



PRESS RELEASE

Focus Group Meeting of CVMP Experts, Interested Parties and Member States

Reflection paper on the use of fluoroquinolones in food-producing animals

On 12 October 2006 a Focus Group meeting of the Committee for Medicinal Products for Veterinary Use (CVMP) with Interested Parties and Member States took place to discuss the CVMP 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- CONSULTATION¹).

This document is a technical reflection on the current status of the use of quinolones and fluoroquinolones as veterinary medicines in the EU and its effect on the development of resistance in certain bacterial species and the potential impact on human and animal health. On a mandate of the CVMP, the Scientific Advisory Group on Antimicrobials (SAGAM) critically reviewed recent data on the use of (fluoro)quinolones 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 was published for consultation. The meeting was attended by representatives of the CVMP and its Scientific Advisory Group, national competent authorities of Member States, members of the animal health industry (IFAH-Europe², AVC³), and other organisations (The Soil Association and the Poultry Health Services, both UK).

The objective of the meeting was to address:

- the recommendations made in the Reflection paper and, in particular, the conditions for the marketing authorisations for new and existing veterinary medicines containing quinolones or fluoroquinolones,
- how to ensure prudent use of quinolones and fluoroquinolones including the implementation of internationally agreed prudent use guidance,
- the education of veterinarians and others involved in the use of antimicrobials in animals.

The meeting was considered successful by all participants. It was agreed that precautionary phrases should be included in the Summary Product Characteristics (SPCs) of all veterinary medicines containing quinolones or fluoroquinolones. Experts of the CVMP and SAGAM are currently considering the exact wording to be proposed, based on phrases included in the literature for currently authorised products. Once agreed, liaison will take place with the Heads of Veterinary Medicines Agencies (HMA-V) with a view to harmonised implementation across Europe. It is hoped that these measures can be put in place through voluntary agreement between licensing authorities and manufacturers and that there will be

¹ <http://www.emea.europa.eu/pdfs/vet/srwp/18465105en.pdf>

² International Federation for Animal Health Europe

³ Association of Veterinary Consultants

no need to use the legal provisions that exist for compulsory enforcement. The meeting recognised the key role to be played by the network of national regulatory agencies, coordinated by the HMA-V, in successful implementation of these measures.

The meeting agreed that monitoring of the implementation of the measures would be needed and that a first analysis of the success of the approach adopted would be proposed to HMA-V to take place in November 2006.

The meeting agreed that inclusion of advice on product literature was only a first step towards implementing an effective policy to ensure the prudent use of antimicrobials in veterinary medicine across the EU. Among the additional proposals discussed were measures to ensure that products are indicated only for appropriate conditions and that dosage strategies are set to minimise the likelihood of development of antimicrobial resistance. Training of veterinarians in the principles and practice of prudent use was seen as an essential step in implementing an effective policy.

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