



PRESERVING ACCESS TO ANTIBIOTICS

Issue:

Agriculture has a primary interest in ensuring that all animal health products continue to be safe and effective. In order to raise healthy animals, farmers and ranchers need tools to keep animals healthy—including antibiotics or antimicrobials that have been approved by the Food and Drug Administration (FDA). Eliminating access to these important tools will jeopardize animal health and compromise our ability to raise animals to provide safe meat, milk, and egg products.

Background:

Bacterial resistance to certain antibiotics poses a serious public health threat and prompts wide concern for human health. While all users of antimicrobials contribute to risk of resistance, antibiotic use in animals has not currently been definitively linked to increases in human antibiotic resistance.

Legislative/Regulatory Status:

Since 2012, the FDA has issued three documents to guide the agency's strategy for antibiotic use in food animals. Guidance for Industry (GFI) #209 outlines resistance issues and identifies judicious use principles for medically important antimicrobials in food-producing animals including limiting use to therapeutic purposes and calling for veterinarian oversight. GFI #213 calls for drug companies to voluntarily remove production claims (growth promotion and feed efficiency) on medically important antimicrobials delivered by feed or water and brings therapeutic uses (treatment, prevention, and control) of those drugs under veterinarian oversight. GFI #120 implements a Veterinary Feed Directive (VFD) to fulfill the veterinarian oversight provisions outlined in GFI #213. The VFD compliance deadline was Jan. 1, 2017. Injectable or oral drugs are not affected by these changes.

According to FDA, the agency is taking this series of actions to preserve the effectiveness of medically important antimicrobials for treating disease in humans. Animal production claims (growth promotion and feed efficiency) will be prohibited for these shared-class drugs, but veterinarian oversight will allow for continued use to prevent, control or treat illnesses in food-producing animals.

In Sept. 2014, the President's Council of Advisors on Science and Technology (PCAST) released a report on resistance to antibiotics. In the report, PCAST recommends a set of practical and actionable steps that the government should take in human and animal health to bring the antibiotic-resistance crisis under control through focused efforts in three areas:

- 1) Improving surveillance of the rise of antibiotic-resistant bacteria to enable effective response, stop outbreaks, and limit the spread of antibiotic-resistant organisms.
- 2) Increasing the longevity of current antibiotics by improving the appropriate use of existing antibiotics, preventing the spread of antibiotic-resistant bacteria and scaling-up proven interventions

to decrease the rate at which microbes develop resistance to current antibiotics.

- 3) Increasing the rate at which new antibiotics (as well as other interventions) are discovered and developed.

In conjunction with the report, an Executive Order from the Obama administration required that a Task Force for Combating Antimicrobial Resistant Bacteria be co-chaired by the secretaries of the Departments of Defense, Agriculture, and Health & Human Services to identify actions to provide for the facilitation and monitoring of implementation of the National Strategy for Combating Antibiotic-Resistant Bacteria.

AFBF Policy on Antimicrobials:

It is important that decision-makers review demonstrated scientific evidence of the risks and benefits of potential actions regulating the use of antimicrobial products. Farm Bureau has serious concerns about the impact of removing important antimicrobials from the market, which would hinder efforts of veterinarians and livestock and poultry producers to ensure animal health and protect our nation's food supply. We favor judicious use and withdrawal restrictions of feed additives and therapeutics, and we oppose banning these animal health products.

Farm Bureau supports:

- 1) Sound science as the basis for decision-making and policy development regarding antimicrobials used in food animal production;
- 2) Use of the National Antimicrobial Resistance Monitoring System, the National Animal Health Monitoring System and USDA's food safety monitoring system to address issues of antimicrobial resistance trends in food-borne bacteria and animal health;
- 3) Regulation of antibiotics/antimicrobials at the national level to avoid a state-by-state patchwork;
- 4) A multi-agency approach to on-farm antimicrobial-resistant bacteria trend research and surveillance that includes APHIS, ARS, Food Safety and Inspection Service and livestock producers;
- 5) Current slaughter surveillance, testing, and inspection as appropriate food safety and animal health protocol;
- 6) Rather than limitations or elimination of animal health and food safety protection tools, we would accept veterinarian oversight of antibiotic use, where veterinarian oversight is defined as a working relationship with a licensed veterinarian and allows for the purchasing of animal pharmaceuticals using a prescription without the requirement of purchasing directly from a veterinarian;
- 7) The veterinary-client-patient relationship as it relates to medical use and antibiotics and the information should remain confidential and not subject to Freedom of Information Act requests. Similar to other farm data, all animal health records are the property of the farm and require the owner's written permission to be accessed;
- 8) The continued sale of prescribed and over-the-counter animal health products and oppose further restrictions on their use, including any required on-farm reporting of drugs administered to livestock;
- 9) Clarification and further review of FDA's veterinary feed directive (VFD) in regards to therapeutic drug use protocols. We also support a plan for education regarding the purpose and implementation of the VFD for producers, feed distributors and veterinary professionals;
- 10) FDA's Veterinary Feed Directive (VFD) preserving the right for producers to use feed additives and injectable antibiotic products;



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- 11) Amending the VFD to allow veterinarians to prescribe extra-label use of antimicrobial drugs in animals when warranted, including in the treatment of minor species. The VCPR establishes sufficient oversight of veterinarians for extra-label use when necessary.
 - 12) Changing the federal definition of a veterinary-client-patient relationship (VCPR) to allow for use of telemedicine when making an animal health diagnosis and recommending a course of treatments;
 - 13) Adequate funding for FDA's proposals to increase the research development and availability of approved animal drugs for minor uses and minor species (MUMS Document) as well as the concept that there should be different requirements for drug approval for minor species and minor uses;
 - 14) Producers' continued access and ability to use polyether ionophores (e.g., monensin, lasalocid) as a feed additive to reduce methane production in cattle and to serve as a coccidiostat in poultry;
 - 15) Ionophores used in livestock/poultry production should be reclassified as antiparasitics, not antibiotics.
 - 16) FDA allowing the extra label use of cephalosporin antimicrobial drugs in animals when warranted; and
 - 17) Legislation that would continue the ability of veterinarians to prescribe drugs and the accepted extra label usage of drugs needed for proper animal care.

Farm Bureau opposes any attempt to reclassify over-the-counter non-prescription injectable antibiotics to prescription-only status.

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