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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4) referral for Combimox Lactating Cow Intramammary Suspension

International non-proprietary name (inn): amoxicillin, clavulanic acid and prednisolone

Background information

Combimox Lactating Cow Intramammary Suspension (Combimox) is an intramammary suspension containing amoxicillin, clavulanic acid and prednisolone. Combimox is intended for the treatment of mastitis in lactating cows.

The marketing authorisation holder, Norbrook Laboratories Ltd, submitted an application for Combimox via a mutual recognition procedure in Ireland on the basis of the marketing authorisation granted by the United Kingdom. The application was submitted as a generic of the reference product, Synulox Lactating Cow Intramammary Suspension marketed by Pfizer Ltd. The mutual recognition procedure (UK/V/0354/001/MR) started on 26 November 2009.

On 2 July 2010, the United Kingdom, as Reference Member State, referred the matter to the European Medicines Agency under Article 33(4) of Directive 2001/82/EC, due to concerns raised by the Concerned Member State, Ireland, that the safety and efficacy of the product had not been sufficiently demonstrated. There was disagreement between the Reference Member State and Concerned Member State on the demonstration of bioequivalence and the adequacy of the proposed withdrawal period.

The referral procedure started on 14 July 2010. The Committee appointed Mr Johan Schefferlie as rapporteur and Mrs Ruth Kearsley as co-rapporteur. Further to the resignation of Mrs Ruth Kearsley as CVMP member, Ms Helen Jukes was appointed to replace her and took over the co-rapporteurship. Written explanations were provided by the marketing authorisation holder on 13 September 2011 and 10 March 2011. Oral explanations were given on 12 January 2011.

Based on the evaluation of the rapporteur's assessment of the currently available data, the CVMP considered that the benefit/risk profile of Combimox Lactating Cow Intramammary Suspension is

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

negative, and therefore adopted an opinion on 6 April 2011 recommending the refusal of the granting of the marketing authorisation and suspension of the existing marketing authorisation.

Nine CVMP members expressed divergent positions, which are appended to the opinion.

The list of product names concerned is given in Annex I. The scientific conclusions and the grounds for refusal of the granting of the marketing authorisation and suspension of the existing marketing authorisation are provided in Annex II. The grounds for the lifting of the suspension of the marketing authorisation are provided in Annex III.

The final opinion was converted into a Decision by the European Commission on 5 August 2011.