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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for Florgane 300 mg/ml suspension for injection for cattle and pigs and associated names

International non-proprietary name (INN): florfenicol

Background information

Florgane 300 mg/ml suspension for injection for cattle and pigs contains florfenicol as active ingredient and is intended for use in pigs for the treatment of acute outbreaks of respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol. The proposed dose is 22.5 mg florfenicol per kg bodyweight given by intramuscular administration as a single injection. Florfenicol is structurally related to thiamphenicol and has a similar pharmacological profile.

The applicant, Emdoka bvba, submitted an application for a decentralised procedure for Florgane 300 mg/ml suspension for injection for cattle and pigs and associated names. This application is an extension to add pigs as a target species to the existing 300 mg florfenicol/ml suspension for injection product authorised for use in cattle. Florgane 300 mg/ml suspension for injection has been authorised for use in cattle as a hybrid of Nuflor 300 mg/ml solution for injection using the decentralised procedure (DE/V/0132/001/DC) with Germany as a reference Member State and Austria, Belgium, Bulgaria, Czech Republic, Denmark, France, Greece, Hungary, Ireland, Italy, Lithuania, Luxemburg, the Netherlands, Poland, Portugal, Romania, Slovakia, Spain and the United Kingdom as concerned Member States.

This extension application (DE/V/0132/001/DX/001) was submitted according to the same procedure (DCP) and type of application (hybrid, according to Article 13(3) of Directive 2001/82/EC) as for the initial application for cattle, to the same Member States. The reference product was Nuflor Swine Injectable Solution 300 mg/ml (FR/V/0118/001).

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

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The decentralised procedure started on 17 December 2010. Potential serious risks were identified during the decentralised procedure by Denmark regarding the efficacy of the product and the potential for development of antimicrobial resistance to florfenicol.

On day 210, these issues remained unsolved and therefore a referral under Article 33(1) of Directive 2001/82/EC to the Coordination group for Mutual recognition and Decentralised procedures (veterinary) (CMD(v)) was started on 20 February 2012. Day 60 of the CMD(v) procedure was on 19 April 2012, and since the Member States concerned failed to reach an agreement regarding the product the procedure was referred to the CVMP.

On 19 April 2012, the reference Member State, Germany, notified to the European Medicines Agency that the CMD(v) had failed to reach an agreement regarding the product and referred the matter to the CVMP pursuant to Article 33(4) of Directive 2001/82/EC.

The referral procedure started on 15 May 2012. The Committee appointed Prof. Christian Friis as rapporteur and Dr Cornelia Ibrahim as co-rapporteur. Written explanations were provided by the applicant on 11 September 2012 and 9 January 2013. Oral explanations were given on 5 March 2013.

Based on the evaluation of the currently available data, the CVMP considered that the benefit-risk profile of Florgane 300 mg/ml suspension for injection for cattle and pigs is positive. Therefore, the Committee adopted by majority a positive opinion on 6 March 2013 recommending the granting of a marketing authorisation for Florgane 300 mg/ml suspension for injection for cattle and pigs and associated names.

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 23 May 2013.