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Veterinary Medicines Division

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 13[1] referral for Resflor solution injectable and associated names

International non-proprietary name (INN): florfenicol, flunixin

Background information

Resflor is a solution for injection for use in cattle containing florfenicol and flunixin as active ingredients. It is indicated for the treatment of respiratory infections caused by *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* associated with pyrexia. A single subcutaneous injection of 40 mg florfenicol and 2.2 mg flunixin per kg body weight (2 mL/15 kg bw) is recommended.

The marketing authorisation holder Intervet International BV submitted an application for a type II variation to add *Mycoplasma bovis* as a target pathogen. The reference Member State (RMS) is France and 25 concerned Member States (CMS) are involved: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and the United Kingdom.

The variation procedure (FR/V/0167/01/II/017) started on 28 January 2013. Potential serious risks to animal health were identified during the decentralised procedure by Denmark and Germany regarding the demonstration of efficacy in the clinical trials and the justification of the recommended treatment dose of Resflor in the treatment of respiratory infections caused by *Mycoplasma bovis,* which may be associated with an increased risk of development of antimicrobial resistance.

On day 90, these issues remained unsolved and therefore a referral under Article 13(1) of Commission Regulation (EC) No. 1234/2008 to the Coordination group for Mutual recognition and Decentralised procedures (veterinary) (CMD(v)) was started on 25 November 2013. Day 60 of the CMD(v) procedure was on 23 January 2014, and since the Member States concerned failed to reach an agreement, the procedure was referred to the CVMP.

[1] Article 13 of Commission Regulation (EC) No. 1234/2008

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On 24 January 2014, the reference Member State, France, notified the European Medicines Agency that the CMD(v) had failed to reach an agreement and referred the matter to the CVMP pursuant to Article 13(2) of Commission Regulation (EC) No. 1234/2008.

The referral procedure started on 12 February 2014. The Committee appointed C. Ibrahim as rapporteur and M. Holzhauser-Alberti as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 12 May 2014 and 19 June 2014. Oral explanations were given on 10 September 2014.

Based on the evaluation of the available data the CVMP adopted by majority, on 7 October 2014, an opinion recommending the granting of the variation of the marketing authorisations for Resflor solution injectable and its associated names. The CVMP concluded that the clinical benefit of Resflor in the treatment of respiratory infections associated with *M. bovis* has been demonstrated and no specific risk of antimicrobial resistance has been identified with the use of this product.

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

The opinion was converted into a Decision by the European Commission on 5 December 2014.