16 August 2010
EMA/344861/2010
Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 6(12)[1] referral for Porcilis PRRS

Background information

Porcilis PRRS is an immunological veterinary medicinal product containing the Porcine Reproductive and Respiratory Syndrome (PRRS) virus. The product is indicated for use in breeding and finishing pigs from 2 weeks of age.

The marketing authorisation holder Intervet International B.V. submitted an application for a Type II variation subject to Mutual Recognition Procedure for Porcilis PRRS concerning simultaneous administration with Porcilis M Hyo. The application was submitted in the framework of Article 6 of Commission Regulation (EC) No 1084/2003, where the Reference Member State was the United Kingdom and the Concerned Member States were Austria, Belgium, Germany, Greece, Spain, France, Ireland, Italy, Luxembourg, the Netherlands and Portugal. The Mutual Recognition Procedure (UK/V/0145/001/II/007) started on 30 January 2009.

On 2 October 2009 the United Kingdom, referred the matter to the Agency under Article 39 of Directive 2001/82/EC as amended by reference to Article 6(12) of Regulation (EC) No 1084/2003 due to concerns raised by Spain relating to the quality and efficacy of the simultaneous administration of Porcilis PRRS with Porcilis M Hyo.

The referral procedure started on 14 October 2009. The Committee appointed Dr C. Rubio Montejano as rapporteur and Dr A.M. Brady as co-rapporteur. During the procedure Dr C. Muñoz Madero replaced Dr C. Rubio Montejano as rapporteur. Written explanations were provided by the marketing authorisation holder on 15 January 2010 and supplementary information was submitted on 20 April 2010.

Based on the rapporteurs' assessment of the currently available data, the CVMP adopted, on 19 May 2010, an opinion recommending that the variation application applied for the veterinary medicinal product Porcilis PRRS satisfies the criteria for approval.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amended Summary of Product Characteristics and package leaflet in the Annex III.

The final opinion was converted into a Decision by the European Commission on 16 August 2010.

[1] Article 6(12) of Commission Regulation (EC) No 1084/2003.

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