Antibiotics and chemotherapeutics can be an important component of good aquacultural practices. However they must be utilized with extreme care to guard against improper use and to assure that guidelines for imports are met.

**Concerns**

Development of antibiotic resistance in both target pathogens and normal bacterial flora is a concern in aquacultural production. The concerns about the use of therapeutics in aquaculture focus on human and environmental safety issues. Concerns also focus on the potential for the establishment of antibiotic resistant zoonotic pathogens in wild stocks.

An integral part of good veterinary practices is a regime in which every effort is made to maximize therapeutic efficiency and minimize selection of resistant bacteria. Judicious use principles are a guide for proper use of antibiotics under the direction of a veterinarian.

**Veterinarian Responsibilities**

Veterinarians are responsible for diagnosis of disease conditions, or work directly with fish health professional on the production operation. They should be available for questions/concerns following treatment, and are responsible for health care of aquatic species on the site.

Treatments must only be used when needed. Use of drugs in a manner other than the options discussed here are subject to regulatory action by the FDA. There are 4 options for proper drug use in the US. They are FDA-approved or conditionally approved new animal drugs, investigational new animal drugs (INADS), unapproved new animal drugs of low regulatory priority, and extra-label use of approved new animal drug.

**Options for Proper Drug Use-USA**

Approved or conditionally approved drugs in the USA must be used for proscribed indications including specific species and life stages. They must be used for specific proscribed diseases, at proscribed dosage and length of time and must be purchased from an approved source.

**In Accordance with GMPs**

The first requirement for use of an INAD in the USA are that the use of the drug must have an official sponsor or study monitor. In addition there must be some form of Drug Accountability, Proper Disease Diagnosis, Protocol Adherence, prescribed Application Rates and Withdrawal Periods, and finally Documentation of Use and Response.

The rules for INAD use allows certain exemptions. This allows the use of an unapproved drug on production stocks to minimize suffering and losses of stocks, while allowing collection of data that will support an FDA decision on specific drug approvals.

Low Regulatory Priority is when regulatory action is unlikely if GMP's are followed, if GAqPs are followed, if local environmental requirements are met, and if an appropriate grade is used.

Extra Label Use is allowed, but is limited to treat when the health of the animal is threatened, or when suffering or death may occur if not treated.

**Record Keeping**

Records must be kept in each area of chemotherapeutic antibiotic use. Records on treatment status of animals and culture facility must be kept, as well as records on dosage rates and withdrawal times. Producers must also keep records to demonstrate that all drugs and chemicals are used properly under the direction of a veterinarian and have been properly disposed. For INAD exemptions, records must be kept in several areas (see the paragraph on INAD use).

**Source:** Guide to Drug, Vaccine and Pesticide Use in Aquaculture, 2004
World Aquaculture Drug and Vaccine Progress

The drug approval process varies by country and continent. Vaccine approval process also varies by country and continent.

Chemotherapeutics

Aquaculture production companies and exporting countries must be aware and comply with the drug and vaccine use requirements of the importing country. It is incumbent on the exporting country to ensure that the laws of the importing country are met and that the use of chemotherapeutics is kept to a minimum and used only under the direction of a veterinarian. Use of chemotherapeutics can be minimized by following and implementing aquaculture GApPs.

Source: Judicious Use of Antimicrobials for Aquatic Veterinarians (http://www.fda.gov/cvm/JudUse.htm)

Source: Guide to Drug, Vaccine and Pesticide Use in Aquaculture, 2004 (http://aquanic.org/jsa/wgqaap/drugguide/drugguide.htm LINK TO Pdf file)

Options for Proper Drug Use-USA

Approvals by Country or Continent

Africa-Most countries do not have regulations on drug or vaccine use;
Asia-Varies from no regulations to restrictive regulations;
Japan-Controlled by Pharmaceutical Affairs Law;
Philippines-Enforced by the Dept. of Agriculture;
Thailand-Controlled by the Dept. of Fisheries;
China-Approved for use by the Animal Drugs Examination Commission, Ministry of Agriculture
Australia-Applications are submitted to the National Registration Authority to seek exemptions from the need for registration;
Europe-Old and new substances defended by a sponsor, data is required to establish Maximum Residue Limits (MRL);
North America-The USA drug approval process is similar to Canada, which requires approval of manufacturing, human food and target species, safety and efficacy sections
South America-Little information is available, however, in Chile the agency responsible for approvals is The Fisheries Health Department, National Fisheries Service