

Progress Update

2017 NIAA Antibiotic Symposium

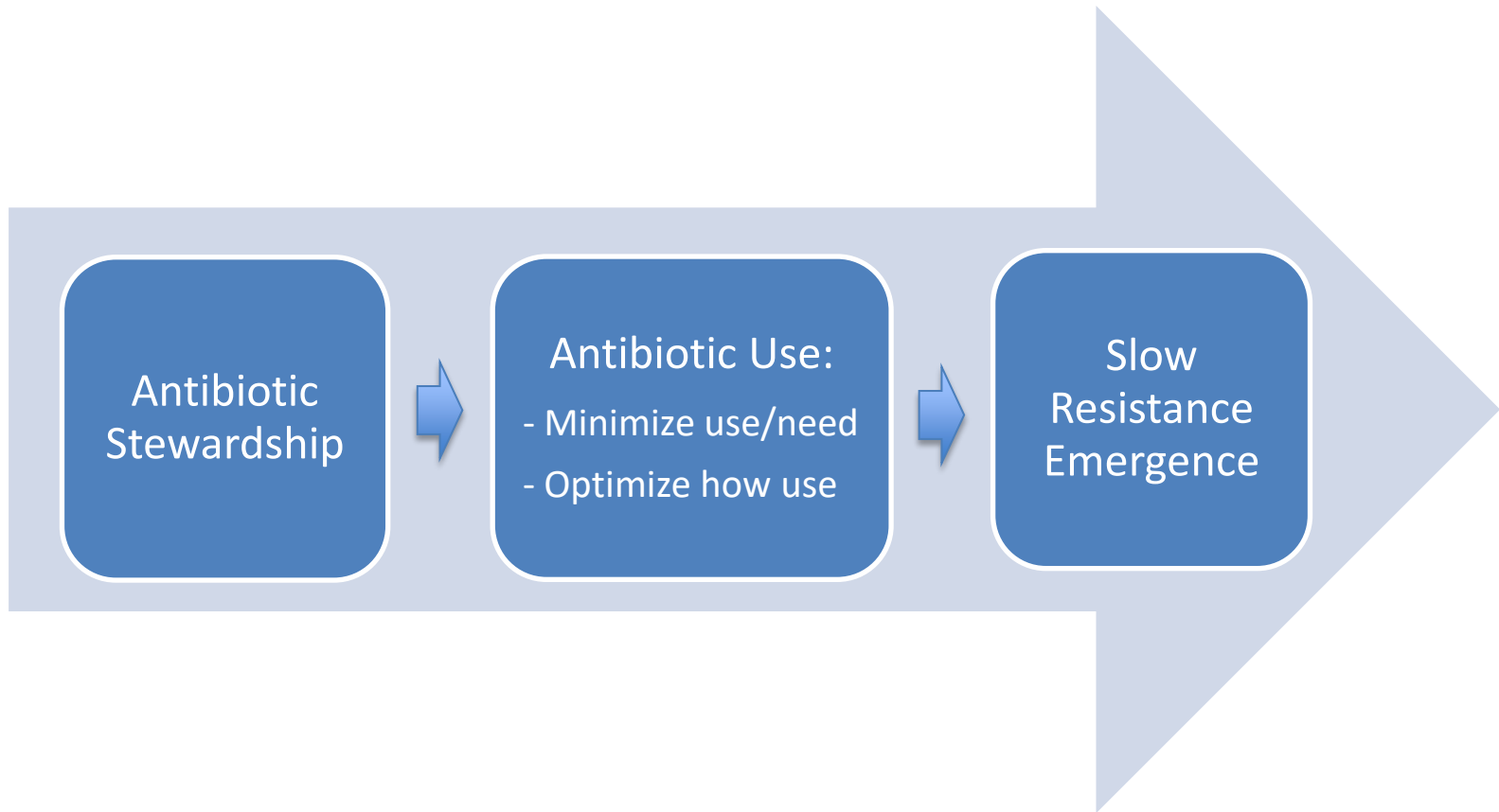
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Goals and Objectives

- Have we made progress?
 - Need to answer in context of desired outcome
- Focus on curbing resistance through fostering antibiotic “stewardship”
- Consensus is forming around core principles of “stewardship” in veterinary settings

Answer: Yes, important progress has been made

What is the goal?



Supporting Stewardship

Important areas where CVM is contributing:

- **Align products** - Align approved use conditions of medically important antimicrobial products with judicious use principles
- **Use practices** – support efforts to implement/reinforce antimicrobial stewardship in all veterinary settings
- **Monitor progress** - Enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals

Strategy to align products

- **Guidance #209 - defined policy goals**
 - Limit medically important antimicrobials to those uses that:
 - 1) are considered necessary for assuring animal health and
 - 2) that include veterinary oversight or consultation
- **Guidance #213 - outlined implementation plan**
 - How products need to change to align with policy goals
 - Established 3 year timeline
- **Veterinary feed directive (VFD) regulation**
 - Identified as obstacle to implementation
 - Needed to update rule to make VFD process more efficient

Scope of Strategy

Risk-based approach; focus actions or mitigations on drugs/uses of greatest concern

- “Medically important” antimicrobials
 - Drugs that are important human therapies
 - Where risk to public health most significant
- Products approved for use in feed and water
 - Greatest exposure potential
 - Included production (growth promotion uses)

Strategy approach

- Collaborative approach
 - Significant outreach to build support for effort
 - Engaged industry to develop plan framework and identify obstacles to implementation
- “Voluntary” approach
 - Drug sponsors voluntarily updated their products
 - Once changes made, new use conditions mandatory

Outcome of Strategy

Completed strategy on January 1, 2017

Of the **292** new animal drug applications initially affected by Guidance for Industry #213:

- **84** were completely withdrawn

Of the remaining **208** applications:

- **93** water-use NADAs – converted from OTC to Rx
- **115** feed-use NADAs – converted from OTC to VFD
- Production (e.g., growth promotion) indications were withdrawn from all **31** applications that included such indications for use

Significant accomplishment

- Unprecedented level of engagement and collaboration over 3-year implementation period
- January 2017 target was established and met
- Result: fundamental change to how antimicrobials have been distributed and used in animal agriculture for decades
 - Shift to veterinary oversight – foundational for supporting stewardship
 - All feed/water uses of medically important antimicrobials now under veterinary oversight

Next Steps

While significant progress made, more work still needed:

- Consider further product updates
 - products that do not currently have an explicitly defined duration of dosing
- Other products that are still OTC
 - Bring all dosage forms of medically important antimicrobials under veterinary oversight
- Companion animal uses
 - Identify and implement strategy for promoting antimicrobial stewardship in companion animals

In Closing

- Goal is to curb resistance through optimizing antimicrobial use practices (stewardship)
- Significant progress has been made; changes implemented January 1 was important milestone
- Supporting stewardship efforts requires engagement of many stakeholders; incremental steps are needed to phase-in changes
- Continued collaboration is key to continued progress

