World Organisation for Animal Health

Regional Workshop on Antimicrobial Resistance in Aquaculture for English-Speaking African Countries

13 - 15 August 2025
Harare, Zimbabwe

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Regional workshop on AMR in aquaculture for English speaking African countries.

Guidelines for registration for veterinary products for use in aquatic animals

13-15 August 2025
Harare, Zimbabwe

Presented by

Dr Adelaide Ayoyi

EAC MRP-Coordinator

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Title of the guideline

AQUATIC ANIMALS' PHARMACEUTICAL PRODUCTS UNDER EAC MRP FOR MARKETING AUTHORIZATION

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Document development process

The 16th Sectoral Council on Agriculture and Food Security (SCAFS) directed the Secretariat to mobilize resources to facilitate the development guidelines for aquatic medicines/ chemicals registration requirements EAC**/SCAFS/16/directive 35.**

This is in line with Article 108 of the EAC Treaty which calls for the EAC Partner States to adopt common mechanism to ensure safety, efficacy and quality of agricultural inputs including medical devices, chemicals, drugs and vaccines.

Development of the Draft guideline document workshop held in Entebbe on 26-28th June 2023,Uganda

Review of the Draft guideline document workshop held in Arusha on 17-20th September 2024,Tanzania

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Validation of the Draft guideline document workshop held in Nairobi on 2nd –4th April 2025,Kenya –TMA

Adoption of the Draft guideline document by SCAFS in the SCAFS meeting held in Arusha on 14th -18TH July 2025,Kenya – EAC

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Module 1.0 Administrative And Prescribing Information

- 1.1Application letter
- 1.1 Manufacturing and Marketing Authorization
- 1.2 Application Information
- 1.4. Application form
- 1.5 Product Information and Labelling1.5.1 Prescribing information (Summary of Product Characteristics)
- 1.5.2 Container labelling
- 1.5.3 Information Leaflet
- 1.6 Good Manufacturing Practice (GMP)
- 1.7 Product samples

MODULE 2: OVERVIEW & SUMMARIES

- 2.2 CTD Introduction
- 2.3 Quality overall summary (QOS)
- 2.3.S Active Substances
- 2.3. S.1 General Information
- 2.3. S.2 Manufacture (name, physical address)
- 2.3. S.3 Control of Drug Substance
- 2.3. S.4 Container Closure System
- 2.3. S.5 Stability

- 2.3. P Aquatic animal medicine
- 2.3. P.1 Description and Composition of the drug Product
- 2.3. P.2 Pharmaceutical Development
- 2.3.P.3 Manufacture (name, physical address)
- 2.3.P.4 Control of Excipients
- 2.3.P.5 Control of Drug Product
- 2.3.P.6 Container Closure System
- 2.3. P.7 Stability

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3.2. S ACTIVE SUBSTANCE(s)

3.2.S.1 General Information
3.2.S.2 Method of manufacture of an active ingredient
3.2.S.2.1 Manufacturer and site of manufacture
3.2.S.2.2 Description of the manufacturing process
Active ingredient produced by chemical synthesis
3.2. S.2.3 Control of materials
3.2.S.2.4.1 Animal-sourced material
3.2. S.4 Control of the active substance
3.2.S.4.1 Active ingredient specifications
3.2. S.4.2. Analytical Procedures
3.2. S.4.4 Batch analysis data
3.2.S.4.5 Justification of Specification
3.2. S.5.Reference Standards or Materials
3.3. S.6.Container Closure System
3.2.S.7 Stability data

3.2.P Aquatic Animal medicines (AAM)

3.2. P.1.2 Composition
3.2. P.1.3 Description of accompanying reconstitution diluent(s)
3.2. P.2. Pharmaceutical Development
3.2. P.2.1 Components of the AAM
3.2. P.2.1.1 Active substance
3.2. P.2.1.2 Excipients
3.2. P.2.2.1 Formulation Development
3.2. P.3 Manufacture
3.2. P.3.1 Manufacturer(s)
3.2. P.4 Control of Excipients
3.2. P.4.1 Specifications
3.2. P.4.2 Analytical Procedures
3.2. P.4.3 Validation of Analytical Procedures
3.2. P.4.4 Justification of Specifications
3.2. P.4.5 Excipients of Animal Origin
3.2. P.4.6 Novel Excipients
3.2. P.5 Control of AAM
3.2. P.5.1 Specification(s)
3.2. P.5.2 Analytical Procedures
3.2. P.5.3 Validation of Analytical Procedures
3.2.P.5.4 Batch analysis
3.2. P.5.5 Characterization of Impurities
3.2. P.5.6 Justification of Specification(s)
3.2. P.6 Reference Standards or Materials
3.2. P.7 Container Closure System
3.2.P.7.1 Labelling Standard for Aqua Inputs
3.2. P.8. Stability data
3.3. R. REGIONAL INFORMATION
3.3. R.1 Production Documentation
3.3. R.1.1 Executed Production Documents for commercial batch size
3.3. R.1.2 Master Production Documents

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3.2.P.7.1 Labelling Standard for Aquatic animal medicine

Excipients **(Inactive ingredients)** all other components of the final drug product, such as coloring and flavoring substances, preservatives, and binding agents. Since the fish are sensitive to the inactive substances of the medicines they must be selected careful, all consideration put in place and declared on the label.

'**Not for Human Consumption**': The label shall have 'Not for Human Consumption' in the bottom strip with bigger font size to avoid any possible consumption by humans.
'**Aquatic Animal Use Only'**: The label shall bear a SYMBOL depicting an appropriate image of the aquatic animal(s) for which the product is to be administered.

AQUATIC VETERINARY

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MODULE 4.0 safety and efficacy of Aquatic animal medicine intended for use in farmed finfish

safety and efficacy study reports

4.1 General considerations
4.1.1 Study reports
4.1.2. General study design
4.2. Pre-clinical studies
4.2.1 Small number of test fish:
4.2.2 Large number of test fish:
4.2.3. Pharmacodynamics
4.2.4. Pharmacokinetics
4.2.4.1. Performance of tests
4.2.5. Resistance
4.2.6. Tolerance in the target species
4.2.6.1. Test product
4.2.6.2. Negative control groups
4.2.6.3. Holding
4.2.6.4. Necropsy histopathology examinations and blood analyses
4.2.6.5. Dose justification and duration of dosage
4.2.6.6. Oral administration
4.2.6.7. Waterborne administration
4.2.6.8. Parenteral administration
4.2.7 Laboratory studies
4.2.7.1. Challenge studies
4.2.7.2. Dose determination studies
4.2.7.3. Dose confirmation studies
4.3. Clinical trials
4.3.1. Selection of farms
4.3.2. Selection of groups
4.3.3. Trial procedure
4.3.4. Diagnostic criteria

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4.2.5. Resistance

The mechanism for, and frequency of, resistance should be discussed including information on possible transmission.

Provide information about the molecule to strengthen epidemiological evidence on AMR and inform aquaculture and fisheries interventions needed to mitigate the impact of AMR globally.

4.2.6. Tolerance in the target species

Target animal safety should be determined in all of the target species, as defined by the investigator, unless otherwise justified.

Excipients normally used in pharmaceutical products for terrestrial animals may not be well tolerated by aquatic species. Safety of excipients should be determined and lack of appropriate data justified.

4.2.6.7. Waterborne administration

Dipping and bathing are methods of administration considered as waterborne administration. Waterborne treatment must usually have a very broad margin of safety due to the difficulty of accurate dosing/estimation of water volume in raceways or sea cages. The duration of treatment should be equal to or longer than the proposed length of treatment.

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Thank you
Asante
Merci

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