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Veterinary Medicines Division

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Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 35[1] referral for veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses

International non-proprietary name (INN): gentamicin

Background information

Gentamicin is an aminoglycoside antibiotic indicated for the treatment of a variety of bacterial infections. It is normally used as the sulphate salt. In veterinary medicine gentamicin is used mainly as a solution for injection for pigs, cattle and horses and as an oral solution for poultry. It is also used in human medicine, usually as a solution for injection for intramuscular administration. It is currently included in the list of essential medicines for human use of the World Health Organisation (WHO).

On 14 February 2014, Denmark presented to the Agency a referral notification under Article 35 of Directive 2011/82/EC, regarding veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses. The CVMP was requested to harmonise the indications and dosing regimens of the concerned products, taking into account the available data and in particular with regard to the target animal safety.

The referral started on 12 March 2014. The Committee appointed K. Baptiste as rapporteur and C. Muñoz Madero as co-rapporteur. Written explanations were provided by the applicants and marketing authorisation holders on 16 May 2014 and 4 September 2014.

Based on the evaluation of the currently available data, the CVMP considered that the overall benefit-risk profile for these products remains positive subject to amendments in the product information. Therefore, on 6 November 2014 the Committee adopted by consensus a positive opinion, recommending variations to the terms of the marketing authorisations for veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses.

[1] Article 35 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 amendments in the summaries of product characteristics, labelling and package leaflets in Annex III.

The final opinion was converted into a Decision by the European Commission on 11 February 2015.