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Veterinary Medicines Division

Questions and answers on suspension of marketing authorisations for injectable veterinary medicines containing paromomycin given to pigs

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/129)

On 18 July 2019, the European Medicines Agency recommended suspending the marketing authorisations for paromomycin antibiotics given to pigs by injection into a muscle. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of these medicines do not outweigh their risks because of inadequate data supporting their use in pigs and the possibility of bacterial resistance.

What is paromomycin?

Paromomycin is an aminoglycoside antibiotic used to treat a wide range of bacterial infections and is given to pigs by injection into a muscle.

Why were veterinary medicines containing paromomycin reviewed?

On 25 September 2018, the Belgian medicines authority requested that the CVMP review all available data on paromomycin's effectiveness and residue depletion (how long a medicine takes to fall below maximum residue limits (MRLs) in the animal's body).

The Belgian authority noted that there were different approved uses, dose schedules and withdrawal periods across the EU. The withdrawal period is the minimum time that has to elapse before an animal treated with a medicine can be slaughtered and its meat or other animal derived products may be used for human consumption.

Which data has the CVMP reviewed?

The CVMP reviewed available data on effectiveness and residue depletion. These included data from companies and published literature.

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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 the benefits of veterinary medicines containing paromomycin given to pigs by injection into the muscle do not outweigh their risks. The Committee based its opinion on the lack of adequate data on how effective these medicines are and residue depletion data. The Committee also noted the possibility that inappropriate doses could lead to bacterial resistance.

Therefore, the CVMP recommended suspending the marketing authorisations for these veterinary medicines until adequate data are available.

The European Commission issued a decision on 11 October 2019.