



COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Reflection paper on the use of fluoroquinolones in food producing animals - Precautions for use in the SPC regarding prudent use guidance -

Introduction:

The CVMP adopted in January 2006 a 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 (EMEA/CVMP/SAGAM/184651/2005-CONSULTATION). The document critically reviews recent information on the use of quinolones and fluoroquinolones in food-producing animals in the EU, its effect on the development of resistance to this category of antimicrobial agents in bacterial species that are of importance for human and animal health, and the potential impact on human and animal health. Based on the scientific considerations and conclusions, the CVMP made proposals for a series of risk management actions. One of the recommendations for suggested actions was to include prudent use guidance in the Summary Product Characteristics (SPCs) and product literature of all (fluoro)quinolone-containing veterinary medicinal products indicated for food producing species.

On 12 October 2006 a Focus Group meeting of the CVMP with Interested Parties and Member States took place to discuss the reflection paper and its recommendations. Following the Focus Group meeting the proposed precautionary phrases to be included in the SPC were finalised by the CVMP considering comments received from IFAH Europe based on the existing precautionary phrases for centralised marketing authorisations or authorisations adopted under the mutual recognition procedure.

As fluoroquinolones and quinolones have different characteristics, and different impact on antimicrobial resistance, the phrases should be different for those two types of substances. The following precautionary phrases were agreed:

All fluoroquinolone products

“Official and local antimicrobial policies should be taken into account when the product is used.”

“Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.”

“Whenever possible, fluoroquinolones should only be used based on susceptibility testing.”

“Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.”

Quinolone products¹ (eg flumequine, oxolinic acid)

“Official and local antimicrobial policies should be taken into account when the product is used.”

“Whenever possible, quinolones should only be used based on susceptibility testing”

“Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the quinolones and may decrease the effectiveness of treatment with other (fluoro)quinolones due to the potential for cross resistance.”

¹ Not required for decoquinatate