7 October 2010
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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 78[1] procedure for Pregsure BVD and associated names

Background information

Pregsure BVD is an inactivated vaccine for the immunisation of cattle at breeding age to prevent bovine viral diarrhoea virus type 1 (cytopathogenic strain 5960) transplacental infection and the birth of bovine viral diarrhoea virus type 1 persistently infected calves.

Due to concerns regarding adverse event reports of bovine neonatal pancytopenia following use of Pregsure BVD in dams, Germany triggered a procedure under Article 78 of Directive 2001/82/EC on 29 April 2010.

The procedure started on 20 May 2010. The rapporteur and co-rapporteur appointed were Dr Manfred Moos and Dr Frederic Descamps, respectively. A written explanation was provided by the representative of the marketing authorisation holders on 7 June 2010 and an oral explanation was given during the 15-17 June 2010 CVMP meeting.

Based on the rapporteurs' assessment of the data available from pharmacovigilance reports, epidemiological and laboratory studies, the CVMP concluded that although the aetiology of bovine neonatal pancytopenia has yet to be determined there was evidence to suggest that Pregsure BVD may be associated with bovine neonatal pancytopenia and that the benefit-risk balance for the product was unfavourable. The Committee adopted on 15 July 2010 an opinion recommending that the marketing authorisations for Pregsure BVD and associated names should be suspended until scientific evidence is available to demonstrate that the administration of the vaccine to dams according to authorised conditions of use does not lead to an increased risk of bovine neonatal pancytopenia or that risk mitigation measures ensuring the safe use of the product can be implemented. In addition, the CVMP recommended that all batches of the product be recalled at wholesale level.

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 relating to the temporary measures was converted into a Decision by the European Commission on 10 August 2010 and the final measures were adopted by the European Commission on 7 October 2010.

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

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