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Veterinary Medicines

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for long-acting formulations for injection containing barium selenate for all food producing species

International non-proprietary name (INN): barium selenate

Background information

Selenium is an essential micronutrient for both animals and man. Barium selenate has been used in slow-release injectable veterinary medicinal products for therapeutic and prophylactic use against selenium deficiencies in cattle and sheep.

On 14 September 2011, Germany presented to the Agency a referral notification under Article 35 of Directive 2011/82/EC, regarding all long-acting formulations for injection containing barium selenate for all food producing species. Germany referred the matter to the CVMP due to serious human health concerns related to exposure to injection site residues from the use of long-acting barium selenate-containing injectable veterinary medicinal products.

The referral started on 15 September 2011. The Committee appointed C. Ibrahim as rapporteur and H. Jukes as co-rapporteur. Written explanations were provided by the applicants and marketing authorisation holders on 14 November 2011 and on 30 November 2012. An oral explanation was given by the applicant/marketing authorisation holders on 6 March 2013.

Based on the evaluation of the available data, the CVMP considered that the benefit-risk balance for the concerned veterinary medicinal products was negative as, following treatment at recommended doses, barium selenate remains at injection sites for long time periods after treatment and, consequently, consumption of injection-site residues could pose a significant risk to human health. The Committee therefore adopted by majority a negative opinion on 10 April 2013, recommending suspension of the marketing authorisations for all concerned products.

[1] Article 35 of Directive 2001/82/EC, as amended

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On 26 April 2013, Cross Vetpharm Group Limited and Tairgi Tread-Lia Baile na Sceilge Teo (Ballinskelligs Veterinary Products – BVP) notified the Agency of their intention to request a re-examination of the CVMP opinion of 10 April 2013.

During its meeting of 14-16 May 2013 the CVMP appointed K. Törneke as rapporteur and K. Baptiste as co-rapporteur for the re-examination procedure.

The consolidated detailed grounds for the re-examination were submitted by Cross Vetpharm Group Limited and Tairgi Tread-Lia Baile na Sceilge Teo (Ballinskelligs Veterinary Products – BVP) on 10 June 2013. The re-examination procedure started on 11 June 2013.

On 17 July 2013, the CVMP adopted by majority an opinion confirming the recommendation for suspension of the marketing authorisations for the concerned veterinary medicinal products.

On 23 August 2013, the European Commission requested the CVMP to review its opinion, mainly to clarify some aspects related to consumer risk assessment.

On 6 November 2013, the CVMP adopted by majority a revised opinion confirming the recommendation included in its opinion of 17 July 2013, that the benefit-risk balance for the concerned veterinary medicinal products was negative and therefore the CVMP recommended the refusal of the granting of the marketing authorisation and suspension of the existing marketing authorisations for the products concerned.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the condition to lift the suspension of the marketing authorisations in Annex III.

The revised opinion was converted into a Decision by the European Commission on 28 March 2014.