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Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 23b[1] procedure for Bayovac IBR Marker Vivum and its associated names

Background information

Bayovac IBR Marker Vivum and its associated names are attenuated vaccines for active immunisation of cattle against the respiratory symptoms caused by Infectious Bovine Rhinotracheitis (IBR) virus.

Due to concerns regarding adverse events reports following use of Bayovac IBR Marker Vivum and its associated names, the United Kingdom suspended the marketing authorisation for the product on 16 March 1999, triggering a procedure under Article 23a of Council Directive 81/851/EEC, as amended.

The CVMP procedure under Article 23b of Directive 81/851/EEC started on 13 April 1999. The Committee appointed H. Lensing as rapporteur and M. Moos as co-rapporteur. Written explanations were provided by the marketing authorisation holders on 9 June 1999, 28 September 1999 and 21 December 1999. Oral explanations were given on 13 October 1999.

Based on the evaluation of the available data, the CVMP concluded that the marketing authorisations for Bayovac IBR Marker Vivum and its associated names should be amended. Therefore, the CVMP adopted a positive opinion on 21 January 2000, recommending variations to the terms of marketing authorisations for the above mentioned products.

The scientific conclusions are provided in Annex I. The list of product names concerned is given in Annex II, together with the Summaries of Product Characteristics in Annex III.

The final opinion was converted into a Decision by the European Commission on 10 July 2000.

[1] Article 23b of Council Directive 81/851/EEC, as amended

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