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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 STRENZEN 500/125 mg/g powder for use in drinking water for pigs and associated names

International non-proprietary name (INN): amoxicillin and clavulanic acid

Background information

STRENZEN 500/125 mg/g powder for use in drinking water for pigs contains amoxicillin and clavulanic acid as active ingredients and is intended for use in pigs for the treatment of respiratory tract infections caused by microorganisms susceptible to the combination amoxicillin/clavulanic acid i.e. *Actinobacillus pleuropneumoniae*, *Pasteurella* spp, *Streptococcus* spp. and gastrointestinal infections caused by *Clostridium* spp., *E. coli* and *Salmonella* spp.

The applicant, Novartis Animal Health Inc., submitted an application for a decentralised procedure for STRENZEN 500/125 mg/g powder for use in drinking water for pigs and associated names. This is a generic application according to Article 13(1) Directive 2001/82/EC, as amended, referring to the reference product Amoksiklav 500/125 mg/g powder for use in drinking water authorised in the Czech Republic (MA No. 96/069/98-C). The Czech Republic is the reference Member State and Austria, Denmark, France, Germany, Ireland, Italy, the Netherlands, Portugal, Spain and the United Kingdom are concerned Member States.

The decentralised procedure started on 29 November 2010. Potential serious risks were identified during the decentralised procedure by the Netherlands and the United Kingdom regarding the environmental safety 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 2 May 2012. Day 60 of the CMD(v) procedure was on 29 June 2012, and since the Member States concerned failed to reach an agreement regarding the product the procedure was referred to the CVMP.

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

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On 11 July 2012, the reference Member State, the Czech Republic, notified 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 11 July 2012. The Committee appointed Mr J. Schefferlie as rapporteur and Dr J. Bureš as co-rapporteur. Written explanations were provided by the applicant on 11 September 2012 and 6 February 2013. Oral explanations were given on 9 April 2013.

Based on the evaluation of the currently available data, the CVMP considered that the benefit-risk profile of STRENZEN 500/125 mg/g powder for use in drinking water for pigs is positive. Therefore, the Committee adopted by consensus a positive opinion on 10 April 2013 recommending the granting of a marketing authorisation for STRENZEN 500/125 mg/g powder for use in drinking water for 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 12 August 2013.