Combating AMR through Antimicrobial Stewardship

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Antimicrobial Stewardship in Veterinary Settings

- Antimicrobial resistance (AMR) is a complex, multifactorial issue; to preserve the availability and effectiveness of antimicrobials for both human and animal health, a multisectoral, One Health, approach is needed to combat AMR.

- The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety of animal drugs. This includes assessing AMR risks and implementing actions to mitigate those risks, as appropriate.

- In 2018, FDA published a 5-year plan for supporting antimicrobial stewardship in veterinary settings.

  - we believe that fostering good antimicrobial stewardship practices in veterinary settings and optimizing use can help slow the development of antimicrobial-resistant bacteria.
Antimicrobial Stewardship in Veterinary Settings

Key Areas of Focus (Goals of FDA 5-year AMR plan)

- Evaluating use conditions of animal antimicrobial drug products
- Promoting/supporting antimicrobial stewardship at the user level
- Collecting data to monitor animal antimicrobial use and antimicrobial resistance

FDA Approach for Implementing Change in Veterinary Sector

- Focusing actions or mitigations on drugs of greatest concern: drugs that are important human therapies ("medically important antimicrobials")
- Emphasizing collaboration and seeking cooperation from industry to take action voluntarily **

**Note: Once drug company voluntarily takes action to change approved use condition of a drug product, the end user is required to follow new conditions of use
Evaluating drug products: Important Actions

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<tr>
<th>Year</th>
<th>Action</th>
<th>Purpose</th>
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<tr>
<td>2003</td>
<td>Guidance #152, implemented new guidance for evaluating AMR risks as part of drug approval process</td>
<td>Outlines recommended risk assessment process for use by drug sponsors seeking approval of new proposed uses of medically important antimicrobials in food-producing animals</td>
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<td>2013</td>
<td>Guidance #213, implemented guidance recommending certain changes be made to already approved feed and water uses of medically important antimicrobials</td>
<td>Outlined a 3-year plan for drug sponsors to voluntarily eliminate growth promotion uses and transition products from over-the-counter (OTC) availability to use under oversight of licensed veterinarians</td>
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<td>2021</td>
<td>Guidance #263, implemented guidance to compete process of bringing medically important antimicrobials under vet oversight</td>
<td>Outlines 2-year plan for drug sponsors to voluntarily transition to veterinary oversight all medically important antimicrobials that are still available OTC</td>
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Changes completed in 2017 (Guidance #213)

All affected drug sponsors worked voluntarily with FDA

Of the 292 approved animal drug applications affected by Guidance for Industry #213:

• 84 were completely withdrawn

Of the remaining 208 applications,

• 93 (water products) – converted OTC to Rx

• 115 (feed products) – converted OTC to veterinary feed directive (VFD)

All production (e.g., growth promotion) indications were withdrawn (31 applications)
Veterinary Oversight of Medically Important Antimicrobials

• With implementation of Guidance #213 in 2017, all feed and water uses were transitioned to veterinary oversight (blue) or were withdrawn (gray)

• With full implementation of Guidance #263 (June 2023), all remaining OTC products** will be transitioned to prescription

**Includes products that are approved for routes of administration other than feed or drinking water (e.g., injectables, intramammary).
Collecting data to monitor animal antimicrobial use and antimicrobial resistance

- Scientifically-sound data are needed to guide actions taken to address AMR and to assess their effectiveness.
- Three important data streams include:
  - Antimicrobial resistance data
  - Antimicrobial sales/distribution data
  - Antimicrobial use data
Collecting Data to Monitor Antimicrobial Resistance in Animals

**FDA**
- Random stratified sampling of retail meat; seafood testing being developed

**USDA**
- Random sampling of national food animal production at slaughter

**CDC**
- Nationwide surveillance of foodborne bacteria from human isolates

**FDA Monitoring of AMR in Retail Meats:**
- 24 States in 2021

**Sampling:** 49 packages per month
- 10 retail chicken
- 10 ground turkey
- 10 ground beef
- 10 pork chops
- 3 salmon
- 3 shrimp
- 3 tilapia

**Microbiology**
- Retail meat: *Salmonella*, *Campylobacter*, *E. coli*, *Enterococcus*
- Seafood: *Vibrio*, CRE, *Aeromonas*
Collecting Data on Antimicrobial Sales and Use

Sales Data

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
Domestic sales increased 3% between 2018 and 2019

Use Data

• Sales collection requirement established by law in 2008; no requirement for use data
• Given the limitations of sales data, FDA has funded pilot projects to collect on-farm use data
  • Feedlot and dairy cattle (Kansas State University)
  • Broilers, turkeys, swine (University of Minnesota)
• In 2020, two pilot projects were funded to collect antimicrobial use information in the companion animal sector (dogs and cats)
• Planning for additional public/industry engagement to seek input on collaborative strategies for continued use data collection

Source: [2019 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals](https://www.fda.gov)
www.fda.gov
# Recent Publications/Ongoing Activities

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<tr>
<td><strong>August 2020</strong></td>
<td>Publication of NARMS Strategic Plan: 2021-2025</td>
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<td><strong>October 2020</strong></td>
<td>Published Concept Paper, “Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs,” and Public meeting</td>
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<tr>
<td><strong>January 2021</strong></td>
<td>Published Concept Paper, “Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use In or On Feed</td>
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For more information on status of FDA’s 5-year plan, please see: [FDA-TRACK: Progress on FDA’s Support of Antimicrobial Stewardship in Veterinary Settings](#)
Key principles of U.S. approach include:

- Recognition of the need for One Health, multisectoral strategies
- Risk-based actions that are informed by sound science
- Focus on antimicrobial stewardship and optimizing the use of antimicrobials in veterinary sector
- Emphasis on stakeholder engagement in developing collaborative, voluntary strategies for implementing change