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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 Melosolute 40 mg/ml solution for injection for cattle, pigs and horses

International non-proprietary name (INN): meloxicam

Background information

Melosolute 40 mg/ml solution for injection for cattle, pigs and horses contains meloxicam as active ingredient. Meloxicam is a Non-Steroidal Anti-Inflammatory Drug. The active substance is included in veterinary medicinal products currently authorised in the European Union via the centralised authorisation procedure, as well as nationally, for use in cattle, pigs, horses, dogs and cats.

The applicant, CP-Pharma Handelsgesellschaft mbH, submitted an application for a decentralised procedure for Melosolute 40 mg/ml solution for injection for cattle, pigs and horses. This is a 'hybrid' application according to Article 13(3) Directive 2001/82/EC, as amended, referring to the centrally authorised reference product Metacam 20 mg/ml solution for injection for cattle, pigs and horses (EU/2/97/004). The application was submitted to the Netherlands as reference Member State and Austria, Belgium, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Poland, Spain and the United Kingdom as concerned Member States.

The decentralised procedure (NL/V/0164/003/DC) started on 17 June 2011. Potential serious risks were identified during the decentralised procedure by two concerned Member States, Ireland and the United Kingdom, regarding the bioequivalence for the target species pigs.

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

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On 29 June 2012 the reference Member State, the Netherlands, 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 11 July 2012. The Committee appointed Ms H. Jukes as rapporteur and Mr G. J. Schefferlie as co-rapporteur.

Written explanations were provided by the applicant on 11 September 2012.

Based on the evaluation of the currently available data, the CVMP considered that the particulars concerning the target species pigs that were submitted in support of the application do not comply with Article 13 of Directive 2001/82/EC, and consequently do not satisfy the criteria for authorisation in respect of safety and efficacy for the target species pigs. Therefore, the Committee adopted a negative opinion on 8 November 2012 recommending the refusal of the granting of the marketing authorisation for Melosolute 40 mg/ml solution for injection for the target species pigs.

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, labelling and package leaflet in the Annex III.

The final opinion was converted into a Decision by the European Commission on 12 February 2013.