EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 July 2014
EMA/492247/2014
Veterinary Medicines Division

EMEA/V/A/100

Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs

International non-proprietary name (INN): tylosin

Background information

Tylosin is a macrolide antibiotic which is produced by *Streptomyces fradiae*. It is active mostly against Gram-positive bacteria and mycoplasmas. It is ineffective against *Enterobacteriaceae*. Tylosin and its phosphate and tartrate salts are used in food producing species for the treatment of conditions caused by sensitive organisms. It may be administered by oral or parenteral routes. Tylosin is not used in human medicine.

On 30 October 2013, Sweden presented to the Agency a referral notification under Article 35 of Directive 2011/82/EC, regarding veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs. The CVMP was requested to consider whether tylosin is still effective against swine dysentery (caused by *Brachyspira hyodysenteriae*) and whether the treatment durations beyond three weeks are justified.

The referral started on 6 November 2013. The Committee appointed E. Persson as rapporteur and A. Wachnik-Święcicka as co-rapporteur. Written comments on the recommendations and proposed changes in the product information were provided by the applicants and marketing authorisation holders on 7 March 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 8 May 2014 the Committee adopted by consensus a positive opinion, recommending variations to the terms of the marketing authorisations for veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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 31 July 2014.