27 January 2010
EMA/839689/2009
Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 33(4)[1] referral for APPM Respipharm

Background information

APPM Respipharm is a multi-component formaldehyde inactivated whole-cell bacterial vaccine containing three strains of *Actinobacillus pleuropneumoniae* (Serotypes 2, 9 and 11) and one strain of *Pasteurella multocida* (Serotype A). The product is indicated for use in pigs (sows and weaned piglets) from 6 weeks of age, intended to induce active immunisation of sows and piglets against pleuropneumonia caused by *Actinobacillus pleuropneumoniae* and against secondary infection by *Pasteurella multocida*.

The Marketing Authorisation Holder, Pharmagal Bio s.r.o., submitted an application via mutual recognition for APPM Respipharm, on the basis of the marketing authorisation granted by Slovakia. The application was submitted in the framework of Article 32 of Directive 2001/82/EC, as amended, where the Reference Member State was Slovakia and the Concerned Member States were Poland and Spain. The Mutual Recognition Procedure started on 3 April 2008.

Due to concerns raised by Spain during the Mutual Recognition Procedure that APPM Respipharm may pose a potentially serious risk to human or animal health or to the environment with respect to quality and efficacy of the product, the Reference Member State, Slovakia, referred the matter to the Agency on 7 October 2008 under Article 33(4) of Directive 2001/82/EC.

The referral procedure started on 15 October 2008. The Committee appointed Dr Anna-Maria Brady as rapporteur and Dr Frédéric Descamps as co-rapporteur. Written explanations were provided by the Marketing Authorisation Holder on 14 January 2009 and supplementary information was submitted on 22 April 2009.

Based on the evaluation of the rapporteur's assessment of the currently available data, the CVMP considered that the application does not satisfy the criteria for authorisation in respect of efficacy. Therefore, the Committee adopted an opinion on 15 July 2009 recommending the suspension of the existing Marketing Authorisation and the refusal of the granting of the Marketing Authorisations for APPM Respipharm.

[1] Article 33(4) of Directive 2001/82/EC, as amended.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

On 28 July 2009, Pharmagal Bio s.r.o. notified the Agency of its intention to request the re-examination of the CVMP opinion of 15 July 2009. The detailed grounds for the re-examination were submitted by Pharmagal Bio s.r.o. on 14 September 2009.

During its 15-17 September 2009 meeting, the CVMP appointed Dr Kristina Lehmann as rapporteur and Prof. Tibor Soós as co-rapporteur for the re-examination of the abovementioned opinion.

The re-examination procedure started on 15 September 2009.

Based on the evaluation of the rapporteur's assessment of the currently available data, the CVMP considered that its opinion of 15 July 2009 should not be revised, and therefore adopted an opinion on 11 November 2009 recommending the suspension of the existing Marketing Authorisation and the refusal of the granting of the Marketing Authorisations for APPM Respipharm.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 27 January 2010.