NATIONAL EXPERIENCE WITH ANTIMICROBIAL DATA COLLECTION IN ANIMALS: USA

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Topics

- Sales/distribution data
  - History
  - Limitations
- Judicious use strategy
  - Medically important antimicrobial drugs
  - Production indications
  - Veterinary oversight
- Enhancing data collection
  - Public comments
  - Evaluation of resistance trends
Antimicrobial Sales Data: History

- Since 1972 CVM has collected annual sales data for all drugs approved for use in animals
  - Used internally for post-market surveillance
  - All animal drugs
    - Not just antimicrobials
    - Not just food-producing animals
  - Reporting period based on anniversary of approval
Antimicrobial Sales Data: History

- Since 2009 CVM has publicly summarized annual sales data for antimicrobial products approved for use in food-producing animals
  - New legal requirement (2008)
  - Restricted to antimicrobials and food-producing animals
  - Reporting period on calendar year basis
  - Annual summary published by FDA
  - Confidential business information protection
    - Unable to report classes marketed by less than 3 sponsors
Antimicrobial Sales Data: Limitations

- Sales ≠ Use
  - Complex distribution channels
  - Time delay between sale and end-use
  - Not all product sold is actually used
- Data prior to 2009 is difficult to analyze
  - Paper records
  - Annual based on anniversary of approval
Antimicrobial Sales Data: Limitations

- Most products approved for multiple species
  - Not possible to precisely determine sales by individual species or production class
Antimicrobial Sales Data: Limitations

- Most products approved for multiple indications
  - Not possible to assess **extent of use**
    - Indication of use
    - Dose administered
    - Duration of therapy
    - Proportion of animals treated
Judicious Use Strategy

- Focus is not on banning drugs in food-producing animals

- Goal: preserve availability of effective drugs (for both humans and animals)

- Antimicrobials must continue to be available to combat disease in animals
  - Including treatment, control, and prevention

- Emphasis is on assuring drugs are used as judiciously as possible

- Primary concern are “medically important” drugs
Judicious Use: Medical Importance

- FDA Criteria: Guidance for Industry 152, Appendix A
  1. Drugs used to treat enteric pathogens that cause food-borne disease
  2. Sole therapy or one of few alternatives to treat serious human disease or drug is essential component among many antimicrobials in treatment of human disease
  3. Antimicrobials used to treat enteric pathogens in non-food-borne disease
  4. No cross-resistance within drug class and absence of linked resistance with other drug classes
  5. Difficulty in transmitting resistance elements within or across genera and species of organisms

Judicious Use: Production Indications

- FDA distinguishes **production uses** (i.e. weight gain and feed efficiency claims) from **therapeutic uses** (disease prevention, control, and treatment)
- FDA does not consider production uses of medically important antimicrobials to be judicious
- Goal: removal of production indications associated with medically important antimicrobials
Judicious Use: Veterinary Oversight

- Limit the use of medically important antimicrobial drugs to those uses that include veterinary oversight/consultation
  - Primary objective is to include veterinarian in decision-making process
  - Not meant to mandate direct veterinarian involvement in drug administration
Judicious Use: Veterinary Oversight

- Convert all over-the-counter uses of medically important antimicrobials
  - Prescription: all non-feed dosage forms
  - Veterinary Feed Directive (VFD): feed
Enhancing Data Collection

- FDA believes having a better understanding of the extent of use of medically important antimicrobial drugs in food-producing animals will support the implementation of the agency’s judicious antimicrobial use strategy.
Enhancing Data: Public Comments

- FDA recently solicited comments from the public
  - Possible enhancements to the existing data collection requirements
    - E.g. drug sponsor estimates of sales by species
  - Alternative format of FDA’s annual summary of antimicrobial sales for use in food-producing animals
    - E.g. by dosage form or medical importance
  - Additional methods for monitoring antimicrobial use in food-producing animals
    - E.g. collaboration with other US agencies
Enhancing Data: Resistance Trends

The collection of more detailed food animal use data will assist FDA’s evaluation of antimicrobial resistance trends identified by the National Antimicrobial Resistance Monitoring System (NARMS) for enteric bacteria.
Enhancing Data: Resistance Trends

- Coupled with NARMS data, more detailed use information would help:
  - quantify the risks associated with different antimicrobial use practices in food producing animals
  - identify interventions to limit the development and spread of resistance in the food chain.
Enhancing Data: Ongoing Activities

- Assessing alternative formats for summarizing antimicrobial sales data
  - Limited by certain requirements to protect confidential business information
- Collaborating with other US Agencies to develop methods to access on-farm data regarding antimicrobial use in food-producing animals
Questions?
Thank You