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**Responsible and Prudent Use of
Antimicrobials in Aquatic Animals**

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Antimicrobial use in aquatic animals

- There is an urgent need to address the issues associated with antimicrobial use in aquatic animals;
- Very few effective compounds have been developed and authorised for use in aquatic animals;
- Use in aquatic animals involves the deliberate introduction of these chemicals into the food chain and the environment;
- Uncontrolled use can lead to the emergence of resistant bacteria, which reduces the therapeutic value of antimicrobials...leading to:
 - public perception of a "drug-based" industry and consumer aversion to aquaculture products.

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International standards: antimicrobial use

- The OIE recognises that this issue has important implications for human health, animal health and the environment;
- The OIE is developing standards and recommendations to Members through an *ad hoc* Group on Antimicrobial Resistance in Aquatic Animals;
- New *Aquatic Code Chapter 6.3. Principles for responsible and prudent use of antimicrobial agents in aquatic animals* - adopted in May 2011.

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Ch 6.3. Principles for responsible and prudent use of antimicrobial agents in aquatic animals

- Article 6.3.1. Purpose
- Article 6.3.2. Objectives of responsible and prudent use
- Article 6.3.3. Definitions
- Article 6.3.4. Responsibilities of Competent Authorities
- Article 6.3.5. Responsibilities of the veterinary pharmaceutical industry
- Article 6.3.6. Responsibilities of wholesale and retail distributors
- Article 6.3.7. Responsibilities of veterinarians and other aquatic animal health professionals
- Article 6.3.8. Responsibilities of aquatic animal producers
- Article 6.3.9. Training of users of antimicrobial agents
- Article 6.3.10. Research

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**Ch 6.3. Antimicrobials:
Responsible and Prudent Use**

Article 6.3.1. Purpose

- provide guidance for the responsible and prudent use of antimicrobial agents in aquatic animals, with the aim of protecting both animal and human health.
- obligations fall on:
 - *Competent Authorities* responsible for the registration and marketing authorisation of products
 - all organisations involved in the production, distribution and use.

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**Ch 6.3. Antimicrobials:
Responsible and Prudent Use**

Article 6.3.2. Objectives of responsible and prudent use

- maintain the efficacy of antimicrobial agents both for veterinary and human medicine;
- ensure the rational use of antimicrobials in aquatic animals;
- comply with the ethical obligation and economic need to keep aquatic animals in good health;
- prevent or reduce the transfer of both resistant micro-organisms and resistance determinants from aquatic animals to humans and terrestrial animals;
- prevent antimicrobial residues that exceed the established maximum residue limit (MRL) occurring in the food.

Ch 6.3. Antimicrobials: Responsible and Prudent Use



Article 6.3.3. Definitions

Article 6.3.4. Responsibilities of Competent Authorities

- promote prudent use of antimicrobial agents in aquatic animals as an element of a comprehensive strategy, e.g. good animal husbandry practices, vaccination policies...aimed at a reduction of the prevalence of animal disease requiring antimicrobial treatment;
- develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications;
- develop marketing authorisation criteria, including an assessment of the risks to animals, humans and the environment resulting from the use of antimicrobial agents in aquatic animals.

Ch 6.3. Antimicrobials: Responsible and Prudent Use



Article 6.3.4.

Responsibilities of Competent Authorities (cont.)

- ensure that advertising of antimicrobial agents complies with relevant legislation ;
- collect information through pharmacovigilance programmes, e.g. lack of efficacy;
- disseminate, to veterinarians or other aquatic animal health professionals, information on trends in antimicrobial resistance and monitor the performance of susceptibility testing laboratories;
- develop effective procedures for the safe collection and destruction of unused or out-of-date antimicrobial agents.

Ch 6.3. Antimicrobials: Responsible and Prudent Use



Article 6.3.5.

Responsibilities of the veterinary pharmaceutical industry

- provide information requested by Competent Authorities on the quality, efficacy and safety of antimicrobial agents;
- provide the Competent Authority with the information necessary to evaluate the amount of antimicrobial agents marketed;
- ensure that the advertising of antimicrobial agents directly to the aquatic animal producer is discouraged.

Ch 6.3. Antimicrobials: Responsible and Prudent Use



Article 6.3.6.

Responsibilities of wholesale and retail distributors

- ensure that their activities are in compliance with the relevant legislation;
- provide information for the appropriate use and disposal of the antimicrobial agent .

Ch 6.3. Antimicrobials: Responsible and Prudent Use



Article 6.3.7. Responsibilities of veterinarians and other aquatic animal health professionals

- Identify, prevent and treat aquatic animal diseases; promote sound animal husbandry methods, hygiene procedures, vaccinationto minimise the need for antimicrobial use;
- only prescribe, dispense or administer treatments with an antimicrobial agent for aquatic animals under their care;
- carry out a thorough clinical assessment of the aquatic animals, (e.g. clinical examination, post-mortem examination, bacteriology with culture and sensitivity, other laboratory tests) to arrive at the most definitive diagnosis possible before initiating a specific course of treatment with an antimicrobial agent.

Ch 6.3. Antimicrobials: Responsible and Prudent Use



Article 6.3.7. Responsibilities of veterinarians and other aquatic animal health professionals (cont.)

- susceptibility testing of the target micro-organism should be used to confirm the choice of treatment;
- inform the aquatic animal producer in detail of the treatment regime, including the dose, the treatment intervals, the duration of the treatment, the withdrawal period and the amount of antimicrobial agents to be delivered;
- Keep records on the use of antimicrobial agents in conformity with the relevant legislation.

Ch 6.3. Antimicrobials: Responsible and Prudent Use



Article 6.3.8. Responsibilities of aquatic animal producers

- implement health programmes on their farms in order to promote aquatic animal health and food safety;
- use antimicrobial agents only on the prescription of a veterinarian or other aquatic animal health professional, and follow directions on the dosage, method of application, and withdrawal period;
- ensure that antimicrobial agents are properly stored, handled, and disposed;
- keep adequate records of antimicrobial agents used;
- inform the veterinarian or other aquatic animal health professional of recurrent disease problems and lack of efficacy of antimicrobial agent treatment regimes.

Ch 6.3. Antimicrobials: Responsible and Prudent Use



Article 6.3.9. Training of users of antimicrobial agents

- should involve all the relevant organisations, such as relevant regulatory authorities, pharmaceutical industry, veterinary schools, research institutes, and veterinary professional organisations and other approved users such as aquatic animal owners.

Ch 6.3. Antimicrobials: Responsible and Prudent Use



Article 6.3.10. Research

- to address the significant lack of information for numerous species of aquatic animals, the relevant regulatory authorities and other stakeholders should encourage public-funded and industry-funded research.

Antimicrobials: Future Work



The AHG has developed new draft chapters on:

- Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals;
- Harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals List of priority bacteria;

These chapters will be reviewed by the AAHSC at their Oct. 2011 meeting and likely go out for Member comment.