Exploring the Potential for a Public-Private Partnership (PPP) to Support the Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals

The broadcast will begin shortly

June 14, 2022
1-3 pm Eastern Time

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Welcome

Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the FDA
Thank you for joining

This webinar is being recorded. The slides, transcript, and video recording will be available on the FDA Foundation website after the meeting.

If you’d like to ask a question, you may enter it in the Zoom Q&A. We will get to as many questions as time allows.

Speakers will not address questions regarding any pending regulatory action or discuss specific companies or medical products by name.

Your microphone and video will remain off during the meeting. Those who registered to present public comment will be unmuted when it is their time to speak. Reminder: public commenters should check in by 1:30 pm ET.
Agenda

1 p.m.* Welcome

1:05 p.m. Opening Remarks from U.S. Food and Drug Administration

1:15 p.m. The Value of Data

1:50 p.m. A Roadmap to a Public-Private Partnership

2 p.m. Public Comment

3 p.m. Adjournment

*Eastern Time
FDA has opened a docket to accept public comments through August 21, 2022 on the report and general insights into the collection of antimicrobial use data in food-producing animals.

Opening Remarks

William T. Flynn, DVM, MS
Deputy Director, Science Policy
Center for Veterinary Medicine
U.S. Food and Drug Administration
Tracking and Monitoring Antimicrobial Use in Food-Producing Animals

Exploring the Potential for a Public-Private Partnership to Support the Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals

Virtual Public Forum
Tuesday, June 14, 2022
1-3pm Eastern Time

William T. Flynn, DVM, MS
Deputy Director for Science Policy
FDA Center for Veterinary Medicine
Antimicrobial Stewardship

• CVM’s 5-year antimicrobial resistance action plan is focused on “Supporting Antimicrobial Stewardship in Veterinary Settings

• Focus of stewardship on how antimicrobials are used

• Use data is needed to inform stewardship efforts
Currently Available Data

Sales and Distribution Reports

- Represents volume distributed, but not necessarily volume used.
- Does not provide information on reason for use.
- Products are approved for multiple animal species; species data are estimates.

Challenge

- Need for data that better reflects actual use
- Lack of existing infrastructure for coordinated system for collecting antimicrobial use (AMU) data across agricultural and veterinary sectors.
Why is AMU Data collection important?

Establishing a system for collecting representative data on antimicrobial use in animals would benefit public and animal health by:

– Enable monitoring of trends; enhance understanding of AMR drivers
– Fostering antimicrobial stewardship
– Informing regulatory and policy decision making
– Enhancing transparency regarding antimicrobial use
Prior Efforts to Explore Potential Strategies

2015
Held joint public meeting with USDA and CDC to begin discussions around the collection of AMU data

2016
Funded 2 cooperative agreements to develop methodologies for collecting data on antimicrobial use in food-producing animals

2020
Each pilot study published a summary of their findings in special issue of *Zoonoses and Public Health*

2022
Pilot studies are expected to end
Exploring the feasibility of a public private partnership for collecting AMU data
Today’s Public Forum

• Thank you for your participation - your input is critical
  – FDA has also opened a docket to accept public comments through August 21, 2022

• Today’s input (and that submitted to docket) will inform next steps; we expect more stakeholder engagement as we further develop a plan

• We look forward to a productive discussion today
The Value of Data

Moderator
Susan C. Winickler, RPh, Esq.

Panelists
Mike Murphy, DVM, JD, PhD
American Veterinarian Medical Association

Paul Plummer, DVM, PhD
Iowa State University

Randall S. Singer, DVM, MPVM
University of Minnesota

David Wallinga, MD, MPA
Natural Resources Defense Council
A bleak global future, driven by antibiotic use

— Superbug infections as the leading cause of death, by 2050

— From 1.3 million to 10 million annual deaths, across the world

— US deaths between 35,000 and 162,000 today. By 2050 ???

Links:

Wallinga et al. Review of the Effectiveness of Current US Policies on Antimicrobial Use in Meat and Poultry Production, Curr Env Health Reports, June 2022, DOI: 10.1007/s40572-022-00351-x


Tiseo et al., Global Trends in Antimicrobial Use in Food Animals from 2017 to 2030, DOI: 10.3390%2Fantibiotics9120918
 ➢ Antibiotic use, and especially overuse, is what drives the spread of antibiotic resistance. (See links)

 ➢ Comprehensive tracking and transparent reporting of antibiotic prescribing and use is essential, in order to:

 ✓ Identify ongoing patterns of overuse.
 ✓ Inform effective government actions to reduce or eliminate them.
 ✓ Help hold prescribers accountable.
 ✓ Hold FDA accountable for meeting the public health imperative to reduce overuse as much as possible.

Links:


Antibiotic Sales are Entirely Appropriate as a Proxy for Use

Sales of Medically Important Antibiotics for Food-Producing Animals, 2011 to 2020

- 27.3% decline, 2010-2020
- 42.8% decline, 2011-2020

Use of Medically Important Antibiotics in Food-Producing Animals in 25 European Countries*, 2011-2020

- 43.2% decline, 2011-2020

Sources: European Medicines Agency, ESVAC project, Interactive ESVAC database; FDA, Annual ADUFA Summary reports on antimicrobials sold or distributed for use in food-producing animals, 2011-2020, https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-reports

* Includes all top European livestock producers except Romania. Also not included are Malta, Luxembourg, Switzerland, Croatia, and Greece

European Medicines Agency, Eleventh ESVAC Report, Trends from 2010 2020

David Wallinga, MD, NRDC June 14, 2022
A Roadmap to a Public-Private Partnership

Amar Bhat, PhD
Chief Operating Officer
Reagan-Udall Foundation for the FDA
Roadmap to a PPP

Stage One

- Identifying and Listening to Stakeholders; Capturing Key Themes
- Agreeing on Key Objective and Principles
- Achieving Consensus on a Governance Model and a Funding Model
- Committing to Participate in Partnership(s)
- Establishing a PPP
The following key themes emerged from our discussions with stakeholders:

• Antimicrobial sales and distribution data and antimicrobial use data are not the same.

• Context, such as the number, size, species of animals, and indication, is essential to understand antimicrobial use in food-producing animals.

• Collecting standardized data across species and routes of administration is challenging.

• Each food-producing species or food commodity requires unique considerations and species data should not be directly compared to other species.

• Clear data access and privacy protection are essential to build and maintain mutual trust among public and private partners.
Gathering antimicrobial use data in food-producing animals to foster antimicrobial stewardship and animal health and welfare.
Draft Principles
Potential Governance Models

Model 1: One Public-Private Partnership where each animal commodity compiles data and shares analyses at its own pace, but according to common governance approaches.

Model 2: Multiple Partnerships, with varying governance approaches, Feeds into an overall Partnership Hub.
Roadmap to a PPP

Stage Two

1. Identifying and Listening to Stakeholders; Capturing Key Themes
2. Agreeing on Key Objective and Principles
3. Achieving Consensus on a Governance Model and a Funding Model
4. Committing to Participate in Partnership(s)
5. Establishing a PPP
Public Comment

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