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Veterinary Medicines and Product Data Management

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for Nuflor 300 mg/ml solution for injection for cattle and sheep

International non-proprietary name (INN): florfenicol

Background information

Nuflor 300 mg/ml solution for injection for cattle and sheep contains 300 mg florfenicol per ml. Florfenicol is structurally related to thiamphenicol and has a similar pharmacological profile. The active substance is included in veterinary medicinal products currently authorised in several Member States in the European Union for use in cattle and pigs for the treatment of respiratory diseases.

The applicant, Intervet International BV, submitted an application for a decentralised procedure for Nuflor 300 mg/ml solution for injection for cattle and sheep. This application was an extension (Article 19 of Regulation 1234/2008/EC) to add sheep as new target species. The application was submitted to Ireland as reference Member State and Belgium, Denmark, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain and the United Kingdom as concerned Member States.

The decentralised procedure (IE/V/0269/001/DC) started on 13 August 2010. Potential serious risks were identified during the decentralised procedure by two concerned Member States, by France regarding the proposed indications and by Denmark regarding the efficacy of the product.

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 22 July 2011. During the procedure the applicant provided additional data and the issues raised by France regarding the proposed indications were resolved. Day 60 of the CMD(v) procedure was on 20 September 2011, and since the Member States concerned failed to reach an agreement regarding the product the procedure was referred to the CVMP.

On 21 September 2011, the reference Member State, Ireland, 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.

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

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The referral procedure started on 12 October 2011. The Committee appointed Prof Christian Friis as rapporteur and Dr David Murphy as co-rapporteur.

Written explanations were provided by the applicant on 9 January 2012 and 23 April 2012. Oral explanations were given on 15 May 2012.

Based on the rapporteurs' assessment of the currently available data, the CVMP considered that the benefit-risk profile of Nuflor 300 mg/ml solution for injection for cattle and sheep is positive subject to changes in the product information in order to clarify that the recommended treatment dose and treatment interval for sheep is based on the time mean florfenicol concentrations are maintained above MIC_{90}. Therefore, the Committee adopted a positive opinion on 12 June 2012 recommending the granting of a marketing authorisation for Nuflor 300 mg/ml solution for injection for cattle and sheep.

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

The final opinion was converted into a Decision by the European Commission on 17 September 2012.