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Veterinary Medicines Division

Questions and answers on use of enrofloxacin-containing veterinary medicines administered via drinking water to chickens and turkeys

Follow-up assessment after the referral under Article 35 of Directive 2001/82/EC (EMEA/V/A/089)

On 14 February 2018, the European Medicines Agency updated its recommendations for enrofloxacin-containing medicines administered via drinking water to chickens and turkeys. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that these products should no longer be used in chickens and turkeys to treat *Escherichia coli* infections and that the product information for the products should be amended accordingly.

What is enrofloxacin?

Enrofloxacin is an antibiotic belonging to class 'fluoroquinolones'. It works against a broad spectrum of Gram-negative and Gram-positive bacteria as well as *Mycoplasma spp*.

Enrofloxacin is for veterinary use only.

Why were enrofloxacin-containing veterinary medicines administered via drinking water to chickens and turkeys reviewed?

In November 2013, the CVMP made recommendations for these products to ensure that they are used appropriately in chickens and turkeys, and to lower the risk of bacteria developing resistance to enrofloxacin. At that time, marketing authorisation holders were required to provide more data to justify the dosage of enrofloxacin used in poultry. The CVMP has now reviewed these data and has updated its recommendations on the use of enrofloxacin in chickens and turkeys.

Which data has the CVMP reviewed?

The CVMP reviewed the available pre-clinical (laboratory) and clinical data (in chickens and turkeys) on enrofloxacin. These included data from companies and from the published literature.

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What are the conclusions of the CVMP after the follow-up assessment?

Following review of the relevant information submitted in 2013 (during the initial phase of the referral procedure) and the additional data provided by the marketing authorisation holders as a follow-up of the Commission Implementing Decision (C(2014) 1484), in February 2018 the CVMP concluded that the outstanding concern over optimisation of the dosage regimen for the treatment of *Escherichia coli* infections was not resolved. The CVMP noted that the marketing authorisation holders had not demonstrated that the current dosage regimen for *Escherichia coli* in chickens and turkeys is optimal from a clinical perspective nor proposed a new dosage regimen.

The CVMP considered that the currently-approved dosage may accelerate development of bacterial resistance to enrofloxacin, which would limit its use as treatment of last resort for colibacillosis in poultry. Therefore, the CVMP concluded that enrofloxacin should no longer be used for treatment of *Escherichia coli* infections in chickens and turkeys and recommended that the product information of the concerned products be amended accordingly.

The marketing authorisation holders were advised to contact the National Competent Authorities of the Member States in order to discuss the next steps for the implementation of CVMP's recommended changes to the product information.