EUROPEAN COMMUNITY COMMENTS ON DOCUMENT CX/RVDF 03/6

Agenda Item 7: Draft Code of Practice to Minimize and Contain Antimicrobial Resistance

The European Community would like to thank the United States of America and the drafting group for the preparation of this draft Code of Practice to minimise and contain antimicrobial resistance. The efforts undertaken by the United States of America to achieve consensus on the text in the drafting group is highly appreciated.

The European Community is generally in agreement with the drafting document and its scope, although there are concerns related to animal and consumer safety with respect to the wording of the paragraphs on requirements for prescriptions for antibiotic veterinary medicinal products and the phasing out of antimicrobials for non-therapeutic use.

Furthermore, the decision of the drafting group to refer the matters of definitions of non-therapeutic and therapeutic use as well as criteria to be applied for the definition of a critical human disease and drugs of importance to human medicinal therapy to CCRVDF is supported. The European Community notes that a definition for a veterinary medicinal product has already been adopted at the first session of CCRVDF, which include therapeutic, prophylactic or diagnostic use or use with a view to modify physiological functions of behaviour. Thus, non-therapeutic use could be defined by exception of therapeutic use from this definition. The European Community proposes the following definition for discussion in the plenary session: *"non-therapeutic use of antimicrobial means any use of these substances which is not intended to treat or prevent a specific diagnosed disease. It includes for example the use of antimicrobials as growth promoter*."

The European Community finds that a definition of critical human diseases and drugs of importance to human medicinal therapy should not be pursued due to regional variations and evolution in the disease patterns. It is nevertheless considered that such a general reference could be useful for national governments in their consideration of risk management measures.

As regards the other issues for consideration by CCRVDF, namely environmental concerns and specific guidance on pharmacokinetic studies, the European Community considers these areas

outside the scope of both the drafting group and CCRVDF. Development of protocols for scientific studies does not fall within the terms of reference of CCRVDF.

A number of technical comments on the text are provided below.

- In paragraph 10 we find that the text should be revised to restrict the use of antimicrobials to therapeutic use and therefore should in principle only be available on prescription. The reference to the draft guideline published by OIE is questionable as long as it has not been adopted as an OIE standard. Furthermore, there are numerous guidelines on prudent use of antibiotics, which advocate use of antimicrobials on a prescription only basis. The last sentence of paragraph 10 should therefore be deleted. The word food animals in the second sentence should be changed to food producing animals.
- In Paragraph 12 it is assumed that the country in which a veterinary medicinal product is produced automatically also authorises the use of the substance in its own constituency. This is however not the case. A country without the necessary resources to implement an efficient authorisation procedure whose supply mostly depends on import should therefore *"seek information on authorisations valid in other country/countries."* (second bullet point).
- As the scope of the Code is antimicrobial resistance, this should be fully reflected in the document by replacing bacteria with micro-organisms in paragraphs 18 (1st bullet point), 21 (2nd bullet point), 48 (4th bullet point 2nd indent and 5th bullet point 2nd indent). The word antibacterials should be replaced by antimicrobials in paragraph 48 (5th bullet point, 1st and 2nd indent). In paragraph 59, 'bacterial diseases' should be changed to 'infectious diseases'.
- In paragraph 23, 4th line the word '*controls*' is better replaced by '*posology*'.
- In paragraph 26, reference could be made to international guidelines in the area elaborated in the framework of the international co-operation on harmonisation of technical requirements for registration of veterinary medicinal products (VICH) and adopted by some regions.
- In paragraph 30, it is stated that surveillance programmes should be established from the results of a risk analysis. Although the results of risk analyses are very useful in this context, in most cases such results are not readily available. Therefore, the results of risk analyses should not be understood as a precondition for establishing surveillance programmes. Instead the second sentence of paragraph 30 should start as follows "*The relevant authorities should implement a surveillance programme based on their national pattern of use of antimicrobials."*

- In paragraph 34, the 2nd bullet point should read as follows: "*is restricted to authorised professionals and in compliance with each country's legislation. This is considered to be important for the overall restrictions in use of antimicrobials"*.
- Paragraph 40 should read: "*only officially licensed/**authorised** products…..*"
- In the title preceding paragraph 46 reference should also be made to the *"other suitably and authorised persons*" mentioned on paragraph 10. Moreover the necessary adaptations should be made in the following paragraphs where reference is made to veterinarians.
- In paragraph 48, 3rd bullet point last indent, the words '*what time*' are better replaced by '*a specified*', and in the 7th bullet point the word '*manufacturer*'s' is better replaced by '*approved*'. The last paragraph of 48 should read "*In circumstances where recourse to accurate diagnosis and microbial susceptibility testing is impossible, but where it is very likely that animals have been exposed to pathogenic bacteria, it may be justified to treat animals nevertheless with antimicrobials in order to prevent the development of clinical disease and for reasons of animal welfare*".
- In paragraph 52, the last sentence does not provide sufficient safeguards for the consumer. In paragraph 7, it is stated that non-therapeutic use should be terminated or phased out in the absence of risk-based evaluations. It is therefore not conceivable that veterinarians have no responsibility in the control of such measures. The last sentence should preferably be modified as follows: "*Non-therapeutic use of antimicrobials should not be allowed, in the absence of risk based evaluations"*.
- In paragraph 58, 6th bullet point, the words "*provisions of the leaflet and package insert*' should be changed to '*approved product labelling"*.