have been made as detailed in the SPC for the product which is available on the HPRA website. The HPRA reference number for this change is CRN: 7003367.	30th July 2008