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Veterinary Medicines Division

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for Suifertil 4 mg/ml Oral Solution for Pigs and associated names

International non-proprietary name (INN): altrenogest

Background information

Suifertil 4 mg/ml Oral Solution for Pigs contains altrenogest as active ingredient and is intended for use in pigs for the synchronisation of oestrous in sexually mature gilts.

The applicant, aniMedica GmbH, submitted an application for a decentralised procedure for Suifertil 4 mg/ml Oral Solution 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 Regumate oily solution 4 mg/ml. France is the reference Member State and Austria, Germany, Hungary, the Netherlands, Poland, Romania, Spain and the United Kingdom are concerned Member States.

The decentralised procedure started on 7 October 2011. Potential serious risks were identified during the decentralised procedure by Germany 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 17 December 2012. Day 60 of the CMD(v) procedure was on 14 February 2013, and since the Member States concerned failed to reach an agreement regarding the product the procedure was referred to the CVMP.

On 1 March 2013, the reference Member State, France, 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.

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

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The referral procedure started on 6 March 2013. The Committee appointed Dr C. Ibrahim as rapporteur and Dr M. Holzhauser-Alberti as co-rapporteur. Written explanations were provided by the applicant on 21 May 2013.

Having considered all the overall submitted data in writing the CVMP concluded that there is no product specific concern identified for the Suifertil 4 mg/ml Oral Solution for Pigs that is different from the other, already authorised, altrenogest containing veterinary medicinal products. Therefore, the Committee adopted by consensus a positive opinion on 18 July 2013 recommending the granting of a marketing authorisation for Suifertil 4 mg/ml Oral Solution 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 2 October 2013.