17 April 2020
EMA/78778/2020
Veterinary Medicines Division

Questions and answers on the review of withdrawal periods for injectable veterinary medicines containing tylosin base when given to pigs

Outcome of a procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/131)

On 5 December 2019, the European Medicines Agency (the Agency) completed a review of the withdrawal periods for injectable veterinary medicines containing tylosin base when used in pigs. The withdrawal period is the minimum time that has to elapse before an animal treated with a medicine can be slaughtered so that its meat or other animal derived products may be used for human consumption.

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of these medicines continue to outweigh its risks but that the maximum injection volume per site and the withdrawal periods for pigs should be changed.

What is tylosin base?

Tylosin base is a macrolide antibiotic used mainly to treat infections caused by certain types of bacteria and mycoplasmas. Veterinary medicines containing tylosin base can be used in pigs, by injection into the muscle.

Why were veterinary medicines containing tylosin base reviewed?

On 16 January 2019, the French veterinary medicines authority requested that the CVMP review all available data and recommend withdrawal periods for meat and offal from pigs treated with injectable veterinary medicines containing tylosin base.

The French authority considered that the withdrawal periods for pigs in the European Union (EU) might not be adequate to ensure consumer safety, noting that withdrawal periods differed across the EU: from 5 to 46 days for pigs meat and offal.

Consequently, the French authority asked the CVMP to carry out a full assessment of the benefit-risk balance of veterinary medicines containing tylosin base and to issue an opinion on whether the marketing authorisations for the above-mentioned products should be maintained, varied, suspended or withdrawn across the EU.

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Which data has the CVMP reviewed?

The CVMP reviewed available data on residue depletion of tylosin residues in pigs, which indicates how long a medicine takes to fall below maximum residue limits (MRLs) in the animal's body. These included data from companies, from National Competent Authorities and from the published literature.

What are the conclusions of the CVMP?

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CVMP concluded that, for 131 out of 132 products, those containing up to 200 mg tylosin base per ml, the withdrawal period for meat and offal from treated pigs should be 16 days, with a limit to the injection volume of 5 ml.

For one medicine, Tylobel 25%, which contains 250 mg tylosin base per ml, the CVMP concluded that the withdrawal period for meat and offal from treated pigs should be 18 days, with a limit to the injection volume of 4 ml.

The Committee recommended the variation of the marketing authorisations for these veterinary medicines.

The full changes made to the product information are detailed in Annex III of the CVMP opinion under 'All documents'.

The European Commission issued a decision on 17 April 2020.