



## COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

### Informal CVMP meeting, Athens, 20 and 21 May 2003

#### Future Strategy on Antimicrobial Resistance

The CVMP at its Athens meeting during the Greek Presidency reviewed its Risk Management Strategic Plan of January 2000 and following the adoption of 3 key guidelines recently adopted by the Committee which aim to minimize resistance development and encourage prudent use of antimicrobials.

A representative from the DG for Health and Consumer Protection in the Commission explained to the Committee the multiple initiatives already taken in consideration of antimicrobial resistance at Community level in human and animal health. Special emphasis was made by the Commission on the networks at Member States level and international level in dealing with antimicrobial resistance in human and veterinary medicine and the considerations being given to improving surveillance mechanisms to monitor resistance and consumption patterns.

The Committee agreed to prepare a Workshop with its Interested Parties on the interpretation of the guidelines recently adopted on antimicrobial substances. The Workshop should take place during Autumn/Winter 2003 where regulators and stakeholders will be invited to participate.

#### Antimicrobial Surveillance

The Committee was pleased to note the considerable progress made in the implementation of its Risk Management Strategic Plan and acknowledged the various initiatives taken by the Commission to provide detailed data on reference to the use of antimicrobials, from the different Member States. It was hoped that such data would also include the consumption data on quantity of antimicrobials in veterinary medicine, its use by species and class of antimicrobials. Data should be used for post-marketing authorization surveillance and should be related to the use of veterinary medicinal products in treatment and control. It was agreed that representations of the Committee's reflections should be communicated in a paper to the Commission.

#### Other subjects that would require further discussion at the CVMP:

##### **Further consideration of relation between use of antimicrobials in veterinary medicine and onset of resistance in human medicine and any measures that may help in minimizing the problem**

##### **Data on the SPCs to ensure better information for users for more accurate administration**

- Inclusion of MIC data.
- Considerations on the establishment of breakpoints.
- Discussion on if and when prophylaxis is appropriate.

##### **Reporting of antimicrobial resistance in PSURs – inclusion of surveillance of antimicrobial resistance**

- Application of current guidelines during the renewal process on existing products.

**Surveillance – data to be provided**

- Consumption data by species and class of product/substance: Further liaison between CVMP and Commission is recommended, especially on quinolone substances. That information should be obtained from relevant networks from Member States.
- Data from human use would also be relevant for the assessment of veterinary medicinal antimicrobials.
- The use of antimicrobials in pets and its relevance for antimicrobial resistance should also be considered.

**Prudent use**

- The CVMP wishes to encourage the need for and continue education to improve the information provided to veterinarians and farmers.
- To encourage further promotion of prudent use by the pharmaceutical industry.

**Assessment of data from risk**

- The CVMP will develop guidance on how to assess the data provided in accordance with the pre-authorisation guideline and antimicrobial resistance surveillance data.
- Continued liaison with the relevant groups currently dealing with antimicrobial resistance e.g. CPMP, DG for Health and Consumer Protection will need to be created.