

National Action Plan Goal 1
Stewardship in Veterinary Settings
FDA Update

PACCARB Public Meeting
September 13, 2017

Goal 1 - Objectives

- (Objective 1.2) Eliminate production (growth promotion) use of medically important antibiotics and bring therapeutic uses under veterinary oversight
- (Objective 1.3) Identify and implement measures to foster stewardship of antibiotics in animals



Objective 1.2 – Eliminate Production Use / Provide Veterinary Oversight

- All drug sponsors voluntarily aligned affected products (with FDA Guidance #213) by the January 1, 2017, target.
- Final assessment of FDA's Guidance #213 initiative published on January 3, 2017
 - A total of 292 approved applications affected
 - 84 were withdrawn
 - 208 were modified to align with Guidance #213
 - 115 converted to VFD, 93 converted to Rx, 31 production uses removed

Objective 1.2 – PACCARB Recommendations*

- *“Work toward consensus process for establishing metrics for the appropriateness of antibiotic use, especially antibiotics used for preventative purposes.”*
- *“Work to insure such metrics are interpreted appropriately by all stakeholders when the required data become available.”*
- *“Reconcile concerns about confidentiality of producers and specific farms.”*

**From March 2016 initial assessment*

Objective 1.2 – PACCARB Recommendations

- *“consensus process for establishing metrics for the appropriateness of antibiotic use, especially antibiotics used for preventative purposes”*
 - FDA is engaging with key stakeholders; buy-in is critical for meaningful progress
 - Progress is being made in defining core principles of “stewardship”; fundamental to assessing appropriateness of use
 - FDA issued notice seeking public comment on products without defined durations of use, including prevention uses

Objective 1.2 – PACCARB Recommendations

- *“insure such metrics are interpreted appropriately”*
 - FDA has sought additional data enhancements to provide important context
 - e.g., species estimates for sales data; biomass denominator to account for population changes
 - FDA has continued to work closely with USDA’s Center for Epidemiology and Animal Health (CEAH) on framework for reporting data and assessing progress

Objective 1.2 – PACCARB Recommendations

“reconcile concerns about confidentiality”

- FDA funded cooperative agreements (Aug. 2016) to develop approaches for collecting use data that, among other things, protects data confidentiality
- FDA is committed to continuing its close collaboration with USDA’s CEAH; CEAH has well-established expertise in collecting on-farm data



Objective 1.3 – Fostering Stewardship

Outreach to support implementation of FDA's Guidance 213 and VFD regulation

- Webinars, public meetings
- Videos and brochures
- VFD guidance document issued
- Process for responding to individual questions
- Collaborated with USDA/APHIS on training modules

Objective 1.3 – PACCARB Recommendations*

“USDA and FDA should ensure financial and educational support of outreach efforts undertaken by the agriculture extension services and the nongovernmental organizations already engaged in driving antibiotic stewardship in veterinary medicine.”

- FDA does not generally regulate animal husbandry, farming activities, or the practice of veterinary medicine; our direct role in this area is limited
- Effectively implementing stewardship principles requires a collaborative effort across a broad interdisciplinary set of stakeholders
- FDA lacks new funding to financially support antibiotic resistance activities in veterinary sector; but is working to collaborate with and support activities occurring at state/local level and/or coordinated by a variety of NGOs

**From March 2016 initial assessment*

Objective 1.3 – PACCARB Recommendations*

“Antibiotic use in companion animals should be considered a potential focus of stewardship activities”

- FDA agrees that, consistent with a One Health approach, efforts to foster stewardship should focus on all veterinary sectors, including companion animals
- In January 2017, we published *FDA’s CVM Key Initiatives for Antimicrobial Stewardship* that includes, as one of its objectives, developing a strategy for fostering stewardship in companion animals

*From March 2016 initial assessment



Antibiotic Stewardship in Veterinary Settings

Our key initiatives for stewardship include:

- Align antimicrobial drug products with the principles of antimicrobial stewardship in veterinary settings;
- Support efforts to foster stewardship of antimicrobials in veterinary settings; and
- Assess the impact of strategies intended to curb the emergence of antimicrobial resistance associated with the use of antimicrobial drugs in veterinary settings.



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