1 July 2010
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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for all veterinary medicinal products containing quinolones including fluoroquinolones intended for use in food-producing species

Background information

On 28 April 2009, the European Commission presented to the Agency a referral notification under Article 35 of Directive 2001/82/EC, regarding all veterinary medicinal products containing quinolones including fluoroquinolones intended for use in food-producing species. The aim of the referral was to ensure that the products identified are indicated only for appropriate conditions, that dosage strategies are set to minimise the likelihood of development of antimicrobial resistance and that appropriate withdrawal periods are fixed to guarantee consumer protection.

On 15 May 2009 the European Commission submitted a revised notification to the Agency, in which it agreed to the CVMP proposal to take a step-wise approach to achieve the aim mentioned above and to limit the scope of the current referral procedure to the harmonisation of the warnings on prudent use included in the Summary of Product Characteristics (SPCs) for these classes of veterinary medicinal product in line with those recommended in the CVMP document *"Reflection paper on the use of fluoroquinolones in food-producing animals – Precautions for use in the SPC regarding prudent use guidance* (EMEA/CVMP/416168/2006)*"*.

The referral procedure started on 13 May 2009. The rapporteur and co-rapporteur appointed were: Mrs R. Kearsley and Dr J.G. Beechinor, respectively. Written explanations were provided by the applicants/marketing authorisation holders on 18 August 2009.

Based on the rapporteurs' assessment of the available data, the CVMP adopted, on 11 November 2009, an opinion recommending variations of the marketing authorisations for medicinal products containing (fluoro)quinolones intended for food-producing species in order to amend the SPCs and package leaflets in those cases where these were not in line with the prudent use warnings recommended in the CVMP *reflection paper on the use of fluoroquinolones in food-producing animals – Precautions for use in the SPC regarding prudent use guidance.*

[1] Article 35 of Directive 2001/82/EC

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On 23 November 2009, Ascor Chimici s.r.l., and on 3 December 2009, Ceva Santé Animale notified the Agency of their intention to request the re-examination of the CVMP opinion adopted on 11 November 2009.

During its meeting of 8-10 December 2009 the CVMP appointed Dr J. Hederová as the rapporteur and Dr J. Bureš as the co-rapporteur for the re-examination procedure.

The detailed grounds for the re-examination were submitted to the Agency by 18 January 2010 and the procedure started on 19 January 2010. The issues considered during the re-examination related to the evaluation of the prudent use warnings for specific products and not to the overall CVMP recommendation.

On 9 March 2010 the CVMP adopted a final opinion confirming the recommendation, included in its opinion of 11 November 2009, that variations are necessary to the terms of the marketing authorisations for veterinary medicinal products containing (fluoro)quinolones intended for food-producing species where it has been identified that the SPC and package leaflet have not been updated in line with the precautionary phrases in the CVMP "*Reflection paper on the use of fluoroquinolones in food-producing animals – Precautions for use in the SPC regarding prudent use guidance*" (EMEA/CVMP/416168/2006).

The CVMP conclusions relating to the specific products that were the focus of the re-examination procedure are reflected in Annex II (Scientific conclusions) of the CVMP opinion.

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 and package leaflet in the Annex III.

The final opinion was converted into a Decision by the European Commission on 1 July 2010.