10 July 2017
EMA/399858/2017
Veterinary Medicines Division

Questions and answers on veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma* spp.

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/121)

On 16 March 2017, the European Medicines Agency (the Agency) completed a review of the effectiveness of veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma* spp. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that, in the absence of pre-clinical or clinical data, treatment of bovine mastitis caused by *Mycoplasma* spp. with the aforementioned veterinary medicinal products is not effective. The CVMP recommended deletion of the indications related to 'bovine mastitis caused by *Mycoplasma* spp.' or 'bovine mastitis caused by *Mycoplasma bovis*' from the product information for the products concerned.

What is tylosin?

Tylosin is a macrolide antibiotic and is active mostly against Gram-positive bacteria and mycoplasmas. Tylosin and its phosphate and tartrate salts are used in veterinary medicines for treatment of conditions caused by sensitive organisms.

Why were veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma* spp. reviewed?

Finland considered that ineffective treatment of mycoplasma mastitis with tylosin presents a serious concern to animal and public health as it delays the correct diagnosis, enables spread of the pathogen to other cows, impedes efficient/prudent control measures and increases risk for the development of antimicrobial resistance due to unnecessary use of antimicrobials.

On 22 June 2016, Finland initiated a referral procedure under Article 35 of Directive 2001/82/EC for the aforementioned veterinary medicinal products. The CVMP was requested to review all available data and to provide its opinion on whether the indication related to 'bovine mastitis caused by *Mycoplasma* spp.' is justified.

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Which data has the CVMP reviewed?

In the absence of submitted proprietary pre-clinical or clinical data for the products in the scope of this referral in support of the respective indication, the CVMP considered scientific references on efficacy.

What are the conclusions of the CVMP?

Based on the evaluation of the currently-available data, the CVMP concluded that, in the absence of specific pre-clinical or clinical data, and in light of the current scientific knowledge, the indication for treatment of bovine mastitis caused by *Mycoplasma* spp. with veterinary medicinal products containing tylosin which are administered parenterally is not supported. The Committee recommended variations to the terms of the marketing authorisations for the aforementioned veterinary medicinal products in order to remove the indications 'bovine mastitis caused by *Mycoplasma* spp.' or 'bovine mastitis caused by *Mycoplasma bovis*' from the product information.

The European Commission issued a decision on 10 July 2017.