





WOAH Guideline for use of Veterinary Medicinal Products in Aquaculture











- Definitions
- Veterinary medicine use in aquaculture
- Principles for responsible and prudent use of antimicrobial agents in aquatic animals













Veterinary Medicinal Product

any product with approved claims to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal

Aquatic Animals

all viable life stages (including eggs and gametes) of fish, molluscs, crustaceans and amphibians originating from aquaculture establishments or from the wild













Aquaculture

Farming of aquatic animals

Competent Authority

a Governmental Authority of a Country having the responsibility for the implementation of certain standards of the Aquatic Code

Aquatic Animal Products

non-viable aquatic animals, parts of aquatic animals, or manufactured goods containing any material derived from aquatic animals that are intended for sale or trade













Veterinary medicine use in aquaculture

Effective and sustainable animal disease control while minimizing risks to humans and animals, veterinary legislation provide regulations on the authorization, manufacturing, distribution and use of veterinary products

Chapter 6.2 (Aquatic Animal Health code)
Principles for responsible and prudent use of antimicrobial agents in aquatic animals

Aim protecting both animal and human health.

Small number of approved antimicrobial agents for use in aquaculture!





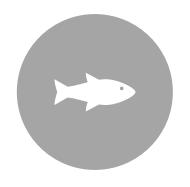




Objectives of responsible and prudent use



MAINTAIN THE EFFICACY OF ANTIMICROBIAL AGENTS AND TO ENSURE THE RATIONAL USE OF ANTIMICROBIALS



COMPLY WITH THE ETHICAL
OBLIGATION AND
ECONOMIC NEED TO KEEP
AQUATIC ANIMALS IN GOOD
HEALTH



PREVENT/REDUCE THE
TRANSFER OF AMR FROM
AQUATIC ANIMALS TO
HUMANS AND
TERRESTRIAL ANIMALS



PREVENT ANTIMICROBIAL
RESIDUES EXCEEDING
ESTABLISHED MRLS
OCCURRING IN THE FOOD

Responsibilities of Competent Authorities

Granting marketing authorisation (specifying the terms of the authorization) when criteria of quality, efficacy and safety are met

Develop up-to-date guidelines on data requirements for evaluation of VMP applications

Adopt a proactive approach to promote prudent use (comprehensive strategy for the containment of AMR)

ensure that advertising of antimicrobial agents comply with relevant legislation and marketing authorizations granted

Disseminate information on trends on AMR

World Organisation for Animal Health

Responsibilities of the veterinary pharmaceutical industry

- Providing information requested by Competent Authorities on the quality, efficacy and safety
- Cover pre- and post-marketing phases (manufacturing, sale, importation, labelling, advertising and pharmacovigilance)
- Provide data on quantity of antimicrobial agents marketed
- Discourage advertising of antimicrobial agents directly to the aquatic animal producer













Responsibilities of wholesale and retail distributors

- Activities comply with the relevant legislation
- Provide information for the appropriate use and disposal of the antimicrobial agents
- Be responsible for maintaining and disposing of the product in accordance with the manufacturer recommendations









Responsibilities of veterinarians and other aquatic animal health professionals



Identify, prevent and treat aquatic animal diseases, promoting sound animal husbandry to minimize the need for AMU



Only prescribe, dispense treat with an antimicrobial agent for aquatic animals under their care



Conduct thorough clinical assessment of the aquatic animal(s) for definitive diagnosis before initiating treatment



Consider environmental & husbandry factors at production site (water quality) prior to antimicrobial agent treatment



Importance of the antimicrobial agent in aquatic animal health and human health (WOAH List of Antimicrobial Agents of Veterinary Importance and WHO List of Critically Important Antimicrobials)

Responsibilities of veterinarians and other aquatic animal health professionals



When necessary, initiate therapy with an antimicrobial agent as soon as possible



Select the agent based on the knowledge and experience of the veterinarian to prescribe veterinary medicines



Provide precise info to the producer on treatment regime, the dose, treatment intervals, duration, withdrawal period and quantity of antimicrobial agents to be delivered



Extra-label/off-label use may be permitted in appropriate circumstances



Keep records on the use of antimicrobial agents





Responsibilities of aquatic animal producers

- Implement health programmes on their farms to promote aquatic animal health and food safety
- Use antimicrobial agents only on the prescription
- Proper storage, handling, and disposal of antimicrobial agents
- Keep records of AMU, bacteriological and susceptibility tests, and avail such records to the veterinarian
- Inform veterinarians of recurrent disease problems and lack of efficacy of antimicrobial agent treatment regimes











Thank you!

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Veterinary Products: A Vital Tool for Improving Animal Health and Welfare

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