EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 34[1] referral for Linco-Spectin 100 and associated names

International non-proprietary name (INN): lincomycin and spectinomycin

Background information

Linco-Spectin 100 is a powder for oral solution containing 33.3 g lincomycin (as lincomycin hydrochloride) and 66.7 g spectinomycin (as spectinomycin sulphate) per 150 g pack. Lincomycin is a lincosamide antibiotic, closely related to macrolide and streptogramin B antimicrobials. Spectinomycin is classified as an aminocyclitol antibiotic, close to aminoglycosides.

Due to divergent national decisions taken by Member States with respect to target species, indications, posology and withdrawal periods concerning the authorisations of Linco-Spectin 100 and its associated names, on 28 September 2012 Belgium referred the issue to the CVMP under Article 34(1) of Directive 2001/82/EC, in order to resolve divergences in the nationally authorised product information across the European Union.

The referral procedure started on 10 October 2012. The Committee appointed B. Urbain as rapporteur and C. Muñoz Madero as co-rapporteur.

Written explanations were provided by the marketing authorisation holders on 10 September 2013 and 10 February 2014.

Based on the evaluation of the currently available data, the CVMP considered that the benefit-risk profile of of Linco-Spectin 100 and its associated names remains positive, subject to variation of the marketing authorisations in accordance with the recommended product information. The Committee adopted a positive opinion by consensus on 10 April 2014.

[1] Article 34 of Directive 2001/82/EC, as amended

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The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amended summary of product characteristics, labelling and package leaflet in Annex III.

The final opinion was converted into a Decision by the European Commission on 11 July 2014.