

Effects of the New Veterinary Feed Directive on Dairy Feeding Programs

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The use of pharmaceutical products in food animals is under close scrutiny by the general public and regulatory agencies around the world. The scrutiny is especially intense with respect to antimicrobial use (antibiotic and antimicrobial are the same thing). Increasing bacterial resistance to antimicrobials and fear of antimicrobial residues in food drives this scrutiny. Either of these situations have potentially life-threatening implications for anyone who might come in contact with a resistant bacteria or chemical residue, so the scrutiny is justifiable (Note the issue of antimicrobial resistance is not just a human issue but an animal one as well as, evidence of the increasing development of antibiotic resistance in pathogens of animal importance). More importantly, they put the entire food animal industry at risk for increased scrutiny, increased regulations, and ultimately loss of public confidence. Confusion about use of antimicrobials in food animals adds to the scrutiny. Reasons for this confusion that have been postulated include: 1) the fact that antimicrobial use in food animals is not a black-and-white issue; it is a complex issue that is frequently over simplified by both critics and proponents, 2) failure to understand that a concern is not equivalent to risk, 3) disconnect between consumers and agriculture, with most consumers being at least three generations removed from the farm, and 4) activist messaging - the media and the internet are often inaccurate and misleading regarding antimicrobial use, and

in particular, antimicrobial resistance and its relationship to use in food-animal production (NIAA, 2011).

We can have a healthy debate about the source of antimicrobial resistance and if residues exist; however, the reality is that if we use antimicrobials in food animals, we contribute to the potential risk of antimicrobial resistance developing and antimicrobial residues showing up in human food. It is **IMPERATIVE** that we do everything we can to reduce these risks, while at the same time making sure we properly care for the health of our animals.

Antimicrobial stewardship is the responsibility of everyone involved in the care of food animals. This includes livestock owners, employees, allied industry personnel (e.g. nutritionists), and veterinarians, among others. This message needs to be heard and applied by all of us to take measures towards doing what's right when it comes to responsible use of antimicrobials. No areas of the livestock industry are exempt from the need to use antimicrobials responsibly, as the majority of livestock eventually end up in the human food chain. Whether you run a dairy operation, a heifer raising operation, a feedlot, a cow-calf operation, or raise 4-H steers, how you care for those animals has potential human health impacts. Part of how you care for your animals includes the responsible use of antimicrobials.

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By the way, although this discussion revolves around prudent antimicrobial use, the same arguments pertain to any pharmaceutical product used in food producing animals. Anthelmintics, non-steroidal anti-inflammatories, etc. Misuse of any of these drugs has animal health and public health consequences.

Antimicrobial use in food animals is regulated by the U.S. Food and Drug Administration Center for Veterinary Medicine (**FDA CVM**). However, there are many other agencies involved in the oversight of drug use in cattle besides the FDA. These include the Environmental Protection Agency (**EPA** - approves pesticide labels), the US Department of Agriculture Food Safety and Inspection Service (**FSIS** - inspects cattle harvest ante- and postmortem and tests for drug residues), United States Department of Agriculture Center for Veterinary Biologics (**CVB** - vaccine approval), the Drug Enforcement Agency (**DEA** - defines and enforces regulations related to the distribution and use of controlled substances), individual state veterinary medical boards (define and enforce veterinary practice act), and individual state pharmacy boards (define and enforce pharmacy and drug distribution law) (Fajt, 2013). For dairy operations, there is also the National Conference on Interstate Milk Shipments (**NCIMS**), which oversees the Pasteurized Milk Ordinance (**PMO**). The PMO defines procedures for milk sanitation and prevention of milk borne disease. Regulatory oversight provides assurance in the development of safe products and that no harmful residues enter the food supply.

Efforts have been made to promote the judicious use of antimicrobials in animals (AVMA/AABP, 2016; National Dairy Farm Program, 2016). These have been largely educational efforts to increase awareness and

best practices with respect to prudent drug use in food animals. In 2012, the FDA finalized Guidance for Industry #209 (FDA GFI #209, 2012) which provides a framework for the voluntary adoption of practices to ensure the appropriate or judicious use of medically important antimicrobial drugs in food-producing animals. This framework includes the principles of phasing in such measures as: 1) limiting medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health and 2) limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation. It is apparent that FDA will be introducing policies over time with this framework in mind. Let's examine each of these more carefully.

Principle 1: The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health. FDA believes the use of medically important antimicrobials in food-producing animals for production purposes (e.g., to promote growth or improve feed efficiency) represents an injudicious use of these important drugs. FDA believes that use of medically important antimicrobials for treatment, control, or prevention of specific diseases (disease prevention is defined as administration of an antimicrobial drug to animals, none of which are exhibiting clinical signs of disease, in a situation where disease is likely to occur if the drug is not administered – see further discussion later), including administration through feed or water, to be a judicious use that is necessary for assuring the health of food-producing animals. The term “medically important antimicrobials” generally refers to antimicrobials that are important for therapeutic use in humans. A list of “medically important antimicrobials” can be found in Appendix A of the FDA Guidance for Industry #152 (FDA GFI #152, 2003)

Principle 2: The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.

In addition to instituting voluntary measures that would limit use of medically important antimicrobial drugs in food-producing animals to uses that are considered necessary to assure the animals' health (Principle #1), FDA also believes it is important to phase-in the practice of including veterinary oversight or consultation in the use of these drugs. Essentially what this means is that all antimicrobials considered medically important will eventually fall under the oversight of veterinarians. There are three classes of animal drugs: Over-the-Counter (OTC), Prescription (RX), and Veterinary Feed Directive (VFD). OTC drugs can be sold by any person or establishment without the prescription of a veterinarian. Prescription drugs can only be sold to farmers by a veterinarian or pharmacist, and only with the prescription of a veterinarian. VFD covers drugs intended for use in or on feed, which is limited by an approved application to use under the professional supervision of a licensed veterinarian. Eventually, it is likely that all antimicrobials that are considered medically important will no longer be available OTC. Examples of this would include injectable penicillin or oxytetracycline, or feed additive antimicrobials such as AS-700.

In 2013, FDA finalized Guidance for Industry #213 (FDA GFI #213, 2013). This document essentially implemented the two principles of GFI #209 for feed and water antimicrobials. This document does two things: 1) it eliminated the use of medically important antimicrobials for production uses (e.g. growth promotion), and 2) it requires that feed and water antimicrobials must be used under the guidance of licensed veterinarians. Complete implementation of these rules are to occur by January 1, 2017.

The veterinary feed directive, or VFD, is the mechanism that has been devised to give veterinarians the tools to control and deliver medically important antimicrobials to food animals. Although logistically different, a VFD is essentially a prescription; the difference is that a prescription can only be filled by a licensed pharmacy whereas a VFD can be filled by an approved feed distributor. A VFD can be written only by a veterinarian licensed in the state where the targeted animals are to be fed. The veterinarian must have a Veterinary Client Patient Relationship (VCPR) with that client as defined by the state where the animals are fed. Logistically, the veterinarian will write a VFD and send a copy to the client and the feed distributor. At this time, the VFD must be written or it can be sent electronically. No "over-the-phone" or verbal contingencies for issuing a VFD are in place. More information can be found about the VFD at the FDA VFD resource page accessible at: <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>

So, as professionals interested and responsible for the safe use of antimicrobials, what can we do to ensure responsible use of antimicrobials and compliance to the new rules with respect to antimicrobial use in feed and water? Here are 5 things WE can do TODAY to improve antimicrobial stewardship:

1. Encourage proper VCPR. This relationship is necessary to obtain most antimicrobials and likely will become more important in the future. The American Association of Bovine Practitioners (AABP) has established guidelines for a VCPR; "Establishing and Maintaining the Veterinarian-Client-Patient Relationship in Bovine Practice" (AABP VCPR, 2013). Key components of a VCPR include: 1) an agreement by both a veterinarian and producer that a VCPR exists, 2) a veterinarian of record with

oversight of herd veterinary treatments, 3) clarity of relationships with consultants and other veterinarians, 4) written treatment protocols for all drugs to be used on the farm, 5) written or electronic treatment records, and 6) provision of drugs for only specific time frames and for specific protocols. Outside of future regulatory requirements, this relationship is really important in helping to ensure the health of your animals and the safety of the food they produce. Note: Every state has defined a VCPR. State VCPR regulations can be accessed at: <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm>

2. Keep good records. Records provide many GOOD things in terms of managing the health, safety, and productivity of our animals. Unfortunately, records are often one of the most neglected management tools. Whether it is to ensure that we follow proper withdrawal times or monitoring our treatment success, records are critical for managing the safe use of antimicrobials, as well as the health of our herds. In fact, one of the best ways to keep yourself out of trouble with regulatory agencies (should you ever have a drug residue issue) is to have good records.
3. Develop appropriate treatment protocols for common health problems. Protocols help to avoid the “shotgun” approach to treating problems. Protocols should be developed for the most common health problems you face with the assistance of your veterinarian. They should be written down, easily accessible, and reviewed regularly (at least once a year). Protocols should not depend on routine extra-label use where there are alternatives that can be used. For example, talk with your veterinarian about alternatives to Procaine

Penicillin that will be effective at the labeled dosage.

4. Learn about the VFD and work closely as a team with all those involved with developing and delivering diets to animals. This would include farm management, veterinarians, nutritionists, and employees. A suggestion would be to make one person the “go to” person for learning about, educating others, and implementing the VFD in your organization.
5. Be GREAT stewards of antibiotic use. It is important that we all make every attempt to use antibiotics in a prudent manner in order to maintain their effectiveness for both humans and animals.

Let’s be clear, the livestock industry as a whole has a great track record of providing safe food. However, times keep changing and the demands of not only consumers but of the public as a whole, make it essential that the livestock industry be above reproach in regard to antimicrobial use. That means that what we did yesterday may not be good enough today. Let’s all step forward and take a role in ensuring careful use of antimicrobials. It is in the best interest of the animals we care for and the public who buy our products. *It is the right thing to do!*

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