10 November 2011
EMA/CVMP/561772/2011
Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 78[1] procedure for HIPRABOVIS PNEUMOS Emulsion for injection for cattle and associated names

Background information

HIPRABOVIS PNEUMOS Emulsion for injection for cattle is an inactivated vaccine for reduction of the clinical signs and lung lesions caused by *Mannheimia haemolytica* serotype A1 and *Histophilus somni* in calves from 2 months of age.

Due to concerns regarding reports of anaphylactic-type events following use of HIPRABOVIS PNEUMOS Emulsion for injection for cattle, France suspended the marketing authorisation for the product on 6 April 2011 triggering a procedure under Article 78 of Directive 2001/82/EC.

The procedure started on 5 May 2011. The rapporteur and co-rapporteur appointed were Dr Jean-Claude Rouby and Dr David Murphy, respectively. A written explanation was provided by the representative of the marketing authorisation holder on 23 May 2011.

Based on the rapporteurs' assessment of the data available from pharmacovigilance reports and a laboratory study, the CVMP concluded that the underlying cause of the adverse events observed has yet to be determined; the data evaluated indicated an association between vaccination of cattle with HIPRABOVIS PNEUMOS Emulsion for injection for cattle and the occurrence of anaphylactic-type events; no corrective measures could be recommended; and the benefit-risk balance for the product was unfavourable.

The Committee, adopted on 14 July 2011, an opinion recommending the suspension of the marketing authorisations for HIPRABOVIS PNEUMOS Emulsion for injection for cattle and associated names until the marketing authorisation holder proposes appropriate measures to mitigate the risk of occurrence of such adverse events and demonstrates a favourable benefit-risk balance for the product when used according to the recommendations of the summary of product characteristics

The list of product names concerned is given in Annex I. The scientific conclusions and grounds for suspension of the marketing authorisations are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 3 November 2011.

[1] Article 78 of Directive 2001/82/EC

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