

Supporting Antimicrobial Stewardship FDA Update

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Topics

- Changes implemented
- 5-year AMR plan
 - Update on key projects

Changes Implemented

Guidance #209/213 initiative:

- **Goal:** Limit use of medically important antimicrobial drugs in food-producing animals to those uses that:
 - are considered necessary for assuring animal health and,
 - that include veterinary oversight or consultation

Changes Implemented

GFI #213 plan initiated in 2013

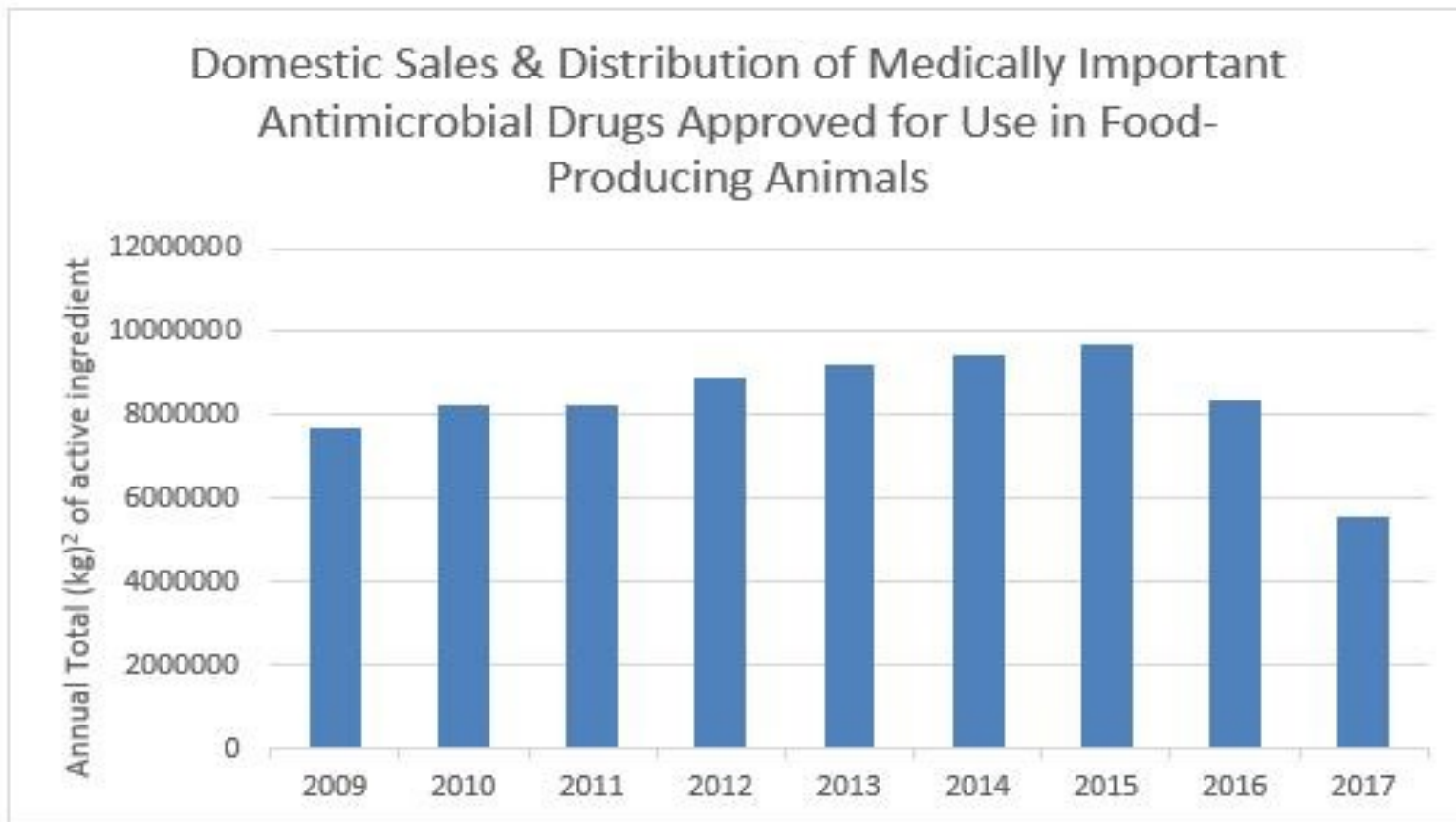
- **Focus**
 - medically important antimicrobials
 - feed and water use in food-producing animals
- **Goal:**
 - Eliminate production (growth promotion) uses
 - Bring products under veterinary oversight

Note: “Medically important” antimicrobial drugs are those that are considered important for therapeutic use in humans

GFI #213 Implementation

- Completed January 1, 2017
 - Drug sponsors worked voluntarily with FDA
 - Changes to feed and water use of medically important antimicrobials
 - feed now require a VFD
 - drinking water now require a Rx
 - No longer legal to use these drugs for production (growth promotion) purposes

Antimicrobial drug sales



Domestic sales decreased:

- 33% between years 2016 and 2017
- 43% since 2015 (peak year of sales/distribution)
- 28% since the first year of reported sales in 2009

Next Steps

SUPPORTING ANTIMICROBIAL STEWARDSHIP IN VETERINARY SETTINGS

GOALS FOR FISCAL YEARS 2019 – 2023

FDA CENTER FOR VETERINARY MEDICINE

September 2018

INTRODUCTION

Antimicrobial resistance is a national and worldwide public health challenge. Antimicrobial drugs¹ have been successfully and widely used in human and veterinary medicine for more than 60 years. When used judiciously, antimicrobials can effectively fight bacterial infections. Their use and misuse, however, can promote the development of antimicrobial-resistant bacteria. When bacteria develop resistance to an antimicrobial drug, that drug may be less effective in fighting infection caused by that bacteria. It is critical that we apply a One Health approach to address this important public health concern, including implementing good antimicrobial stewardship practices in human healthcare and veterinary settings to slow the development of resistance and extend the useful life of antimicrobials. One Health is the integrative effort of multiple disciplines working locally, nationally, and globally to attain optimal health for people, animals, and the environment.² The focus of this plan is on actions being taken by the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) and other stakeholders to support antimicrobial stewardship in veterinary settings.

As part of its regulatory mission, CVM is responsible for ensuring the safety and effectiveness of animal drugs, including antimicrobials, and has taken important steps to update the approved use conditions of medically important antimicrobials (i.e., antimicrobials important for treating human disease) to support their judicious use in food-producing animals. While important progress has been made, additional work is needed to further address the challenge of antimicrobial resistance.

¹ The term "antimicrobial" refers broadly to drugs with activity against a variety of microorganisms including bacteria, viruses, fungi, and parasites. Antimicrobial drugs that have specific activity against bacteria are referred to as antibacterial or antibiotic drugs. The broader term "antimicrobial," however, commonly used in reference to drugs with activity against bacteria, is used in this document interchangeably with the terms antibacterial or antibiotic. Antimicrobial resistance is the ability of bacteria or other microbes to resist the effects of a drug. Antimicrobial resistance, as it relates to bacterial organisms, occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals, or other agents designed to treat bacterial infections.

² American Veterinary Medical Association, "One Health – What is One Health?" <https://www.avma.org/KB/Resources/Reference/Pages/One-Health94.aspx>, accessed September 5, 2018.

FDA 5-Year Plan

- Published September 2018
- Guides activities over next 5 years (2019-2023)
- Builds on GFI #209/213 initiative
- Scope
 - Still focused on medically important antimicrobials
 - Broadened to include all animals (i.e., companion)

Goals of 5-Year Plan

1. Align antimicrobial **drug product** use with the principles of antimicrobial stewardship
2. Foster **stewardship** of antimicrobials in veterinary settings
3. Enhance **monitoring** of antimicrobial resistance and antimicrobial drug use in animals

5-Year AMR Plan: Ongoing key projects

- Transition OTC products to RX
- Defining durations of use
- Updating list of medically important antimicrobials
- Pilot projects on collecting use data
- Assessment report

Ongoing AMR Activities

Key Project – OTC to Rx Transition

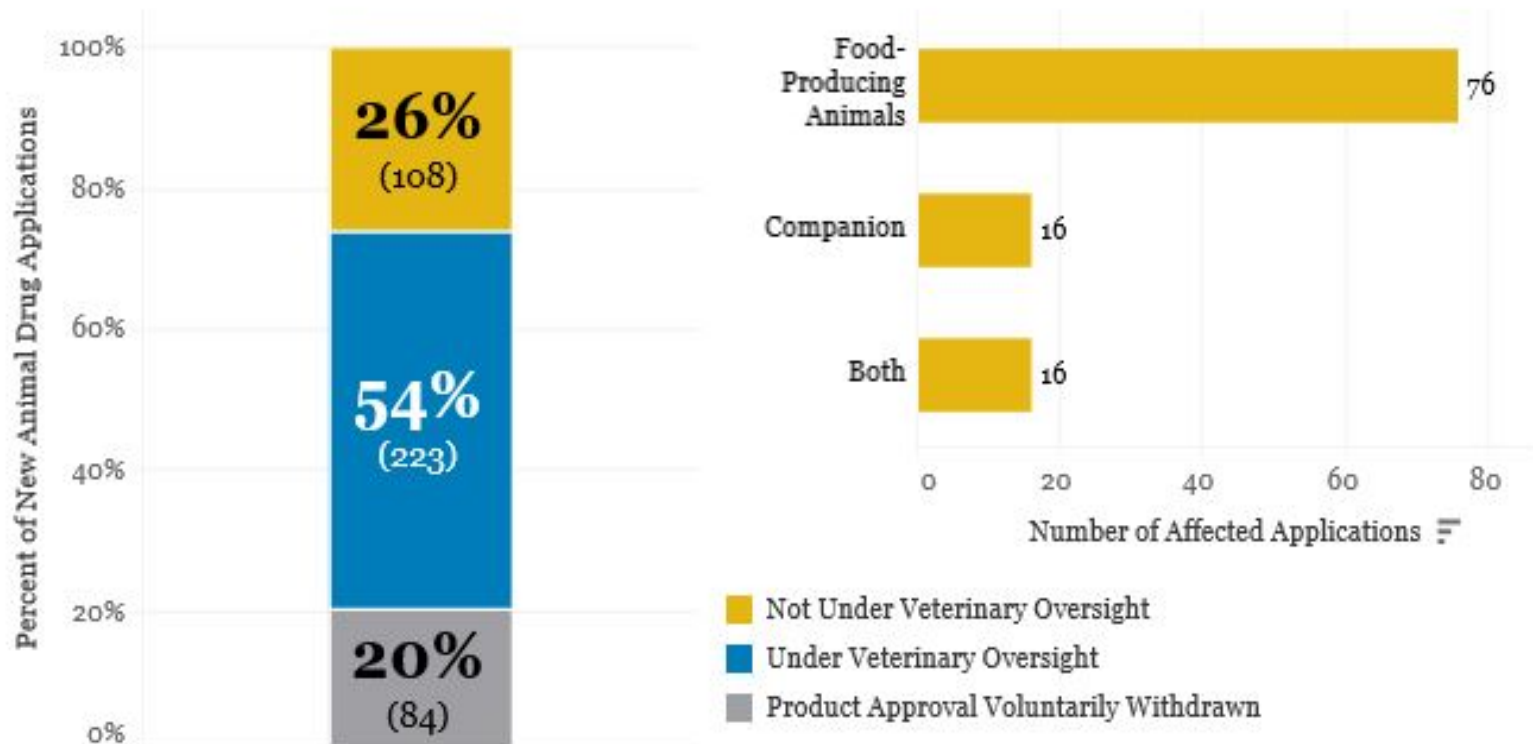
Bring remaining dosage forms* of medically important antimicrobials under the oversight of licensed veterinarians

- Draft strategy published September 23, 2019 (GFI #263)
- Follows similar model used for implementing GFI #213
- List of affected products on CVM website
- Proposes 2-year implementation period

*Includes products that are approved for routes of administration other than feed or drinking water (e.g., injectables, intramammary).

OTC to Rx Transition

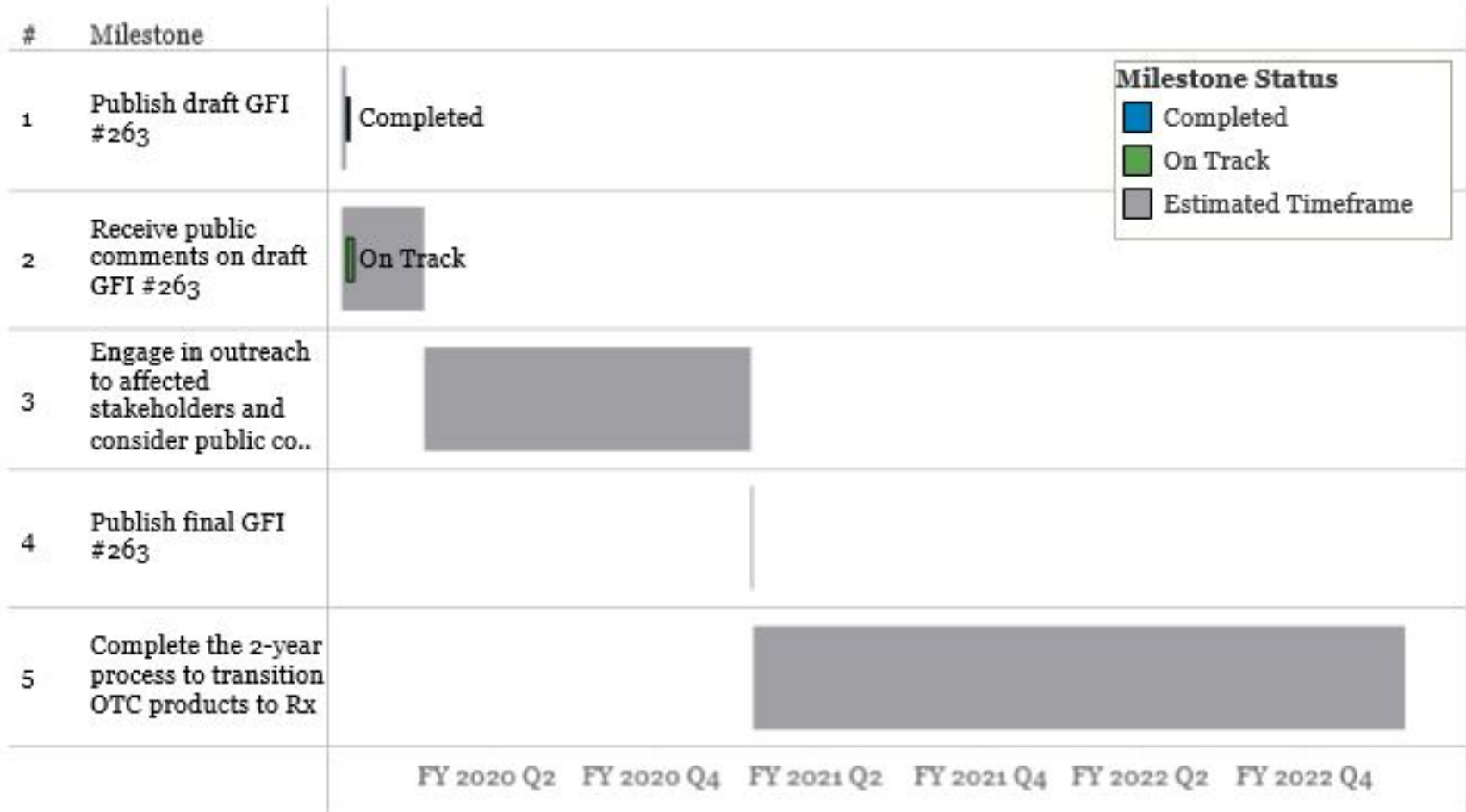
Progress Toward Veterinary Oversight of Medically Important Antimicrobials*



* Performance measures: Percent and number of medically important antimicrobial animal drug applications approved for use in food-producing and companion animals by marketing status.

OTC to Rx Transition

Key Project: Transition Over-the-Counter Products to Veterinary Oversight



Ongoing AMR Activities

Key Project – Update Durations of Use

Defining appropriate durations of use for medically important antimicrobial drugs

- **Objective** - Update use conditions of affected products (to better define when and for how long to administer) so that effectiveness is maintained, but extent of exposure is minimized.
 - Affects only feed-use products (85)
 - List on website
 - Affected products already brought under veterinary oversight (VFD)

Ongoing AMR Activities

Key Project (cont'd)

Defining appropriate durations of use

- **Target** – issue draft strategy by end of September 2020.
 - expect to issue in form of draft guidance
 - further stakeholder input needed as strategy is developed
- **Funding opportunity** – announced April 2019
 - list of affected products was made available online
 - data needed to help target and define durations of use
 - two grants awarded (announced Sept. 2019)
 - additional funding opportunity possible

Ongoing AMR Activities

Key Project – “Appendix A” Update

Update list of “medically important” antimicrobials

Target: Initiate public comment process in 2020

- Originally published in 2003 as Appendix A of FDA’s GFI #152
- Ranks antimicrobial drugs according to their human importance
- Defines which drugs are considered “medically important”

Ongoing AMR Activities

Key Project – Use data collection

Collecting Use Data: ongoing pilot projects

- Funding opportunity announced in March 2016
- Sought proposals for methodologies to collect information on antimicrobial use practices in various animal production settings
- Two pilot projects were awarded in August 2016
 - Feedlot/dairy cattle (Mike Apley)
 - Broilers, turkeys, swine (Randy Singer, Peter Davies)

Ongoing AMR Activities

Key Project

Issue “Assessment report” - report that integrates and analyzes available information on antimicrobial use in veterinary settings

To provide more comprehensive assessment of progress

Target - Issue report in late 2020

- Intent is to Include:
 - Use data captured from pilot projects
 - USDA survey data on use
 - NARMS resistance data
 - Sales and distribution data
 - Animal demographic/health data

Antimicrobial Resistance Activities

Recent and Upcoming Publications

- VFD Compliance Assessment
 - Published August 26, 2019
- OTC-to-Rx draft Guidance
 - Published September 23, 2019
- 2018 Sales and Distribution Report
 - Target: By end of December 2019
- 2016 – 2017 Summary NARMS Report
 - Target: By end of December 2019

In closing

- Significant progress has been made
- Build on what has already been accomplished; continue to pursue a collaborative approach
- Consistent with One Health, expanding focus to include all veterinary sectors
- 5-year plan is intended as a guide for moving forward
- Activities guided/adjusted as needed in response to evolving science and available data

