22 July 2010
EMA/193771/2010
Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for TILDREN 500 mg, lyophilisate for solution for infusion

Background information

Tiludronic acid as the disodium salt, is a synthetic derivative of pyrophosphate belonging to the class of biphosphonates. TILDREN 500 mg, lyophilisate for solution for infusion is a veterinary medicinal product indicated as an aid in the treatment of clinical signs of lameness associated with bone spavin in combination with a controlled exercise regime in horses over 3 years of age.

The marketing authorisation holder, CEVA Animal Health Ltd, submitted an application for a mutual recognition procedure for TILDREN 500 mg, lyophilisate for solution for infusion, on the basis of the marketing authorisation granted by the United Kingdom. The application was submitted in the framework of Article 32 of Directive 2001/82/EC, where the Reference Member State was the United Kingdom and the Concerned Member States were Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Slovakia, Spain and Sweden. The Mutual Recognition Procedure UK/V/0321/001/MR started on 1 May 2008.

On 4 November 2008, the United Kingdom, referred the matter to the Agency under Article 33(4) of Directive 2001/82/EC, due to concerns, raised by Belgium and Sweden, that the efficacy of the product has not been sufficiently demonstrated.

The referral procedure started on 12 November 2008. The Rapporteur and Co-Rapporteur appointed were: Prof. Christian Friis and Dr Valda Sejane, respectively. Written explanations were provided by the Applicant on 16 February 2009. Oral explanations were given on 16 June 2009.

Based on the evaluation of the rapporteurs' assessment of the currently available data, the CVMP considered that the application does not satisfy the criteria for authorisation in respect of efficacy. Therefore, the Committee adopted an opinion on 15 July 2009 recommending the suspension of the existing marketing authorisation and the refusal of the granting of the marketing authorisations for Tildren 500 mg, lyophilisate for solution for infusion.

On 5 August 2009, CEVA Animal Health Ltd notified the Agency of its intention to request a re-examination of the CVMP opinion of 15 July 2009.

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

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During its 15-17 September 2009 meeting, the CVMP appointed Dr David Murphy as rapporteur and Dr Jiří Bureš as co-rapporteur for the re-examination of the above mentioned opinion.

The detailed grounds for the re-examination were submitted by CEVA Animal Health Ltd on 21 September 2009 and the re-examination procedure started on 22 September 2009.

Based on the evaluation of the rapporteurs' assessment of the detailed grounds for the re-examination, on 11 November 2009, the CVMP considered the rapporteurs' proposal for amending the opinion adopted on 15 July 2009. The proposal was rejected by the majority of CVMP members. Given that no absolute majority was attained, the opinion of 15 July 2009 stands.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II.

The opinion was converted into a Decision by the European Commission on 22 July 2010.