

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

SEPTEMBER 2010 REPORT

USA COMMENTS

CHAPTER 6.3.

PRINCIPLES FOR RESPONSIBLE AND PRUDENT
 USE OF ANTIMICROBIAL AGENTS IN
~~VETERINARY MEDICINE~~ AQUATIC ANIMALS

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Article 6.3.2.

Objectives of prudent use

Prudent use includes a set of practical measures and recommendations intended to reduce the risk associated with the selection and dissemination of antimicrobial resistant micro-organisms and antimicrobial resistance determinants in *aquatic animal* production to:

1. maintain the efficacy of *antimicrobial agents* both for veterinary and, as applicable, human medicine and to ensure the rational use of antimicrobials in *aquatic animals* with the purpose of optimising both their efficacy and safety;

Rationale : antimicrobials used in aquatic animal medicine are not used in human medicine and, therefore, would not be expected to affect efficacy/safety in people. An example is hydrogen peroxide, which is approved by the US Food and Drug Administration (FDA) (www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042860.pdf) and labeled for use in fish against certain bacterial diseases. (www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/UCM051421.pdf). Hydrogen peroxide is not found in FDA's Orange Book (<http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>), is not approved as a drug for humans, and would therefore not be associated with failure of any therapeutic use in human medicine.

2.

5. ~~prevent the contamination of animal-derived food with antimicrobial residues that exceed the established maximum residue limit (MRL) occurring in the food.~~

Rationale : In the United States, Maximum Residue Limits (MRLs) are established for the purpose of human food safety, without stated intent to reduce the risk associated with the selection or dissemination of antimicrobial resistant microorganisms and antimicrobial resistance determinants. There is no evidence that clearly establishes any MRL with a reduction in risks associated with selection or dissemination of resistance or its determinants. Therefore, MRLs have no specific relevance to responsible and prudent use of antimicrobial agents. The United States recommends striking the entire sentence because the statement propagates the misconception that violative residues are commonplace and are a primary driver of human antimicrobial resistance trends.

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Article 6.3.4.

Responsibilities of the regulatory authorities

The ~~national~~ Regulatory Authorities, which are responsible for granting marketing authorization for antimicrobials, have a significant role in specifying the terms of the authorization and in providing the appropriate information to the *veterinarian* or other *aquatic animal* health professional through product labeling and/or by other means, in support of prudent use of veterinary antimicrobial drugs in *aquatic animals*.

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~~Regulatory~~ Competent authorities should disseminate, to *veterinarians* or other *aquatic animal* health professionals, information on trends in antimicrobial resistance collected during surveillance programmes and should monitor the performance of susceptibility testing laboratories.

The *Competent Authorities* should [work with relevant stakeholders](#) to develop effective procedures for the safe collection and destruction of unused or out-of-date antimicrobials.

Rationale: Effective guidance products in the United States have resulted from efforts between the Federal Government and stakeholders including the American Veterinary Medical Association (AVMA). A recent example is the AVMA's Best Management Practices for Pharmaceutical Disposal (www.avma.org/drugdisposal), which was developed in close collaboration between the AVMA and the Environmental Protection Agency. . The United States believes that effective, collaborative efforts should be encouraged to develop sound, science-based, and feasible guidance documents.

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Article 6.3.6.

Responsibilities of wholesale and retail distributors.

Distributors should ensure that their activities are in compliance with the national or regional legislation.

Distributors should ensure that information for the appropriate use and disposal of the antimicrobial agent preparation ~~should~~ accompany all distributed products and should also be responsible for maintaining and disposing of the product ~~under~~ according to the manufacturer recommendations.

Distributors should have responsibilities in collection and destruction of *antimicrobial agents* that have passed their expiry date.

Rationale: Editorial comment

Article 6.3.7.

Responsibilities of veterinarians and other aquatic animal health professionals

Responsibilities of *veterinarians* or other *aquatic animal* health professionals include identifying, preventing and treating *aquatic animal diseases* as well as the promotion of sound animal husbandry methods, hygiene procedures, vaccination and other alternative strategies to minimise the need for antimicrobial use in *aquatic animals*.

Veterinarians or other *aquatic animal* health professionals should only prescribe ~~or~~, dispense, administer or recommend antimicrobial a specific course of antimicrobial treatment for *aquatic animals* under their care.

<p>Rationale : In the United States veterinarians are allowed to administer and dispense prescription drugs as well as prescribe them. Such roles are supported by various US entities (eg, FDA; see www.fda.gov/AnimalVeterinary/ResourcesforYou/FDAandtheVeterinarian/ucm077384.htm). The revisions suggested are also in keeping with the <i>Judicious Use of Antimicrobials for Treatment of Aquatic Animals by Veterinarians</i> (www.avma.org/issues/policy/jtua_fish.asp). These guidelines are based on carefully reviewed, scientifically sound research and were developed with support and input from the Centers for Disease Control, Infectious Diseases Society of America, the FDA, and the USDA, and through collaboration with species-specific allied veterinary organizations.</p>

The responsibilities of *veterinarians* or other *aquatic animal* health professionals are to carry out a proper clinical examination of the *aquatic animal(s)* and make a diagnosis, based on the clinical examination, the results of laboratory tests and evaluation of environmental factors at the production site (e.g. water quality).

If therapy with an antimicrobial agent is deemed ~~appropriate~~ necessary it should be initiated as soon as possible. The selection of the agent should be based on the knowledge and experience of the *veterinarian* or other *aquatic animal* health professional.

As soon as possible, susceptibility testing of the target micro-organism should be used to confirm the choice of treatment. Results of all susceptibility tests should be ~~communicated~~ retained and should be available to the relevant ~~national~~ Competent Authority:

The *veterinarian* or other *aquatic animal* health professional should indicate precisely to the *aquatic animal* producer the treatment regime, including the dose, the treatment intervals, the duration of the treatment, the withdrawal period and the amount of drug to be delivered, depending on the dosage and the number of *aquatic animals* to be treated.

The *veterinarian* or other *aquatic animal* health professional may prescribe or recommend in appropriate circumstances the use of antimicrobial agents extra-/off-label, in conformity with the relevant ~~national~~ legislation and any requirements of importing countries.

Records on the use of antimicrobial agents should be kept in conformity with the national legislation. *Veterinarians* or *aquatic animal* health professionals should also periodically review farm records on the use of the antimicrobial agents to ensure compliance with their directions and use these records to evaluate the effectiveness of treatment regimens. Suspected adverse reactions, as well as a including lack of effectiveness, should be reported to the *Competent Authorities*. The associated susceptibility data should accompany the report of lack of effectiveness, as applicable.

Rationale: In the United States, lack of effectiveness is a type of adverse event, and is to be reported to the federal government, using the same form as used to report other types of adverse events
www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/AnimalDrugForms/ucm048817.pdf

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