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FDA Policies on Antibiotic Use in Food Animals

Key Elements and How to Strengthen Them

Overview

Antibiotic resistance is a growing and urgent public health threat fueled by the frequent and widespread use of antibiotics. The more antibiotics are used, the more likely it is that bacteria will develop resistance, making it essential to minimize inappropriate or avoidable use of the drugs in both humans and animals. As part of the effort to combat antibiotic-resistant bacteria, the U.S. Food and Drug Administration is taking steps to help ensure that antibiotics are used responsibly in food animals, meaning only as medically necessary and appropriate.

Although publicly available data regarding the use of antibiotics in animal agriculture are limited, FDA reports suggest large-scale use of antibiotics important to human medicine in food animals. In 2014, more than 20 million pounds of medically important antibiotics were sold for use in food-producing animals in the United States—a 23 percent increase since 2009.[1] Further, 97 percent of these drugs were purchased over the counter, meaning without any veterinary involvement or oversight, and administered to animals primarily through feed or water.

The landmark policies detailed below should help address some of the problems highlighted by these 2014 statistics, but more work is needed. Next steps include strengthening the policies already in place, as well as providing technical assistance for compliance and collecting more robust data to monitor and assess their impact.

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Phasing out antibiotics for growth promotion: Guidance for Industry #213

Guidance #213 acts as a blueprint for implementing the principles set forth in Guidance for Industry #209: Antibiotics important in human medicine should be used in food animals only to assure animal health and should be limited to uses under the oversight of a licensed veterinarian.

Key elements of Guidance #213

- Asks drug companies to notify FDA of their intent to remove growth promotion from product labels; all affected companies indicated their intent to comply. Once manufacturers revise the use conditions on the approved label, food animal producers cannot legally use the drugs for production purposes. Guidance #213 will be fully implemented by the end of December 2016.
- Clarifies that drug companies can change use claims and marketing status to comply with Guidance #213 without submitting additional safety or effectiveness data unless they are claiming new treatment uses or changing the makeup of a drug.
- Defines appropriate therapeutic uses of antibiotics in food animals as the "treatment, control, and prevention of specific diseases … necessary for assuring the health of food-producing animals."
- States that new drug uses must have a specific dosing duration and level for an identified disease and must be available only for those animals needing the drug, not an entire herd or flock. Many existing prevention and control drug labels do not currently specify this.
- Establishes criteria for veterinarians to justify the use of antibiotics for "disease prevention."

How to strengthen Guidance #213

Tailor drug labels to ensure the appropriate use of antibiotics for disease prevention. While Guidance #213 defines appropriate uses for disease prevention, some antibiotics still have labels with approved disease prevention indications that are inconsistent with those principles. For example, some antibiotics currently on the market have approved disease prevention uses that are not targeted toward a specific disease or do not include defined durations of use. Legitimate prevention should not include instances where medically important antibiotics are routinely needed or used over multiple consecutive production cycles for the same diseases, especially on entire herds or flocks. The agency should go further and work with drug companies and other stakeholders to remove prevention indications that are inconsistent with judicious use.

Develop a clear plan for evaluating success. FDA provides periodic public updates regarding antibiotic label changes occurring in compliance with Guidance #213. However, more data will be needed in order to effectively evaluate the impact of this policy. Under the Animal Drug User Fee Act, FDA has already expanded its reporting of sales and distribution data, and two additional initiatives will also be important to collecting more robust information.

- In May 2016, FDA finalized a rule to require that animal drug companies provide species-level sales estimates on medically important antibiotics. These data would contribute to the overall understanding of how these vitally important products are used, such as reflecting recent changes that leading poultry producers have made to shift away from routine antibiotic use. The data would also enable stakeholders to follow trends in demand as Guidance #213 is implemented.
- In September 2015, FDA, the U.S. Department of Agriculture, and the Centers for Disease Control and Prevention held a public meeting to launch the process for developing a plan to collect improved on-farm antibiotic use and resistance data. These agencies should develop and finalize a concrete, comprehensive data collection plan with timelines.

> Food producers and veterinarians will need technical assistance and training to comply with these policy changes.

Ensuring oversight of antibiotics used in feed: Veterinary Feed Directive

FDA's Veterinary Feed Directive (VFD) rule and associated industry guidance aim to foster the responsible use of antibiotics in food animals by outlining the process and framework for veterinary authorization of drugs used in animal feed.

Key elements of Veterinary Feed Directive:

- Outlines the process for ensuring veterinary oversight of VFD drugs, which are used in animal feed.
- Provides veterinarians in all states with a consistent framework for authorizing the use of medically important antibiotics in feed when needed for specific animal health purposes.
- Defines minimum requirements for a valid veterinarian-client-patient-relationship (VCPR), including that the veterinarian assumes responsibility for making clinical judgments about patient health, has sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where the patient is managed, and provides for any necessary follow-up evaluation or care.
- Creates a state-federal VCPR hybrid approach in which veterinarians must follow existing state VCPR standards where they exist and meet minimum requirements, and, in their absence, adhere to the federal VCPR standards.
- Establishes a six-month expiration date for VFDs unless a shorter duration is indicated on the label.
- Limits antibiotic refills to product label specifications.
- Establishes minimum VFD record-keeping requirements.

How to harness data from the Veterinary Feed Directive

Consider a plan to systematically collect VFD data. These data would provide useful monitoring information regarding compliance with Guidance #213 and insight into why antibiotics are being used (e.g., the indication). At a minimum, FDA could initiate a pilot program in various regional and production settings to better understand the potential usefulness of this information.

Technical assistance for complying with the new policies

Food producers and veterinarians will need technical assistance and training to comply with these policy changes. While Guidance #213 directly applies to drug companies and businesses that make medicated feed, it indirectly forces changes in farming practices. Food producers will need to understand the full implications of Guidance #213 and alternate production methods that do not rely on medically important antibiotics for growth promotion, or over-the-counter sales of antibiotics to be administered through feed or water. Veterinarians will need further education on the proper use of the VFD and associated compliance requirements. Additionally, food producers and veterinarians may encounter practical roadblocks that USDA extension services and other third-party veterinary and agricultural organizations can help address through educational outreach and stakeholder engagement.

Endnotes

1 U.S. Food and Drug Administration. *2014 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals* (December 2015), http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM476258.pdf.

For further information, please visit:

saveantibiotics.org

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