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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for Nuflor Swine Once 450 mg/ml solution for injection

International non-proprietary name (INN): florfenicol

Background information

Nuflor Swine Once 450 mg per ml solution for injection contains florfenicol as active ingredient and is intended for use in pigs for the treatment of respiratory infections caused by strains of *Actinobacillus pleuropneumoniae*, *Haemophilus parasuis* and *Pasteurella multocida* susceptible to florfenicol. The proposed dose is 30 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, Intervet International BV, submitted an application for a decentralised procedure for Nuflor Swine Once 450 mg/ml solution for injection. This was a 'hybrid application' according to Article 13(3) Directive 2001/82/EC, as amended, referring to the reference product, Nuflor Swine 300 mg/ml solution for injection (FR/V/0118/001). Nuflor Swine Once 450 mg/ml solution for injection differs from the reference veterinary medicinal product by a higher concentration of active substance, single administration, a change in therapeutic indication but also by a different co-solvent. The application was submitted to Germany as reference Member State and Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and the United Kingdom as concerned Member States.

The decentralised procedure (DE/V/0122/002/DC) started on 12 November 2010. Potential serious risks were identified during the decentralised procedure by Denmark regarding the cumulative failure rate observed in the pivotal clinical field trial and 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

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

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(veterinary) (CMD(v)) was started on 17 October 2011. Day 60 of the CMD(v) procedure was on 15 December 2011, and since the Member States concerned failed to reach an agreement regarding the product the procedure was referred to the CVMP.

On 19 December 2011, 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 10 January 2012. The Committee appointed Prof. Christian Friis as rapporteur and Dr Cornelia Ibrahim as co-rapporteur. Written explanations were provided by the applicant on 20 March 2012. Oral explanations were given on 15 May 2012.

Based on the evaluation of the available data, the CVMP adopted, on 13 June 2012, an opinion recommending the granting of marketing authorisations for Nuflor Swine Once 450 mg/ml solution for injection, subject to certain conditions.

On 31 August 2012, the Netherlands submitted an objection to the opinion adopted by CVMP on 13 June 2012 during the written phase of the Standing Committee procedure.

On 27 September 2012 a plenary meeting of the Standing Committee on Veterinary Medicinal Products took place and on 3 October 2012 the European Commission sent a letter to the CVMP requesting a reconsideration of the opinion adopted on 13 June 2012.

The reconsideration procedure started on 10 October 2012. The Committee re-appointed Prof Christian Friis as rapporteur and Dr Cornelia Ibrahim as co-rapporteur for the reconsideration procedure. Oral explanations were given by the applicant on 10 January 2013.

On 7 February 2013 the CVMP adopted a reconsidered opinion, concluding that the application does not comply with Article 13 of Directive 2001/82/EC, and consequently does not satisfy the criteria for authorisation in respect of efficacy. Therefore the CVMP recommended the refusal of the granting of the marketing authorisations and the suspension of the existing marketing authorisations.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the condition to lift the suspension of the marketing authorisation in Annex III.

The reconsidered opinion was converted into a Decision by the European Commission on 16 May 2013.