



Upcoming Policy Change Governing Injectable Antibiotics Will Alter Their Use by Pig Farmers

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Introduction

Antimicrobial drugs are substances that work against microbes such as bacteria, viruses, fungi, and parasites. Antibiotics are effective against only bacteria. All antibiotics are antimicrobials, but not all antimicrobials are antibiotics. Not all bacteria targeted by a specific antibiotic are susceptible to it and die. The bacteria that can resist the antibiotic survive and reproduce, thus creating a population of microbes with antibiotic resistance. Thus, the antibiotic is no longer effective against those bacteria.

Antibiotic resistance has become a major health issue. Some resistant bacteria cause severe illness in humans that requires a long recovery period and high medical expenses. According to the Centers for Disease Control and Prevention [1], bacteria that are resistant to antibiotics annually infect more than 2.8 million people in the U.S. resulting in at least 35,000 deaths.

Large-scale pork production systems historically added antibiotics to the feed or through water delivery systems for: 1) treatment of illness, 2) control or prevention of disease, and/or 3) improvement of growth performance (for example, rate of body weight gain or the efficiency of converting feed to body weight gain). Animals treated with antibiotics have resistant bacteria in their intestines that can continue to survive and grow. Pigs and other livestock can carry bacteria such as *salmonella* and *campylobacter*, which can make people ill. If resistant bacterial strains infect people handling or eating raw or improperly prepared meat, treatment is difficult.

Because of the potential for producing food-animals such as pigs that increase antibiotic resistance in humans, in 2017, the U.S. Food and Drug Administration (FDA) implemented new policies governing the Veterinary Feed Directive (VFD) [2]. This publication reviews the changes made in 2017, as well as introduces changes governing use of injectable antibiotics that will occur this year.

Policies enacted in 2017 governing the VFD

The new policies governing the VFD increased veterinary oversight of antibiotics used in livestock that are also medically important in treating human illness. A VFD is a written statement from a licensed veterinarian that authorizes the owner or caretaker of pigs to purchase and use feed containing a VFD drug to treat their animals in accordance with the FDA-approved directions for use. Prior to 2017, there were three feed-grade antibiotics (Kavault, Pulmotil, and NuFlor) requiring swine farmers to obtain a VFD. The new policies in 2017, added 283 products, characterized as medically important (to human health), to the VFD list. This ended over the counter (OTC) purchase of feed-grade products on the expanded VFD list and required prescriptions for products applied through water delivery systems. Moreover, all companies marketing drugs in the expanded VFD list removed production claims on drug labels, meaning VFD drugs could be used only to treat, control, or prevent specific diseases and not for enhancement of growth. There remain six products (BMD 50, Albac®, Denagard®, Mecadox, Flavomycin®, and Skycis) not affected by the 2017 FDA policy that can be used for treating or controlling animal health conditions and/or growth promotion.

Policy changes enacted in 2017 did not affect the OTC purchase of injectable antibiotics. However, effective June 11, 2023, the OTC purchase of antibiotics often used by pig farmers, will end as per the FDA's Guidance for Industry #263 [3].

New policy regarding purchase of OTC injectable antibiotics effective June 11, 2023

Farmers will no longer be able to purchase injectable antibiotics from on-line vendors or agricultural supply stores, unless they obtain a veterinarian's prescription. Antibiotics formerly purchased OTC will have the following statement included on the label: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian". Antibiotics affected include, but are not limited to, any product containing oxytetracycline (for example, LA-200®) penicillin (for example, Procaine Penicillin G), tylosin (for example Tylan 50® or Tylan 200®), lincomycin (for example Lincomix 300®), or gentamicin.

To reiterate, these products will be commercially available, but by requiring a prescription, brought under more strict veterinary supervision, just as were the feed grade antibiotics in 2017.

Under the new policy, a valid veterinary client patient relationship (VCPR) is critical

- One consequence of the FDA's action is that many pig farmers will have to increase their interaction with veterinarians. Issuance of a veterinary prescription requires a valid VCPR. Minimum standards for a VCPR are:
- The veterinarian has assumed responsibility for making medical judgements regarding the health of the pigs and the need for medical treatment,
- The client (the owner of the animals or caretaker) has agreed to follow the instructions of the veterinarian,
- The veterinarian has sufficient knowledge of the pigs by virtue of animal examination and timely visits to the premises where the animals are kept, and

- The veterinarian is available to provide any necessary follow-up evaluation or care.

Many states have legal definitions of what constitutes a valid VCPR. Definition of a legitimate VCPR in Virginia is as follows:

Virginia Code § 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry, or **veterinary medicine** who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.

For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects.

Actions that may reduce or eliminate the need for antibiotics on pig farms

The judicious use of antibiotics will continue to be an important tool for ensuring pig health and animal well-being on many farms. However, farmers should develop strategies and management changes that boost herd health and minimize the need for antibiotics on the farm. This may include but not be limited to:

- Improved biosecurity to prevent diseases from entering the farm,
- Appropriate vaccinations to prevent diseases.
- Use of feed additives that may be effective alternatives to antibiotics such as probiotics,
- Improved environment in facilities in which pigs are kept including better management of temperature, ventilation, stocking densities, and so forth.

If they have not already done so, producers should complete the National Pork Board's Pork Quality Assurance-Plus (**PQA-Plus**) training and certification program. For more information on the new FDA policies and the PQA-Plus program visit the National Pork Board's website at: <http://www.pork.org/>.

References

1. Centers for Disease Control and Prevention. Available at: <http://www.cdc.gov/drugresistance/> (accessed March 2, 2023).
2. Federal Register. Guidance for Industry #152. Available at: <https://www.federalregister.gov/documents/2022/12/19/2022-27415/evaluating-the-safety-of-antimicrobial-new-animal-drugs-with-regard-to-their-microbiological-effects> (accessed March 2, 2023).
3. FDA-Center for Veterinary Medicine 2023. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-263-recommendations-sponsors-medically-important-antimicrobial-drugs-approved-use-animals>

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