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PRESS RELEASE

European Medicines Agency is consulting on the reflection paper on the use of fluoroquinolones in food-producing animals in the European Union: development of resistance and impact on human and animal health

The EMEA's Committee for Medicinal Products for Veterinary Use (CVMP) has launched a three-month consultation period on a reflection paper on the use of fluoroquinolones in food-producing animals in the European Union, its effect on the development of resistance in certain bacterial species and the potential impact on human and animal health.

Fluoroquinolones are very potent antimicrobial agents used for the treatment of severe infections in humans and animals.

On a mandate of the CVMP, the Scientific Advisory Group on Antimicrobials critically reviewed recent data on the use of fluoroquinolones in food-producing animals. The reflection paper is based on the findings and conclusions of the Scientific Advisory Group including concrete proposals by the CVMP for risk management actions.

The document "Reflection paper on the use of fluoroquinolones in food-producing animals in the European Union: Development of resistance and impact on human and animal health" (EMA/CVMP/SAGAM/184651/2005-CONSULTATION)" has been released in January 2006 for a period of 3 months of public consultation and is available at the EMEA website:
<http://www.emea.eu.int/hums/vet/swp/srantimicrobial.htm>.

Conclusions from the reflection paper:

- The use of (fluoro)quinolones in animals has selected for resistance in animal pathogens and food borne zoonotic pathogens resulting in negative effects on treatment of infections with these organisms in animals and humans.
- In humans, fluoroquinolones are considered critically important antimicrobials for severe and invasive infections. These infections are predominantly caused by organisms unrelated to animals. Most of the problems with resistance in human medicine are correlated to use of antimicrobials in humans.
- In humans treatment of uncomplicated acute gastroenteritis caused by *Salmonella* or *Campylobacter* with antibiotics is not indicated and in some countries even contra-indicated. For treatment of complicated *Salmonella* infections in humans and in patients at risk fluoroquinolones are important. Resistance to (fluoro)quinolones affects the therapeutic options, but alternative antibiotics exist. For treatment of complicated *Campylobacter* infections in humans and in patients at risk, macrolides (erythromycin, azithromycin) are considered the drugs of choice.
- Infections in humans with nalidixic acid resistant *Salmonella Typhimurium* have resulted in increased risk of hospitalisation and mortality. Infections in humans with fluoroquinolone and macrolide resistant *Campylobacter* have resulted in increased risk of hospitalisation and complications.
- For animals, fluoroquinolones are efficient and valuable antimicrobials. For some serious animal indications, fluoroquinolones are the only alternative available. If (fluoro)quinolones lose their activity or are no longer available for the treatment of animal diseases, antimicrobial therapy of

some diseases will be complicated and may result in animal welfare and public health concerns, and economical losses.

- Currently there is no harmonised approach in the conditions for use of fluoroquinolones in food-producing animals through the different Member States of the EU. International bodies (e.g. WHO, OIE) and regulatory authorities have concerns on development of antimicrobial resistance in human and animal pathogens. Antimicrobial resistance should be addressed internationally as resistant bacteria can spread via imported food.
- When monitoring for resistance to fluoroquinolones in *Salmonella* nalidixic acid should be used as a marker for decreased susceptibility. Alternatively low breakpoints for fluoroquinolones could be used.
- When monitoring for resistance to fluoroquinolones in *Campylobacter* either nalidixic acid or fluoroquinolones can be used.
- Increasing amounts of data on the use of antimicrobial agents and the occurrence of antimicrobial resistance are available, but harmonisation still needs to be improved.
- There is a need for risk management interventions regarding the use of fluoroquinolones for humans and animals.

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