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Veterinary Medicines Division

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Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 35¹ referral for veterinary medicinal products containing colistin to be administered orally

International non-proprietary name (INN): colistin

Background information

Colistin sulfate belongs to the polymyxin group of antibiotics. This group of antibiotics has a polypeptide structure, with mainly bactericidal activity and a medium antibacterial spectrum, which covers Gram-negative microorganisms only.

Veterinary medicinal products containing colistin as a sole active substance for oral administration in food producing animals are widely used in almost all EU Member States. Oral colistin formulations including powder, solution, premix, tablets and paste have been authorised, mainly for group and flock treatment for the treatment and prevention of different specified gastrointestinal diseases caused by sensitive Enterobacteriaceae species (e.g. *Salmonella* and *Escherichia coli*), but marketing authorisations without more specific indications do also exist. The most common target species are pigs followed by chicken and cattle then other poultry species (e.g. turkeys), horses, rabbits, sheep and goats.

On 12 May 2014, the European Commission presented to the Agency a referral notification under Article 35 of Directive 2011/82/EC, regarding veterinary medicinal products containing colistin to be administered orally. The CVMP was requested to give its opinion on the measures that need to be taken in order to ensure the prudent use of colistin in food-producing animals across the EU and to minimise potential risks with the use of the identified products; *inter alia* whether there is a need to include adequate indications and warnings on prudent use in the product information and/or restrict indications for the identified products taking into account the CVMP revised guideline on the SPC for antimicrobial products (EMA/CVMP/SAGAM/383441/2005) ².

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

² CVMP revised guideline on the SPC for antimicrobial products (EMA/CVMP/SAGAM/383441/2005)
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/02/WC500070670.pdf



The referral started on 4 June 2014. The Committee appointed C. Ibrahim as rapporteur and M. Holzhauser-Alberti as co-rapporteur. No written comments on the recommendations and proposed changes in the product information were provided by the applicants and marketing authorisation holders.

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 11 December 2014 the Committee adopted by consensus a positive opinion, recommending variations to the terms of the marketing authorisations for veterinary medicinal products containing colistin to be administered orally.

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 16 March 2015.