16 August 2010
EMA/345914/2010
Committee for medicinal products for veterinary use (CVMP)

# Opinion following an Article 6(12)[1] referral for Porcilis M Hyo

## Background information

Porcilis M Hyo is an immunological veterinary medicinal product containing *Mycoplasma hyopneumoniae*. The product is indicated for finishing pigs from 1 week of age. Pigs should be vaccinated twice with a 3 week interval.

The marketing authorisation holder Intervet International B.V. submitted an application for a Type II variation subject to Mutual Recognition Procedure for Porcilis M Hyo concerning simultaneous administration with Porcilis PRRS. The application was submitted in the framework of Article 6 of Commission Regulation (EC) No 1084/2003, where the Reference Member State was France[2] and the Concerned Member States were Austria, Belgium, Cyprus, Czech Republic, Germany, Denmark, Estonia, Greece, Spain, Finland, Hungary, Ireland, Italy, Malta, Luxembourg, Lithuania, Latvia, the Netherlands, Norway, Poland, Portugal, Sweden, Slovenia, Slovakia and the United Kingdom. The Mutual Recognition Procedure (FR/V/0158/001/II/002) started on 30 January 2009.

On 2 October 2009 the United Kingdom on behalf of France, 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, safety and efficacy of the simultaneous administration of Porcilis M Hyo with Porcilis PRRS.

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 M Hyo satisfies the criteria for approval.

[1] Article 6(12) of Commission Regulation (EC) No 1084/2003.
[2] The United Kingdom acted on behalf of France as the Reference Member State in a work-sharing arrangement

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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.