25 January 2010
EMA/698942/2009
Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33 (4)[1] referral for Poulvac Bursa Plus and associated names

Background information

Poulvac Bursa Plus is a live vaccine against Infectious Bursal Disease Virus (IBDV), also known as Gumboro disease. Given its residual pathogenicity, the vaccine strain, V877, is classified as "intermediate plus" and also known as a "hot" strain.

The Marketing Authorisation Holder (Fort Dodge Animal Health Ltd) submitted an application for Mutual Recognition Procedure of Poulvac Bursa Plus (lyophilisate for suspension in drinking water, $10^{2.2}$–$10^{3.4}$ EID_{50}/dose), indicated for chickens from 10 days of age for oral administration via the drinking water. The application was submitted in the framework of Article 32 of Directive 2001/82/EC, as amended, where the Reference Member State was the United Kingdom and the Concerned Member States were Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Spain, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, the Netherlands, Poland, Portugal, Romania, Slovakia and Slovenia. The Mutual Recognition Procedure UK/V/0335/001/MR started on 29 January 2009.

On 13 July 2009 the United Kingdom, referred the matter to the Agency under Article 33 (4) of Directive 2001/82/EC due to concerns raised by Belgium regarding an unfavourable benefit and risk balance of the vaccine.

The referral procedure started on 14 July 2009. The Rapporteur and Co-Rapporteur appointed were Dr. F. Descamps (Belgium) and Dr. A.-M. Brady (the United Kingdom) respectively. Written explanations were provided by the Marketing Authorisation Holder on 17 August 2009.

On the basis of the grounds for referral, the points considered by the CVMP were whether the studies carried out by the Marketing Authorisation Holder were sufficient to address the risks associated with immunosuppression in a comprehensive way and whether the benefit/risk balance was favourable for the vaccine Poulvac Bursa Plus.

During its 13–15 October 2009 meeting, the CVMP, in light of the overall data submitted and the scientific discussion within the Committee, adopted by a majority of 25 out of 27 votes an opinion concluding that objections raised by Belgium should not prevent the granting of a Marketing Authorisation.

[1] Article 33 (4) of Directive 2001/82/EC.

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The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 25 January 2010.