

# AASP PHARMACEUTICAL ISSUES COMMITTEE

## American Association of Swine Practitioners Basic Guidelines of Judicious Therapeutic Use of Antimicrobials in Pork Production

The *Basic Guidelines of Judicious Use of Antimicrobials in Pork Production*, published in this issue of *Swine Health and Production*, is the first of several species-specific guidelines to be created at the request of the AVMA Steering Committee on Judicious Therapeutic Antimicrobial Use. This committee was formed in 1998 by the AVMA in response to pressure from the Center for Veterinary Medicine of the Food and Drug Administration (CVM/FDA) and advocacy groups such as the Centers for Disease Control and Prevention (CDC). The CDC and similar groups have continued to raise concerns over how the use of antimicrobials in veterinary medicine affects the development of antimicrobial resistance to human pathogens. Certainly these groups have never denied the fact that much of the resistance seen today can be attributed to the use and misuse of antimicrobials in human medicine. In response to the emergence of resistance, physicians have developed these "Prudent Use Guidelines" to improve prescribing

practices in human medicine and have called for the development of similar guidelines in veterinary medicine. The AVMA committee first developed a list of basic principles of judicious use, and then charged the various species groups to develop species-specific guidelines. The AASP and National Pork Producers Council (NPPC) have been represented at the table throughout the process, so it was not surprising that the guidelines for pork production were the first to be approved by the AVMA Executive Board.

The AASP worked closely with the NPPC in developing these guidelines within the structure of the AASP's Pharmaceutical Issues (PI) Committee. The committee members have previously dealt with other issues involving pharmaceuticals, so it was a natural progression of the committee to develop the guidelines. The PI committee invited additional AASP members to join them in developing the guidelines. The following are members who participated in

several lengthy meetings and conference calls:

Greg Armbruster, Bernie Curran, Paul Sundberg, Jim McKean, David Reeves, Martin Mohr, Warren Wilson, Tom Gillespie, Tom Wetzell, Angela Baysinger, Tom Burkgren, and John Waddell

The basic guidelines focus on principles in therapeutic antimicrobial use specific to swine practice, and address 14 principles of judicious use. These principles are intentionally general in nature so that they do not become a formulary that would dictate what products practitioners should use. Instead, these guidelines recognize the vast differences between production systems and how individual veterinarians practice. It is essential that the ultimate decision of antimicrobial use depend on the practitioner's expertise and experience.

—Dr. John Waddell  
Chair, AASP Pharmaceutical Issues  
Committee

Veterinarians agree to protect animal and public health when they pledge the Veterinarian's Oath. This oath is as applicable today as it was when it was written many years ago. Swine practitioners are committed to "the use of scientific knowledge and skills for the benefit of society". This commitment remains the core of veterinarians' efforts to achieve "the protection of animal health, the relief of animal suffering, the conservation of livestock resources, the promotion of public health, and the advancement of medical knowledge."

### Position Statement

When a condition exists that threatens or impairs animal health and well being, it is essential that an accurate clinical diagnosis be obtained. Appropriate diagnostic techniques and clinical experience should substantiate a presumptive diagnosis. Once the decision is reached to use antimicrobials for therapy, veterinarians strive to optimize therapeutic efficacy, minimize resistance to antimicrobials, and protect public and animal health.

The American Association of Swine Practitioners supports and is committed to the following objectives as developed by the American Veterinary Medical Association's Steering Committee on Judicious Therapeutic Antimicrobial Use:

- Support development of a scientific knowledge base that provides the basis for judicious therapeutic antimicrobial use.
- Support educational efforts that promote judicious therapeutic antimicrobial use.
- Preserve therapeutic efficacy of antimicrobials.
- Ensure current and future availability of veterinary antimicrobials.

### Judicious Therapeutic Use of Antimicrobials Principles for Swine Practitioners

(1) > Preventive strategies, such as appropriate husbandry and hygiene, routine health monitoring, and immunization, should be emphasized.

✓ Establish the definitive diagnosis.

✓ Recognize the roles played by the following factors in the course of the disease(s):

- Genetics
  - Genetic sources
  - Genetic predisposition
- Nutrition
  - Water
  - Protein

- Energy
- Micronutrients

□ Housing

- Air space per pig
- Temperature extremes beyond the thermal neutral zone of swine
- Meteorological conditions (eg., seasonal patterns)
- Ventilation

□ Management

- Stocking density
- Isolation and acclimatization of incoming breeding swine.
- Appropriate and timely use of washing and disinfection of premises
- Depopulation/repopulation to eliminate a disease organism.

□ Health

- Immune status of the animals
- Herd dynamics and health status of the sow herd
- Presence and importance of concurrent infections
- Source of pigs (eg., single source or multiple sources)

(2)➤ **Other therapeutic options should be considered prior to antimicrobial therapy.**

- ✓ Examples include acidification of feed or water, electrolyte therapy, supportive care (e.g., antipyretic therapy).

(3)➤ **Judicious use of antimicrobials, when under the direction of a veterinarian, should meet all requirements of a valid veterinarian-client-patient relationship.**

- ✓ Antimicrobials represent a powerful therapeutic option. Specific guidelines on the use of prescription antimicrobials and the extralabel use of any antimicrobial must involve a valid VCPR. We believe that judicious use requires the oversight of a veterinarian at some point in the decision making process.

(See glossary for definition of VCPR as it appears in AMDUCA)

(4)➤ **Prescription, Veterinary Feed Directive, and extralabel use of antimicrobials must meet all the requirements of a valid veterinarian-client-patient relationship.**

- ✓ The law prohibits extra label use of antimicrobials in the feed.

(5)➤ **Extralabel antimicrobial therapy must be prescribed only in accordance with the Animal Medicinal Drug Use Clarification Act amendments to the Food, Drug, and Cosmetic Act and its regulations.**

- ✓ The following drugs are expressly prohibited for extralabel use in food animals: chloramphenicol, clenbuterol, diethylstilbestrol, dimetridazole, ipronidazole, other nitroimidazoles, furazolidone (except for approved topical use), nitrofurazone (except for approved topical use), sulfonamide drugs in dairy cows (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxyypyridazine), fluoroquinolones, and glycopeptides (e.g., vancomycin).

- ✓ For more information on extralabel drug use, see the

AMDUCA guidance brochure entitled *Extralabel Drug Use (ELDU)*, published by the AVMA in January 1998.

(6)➤ **Veterinarians should work with those responsible for the care of animals to use antimicrobials judiciously regardless of the distribution system through which the antimicrobial was obtained.**

- ✓ Judicious use requires the oversight of a veterinarian at some point in the decision making process.
- ✓ Veterinarians are the primary source of information on the use of swine antimicrobials.
- ✓ Veterinarians must accurately communicate written, adequate directions to the client for antimicrobial use.
- ✓ The Pork Quality Assurance (PQA) program of the National Pork Producers Council provides a basis for the judicious use of antimicrobials.
- ✓ The AASP recognizes the legal availability of antimicrobials obtained through over-the-counter (OTC) distribution channels.
- ✓ The extra label uses of OTC antimicrobials fall within the regulatory constraints of the Animal Medicinal Drug Use Clarification Act and thus requires veterinarian oversight.

(7)➤ **Regimens for therapeutic antimicrobial use should be optimized using current pharmacological information and principles.**

- ✓ Package inserts should be considered as sources of information for the practitioner.
- ✓ Continuing education is an important component of maintaining and enhancing the veterinarian's pharmacological knowledge.
- ✓ AASP supports the development of a veterinary antimicrobial decision system for swine to improve accuracy in the selection of therapeutics.
- ✓ The compounding of antimicrobials should be avoided in those instances where there is a lack of supporting scientific pharmacological data.
- ✓ Unapproved combinations that include therapeutic antimicrobials should not be used in the absence of supporting scientific pharmacological data.
- ✓ Cost is not a factor when considering the use of a compounded therapeutic antimicrobial.
- ✓ For more information on compounding, see the FDA Compliance Policy Guide (CPG 7125.40) entitled *Compounding of Drugs for Use in Animals*.

(8)➤ **Antimicrobials considered important in treating refractory infections in human or veterinary medicine should be used in animals only after careful review and reasonable justification. Consider using other antimicrobials for initial therapy.<sup>1</sup>**

1. In this context, this principle takes into account development of resistance or cross-resistance to important antimicrobials.

- (9)➤ **Utilize culture and susceptibility results to aid in the selection of antimicrobials when clinically relevant.**
- ✓ Clinical outcomes, history, and experience should also be used in the selection of antimicrobials.
  - ✓ Veterinarians should utilize appropriate references for proper procedures and accurate interpretation of susceptibility results, such as the NCCLS publication M31-A, *Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Approved Standard*.
- (10)➤ **Therapeutic antimicrobial use should be confined to appropriate clinical indications.**
- ✓ An accurate diagnosis includes characterization of the etiology.
  - ✓ Practitioners should strive to rule out parasitism, mycotoxins, nutritional imbalances, and viral infections.
  - ✓ Secondary bacterial pathogens may require antimicrobial therapy.
- (11)➤ **Therapeutic exposure to antimicrobials should be minimized by treating only for as long as needed for the desired clinical response.**
- ✓ Therapeutic exposure involves both dose and duration.
  - ✓ Continued use of antimicrobials in chronic, non-responsive clinical cases should be discouraged.
  - ✓ Withdrawal times must always be considered during the selection of antimicrobials.
- (12)➤ **Limit therapeutic antimicrobial treatment to ill or at risk animals, treating the fewest animals indicated.**
- ✓ Consider group morbidity and mortality rates when deciding whether or not to initiate herd, group, or individual therapy.
  - ✓ Consider the herd health history for the therapeutic use of antimicrobials in the control and prevention of disease.
  - ✓ When these factors are appropriately considered, preventative therapy is a judicious use of antimicrobials.
- (13)➤ **Minimize environmental contamination with antimicrobials whenever possible.**
- ✓ Water medicators and feeders need to be properly adjusted to deliver the desired dose and avoid spillage and waste.
- (14)➤ **Accurate records of treatment and outcome should be used to evaluate therapeutic regimens.**
- ✓ AASP recommends the use of treatment records such as those proposed by the Pork Quality Assurance (PQA) program of the National Pork Producers Council.
  - ✓ Compliance to treatment regimens can be monitored by the review of pertinent records.
  - ✓ Accurate animal or group identification must be employed within a production system for effective residue avoidance.



## Glossary:

**Antibiotic**—a chemical substance produced by a microorganism which has the capacity, in dilute solutions, to inhibit the growth of or to kill other microorganisms.

**Antimicrobial**—an agent that kills bacteria or suppresses their multiplication or growth. This includes antibiotics and synthetic agents. This excludes ionophores and arsenicals.

**Narrow Spectrum Antimicrobial**—an antimicrobial effective against a limited number of bacterial genera; often applied to an antimicrobial active against either Gram-positive or Gram-negative bacteria.

**Broad Spectrum Antimicrobial**—an antimicrobial effective against a large number of bacterial genera; generally describes antibiotics effective against both Gram-positive and Gram-negative bacteria.

**Antibiotic Resistance**—a property of bacteria that confers the capacity to inactivate or exclude antibiotics or a mechanism that blocks the inhibitory or killing effects of antibiotics.

**Extralabel**—Extralabel use means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

**Immunization**—the process of rendering a subject immune or of becoming immune, either by conventional vaccination or exposure.

**Monitoring**—monitoring includes periodic health surveillance of the population or individual animal examination.

**Therapeutic**—treatment, control, and prevention of bacterial disease.

**Veterinarian/Client/Patient Relationship (VCPR)** — A VCPR exists when all of the following conditions have been met:

1. The veterinarian has assumed the responsibility for making clinical judgements regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.
2. The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s) or by medically appropriate and timely visits to the premises where the animal(s) are kept.
3. The veterinarian is readily available for follow-up evaluation, or has arranged for emergency coverage, in the event of adverse reactions or failure of the treatment regimen.

**Veterinary Feed Directive (VFD) Drug**—The VFD category of medicated feeds was created by the Animal Drug Availability

Act of 1996 to provide an alternative to prescription status for certain therapeutic animal pharmaceuticals for use in feed. Any animal feed bearing or containing a VFD drug shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian's professional practice.

