

California's Experience Transitioning Antibiotics to Prescription-Only Status



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October 11, 2022

FDA's earliest steps into Antimicrobial Stewardship



2003

FDA published *“Guidance for Industry (GFI) #152 Evaluating Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern”*

- **Defined “medically important antimicrobial drugs”**
 - Ranks antimicrobial drugs / classes according to importance in human medicine: Critically important; highly important; important

2012

FDA published GFI #209 *“The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals”*

- Framework for actions to come
- Key principles for antimicrobial use in food animals:
 1. Limit uses to those considered necessary for **assuring animal health**
 2. Limit uses to those that include **veterinary oversight** or consultation

VFD Final Rule (GFI #213)



2013

Following on GFI #209, FDA advised drug sponsors on how to align their drug applications with the key principles published in GFI #213.

1. Limit uses to those considered necessary for *assuring animal health*
 - **Removed growth promotion / production purposes** as approved uses
2. Limit uses to those that include *veterinary oversight* or consultation
 - Administration in **feed** went from OTC → **VFD**
 - Administration in **water** went from OTC → **RX**

Timeframe for implementation = 3 years → January 1, 2017



Livestock: Use of Antimicrobial Drugs

(FAC § 14400 – 14408)



- Puts **limits on antimicrobial use in CA livestock** (January 1, 2018)
 - Requires **veterinary oversight** of MIAD use via a valid veterinarian-client-patient relationship (VCPR)
 - VCPR defined by CA regulation
 - Placed all remaining MIAD administration forms (injectable, oral, etc.) under veterinary oversight (RX)
 - Requirements for the AUS program:
 - A **stewardship** program of outreach and education
 - **Monitoring** of antimicrobial resistance, sales, use, and of livestock management practices
 - **Coordination** with other entities and to not duplicate activities
- A sister bill required California veterinarians' continuing education in antimicrobial stewardship (SB 361, 2015)



FDA 5-yr Action Plan



2018

Published “*Supporting Antimicrobial Stewardship in Veterinary Settings – Goals for Fiscal Years 2019-2023*”

- Identified three goals
 1. Align antimicrobial drug product use with the principles of antimicrobial stewardship
 2. Foster stewardship of antimicrobials in veterinary settings
 3. Enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals



Goal 1: Align use; Objective 1.1:

Revise, as necessary, the use conditions for approved medically important antimicrobials in food-producing animals

- link to specific etiologic agent
- *administer for an appropriately targeted period*

Making all MIADs RX (GFI #263)



2021

FDA published GFI #263 *“Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter”* in June 2021

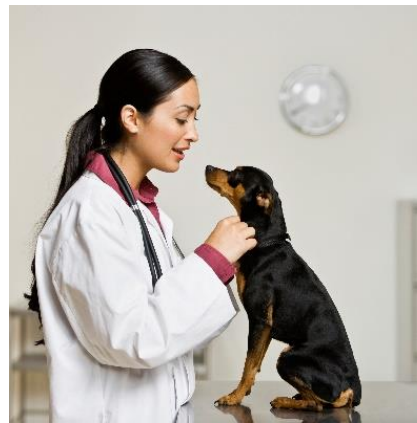
- ***Applies to ALL MIADs for animal use***
 - Not just food-producing species!
- Extends *veterinary oversight* to all drug forms and animal species
- Anticipates full implementation in 2 years → **June 2023**



Who will be impacted?





- Livestock producers
- Owners of pet livestock
- Owners and breeders of exotic pet species
- Veterinarians
- Feed stores / retail establishments



How did California approach OTC-to-RX?



2017 – prior to full CA law change

- CA already had a state Restricted Livestock Drug Program
  *more on this in the next slide* 
- Widely announced pending changes

CA's Restricted Livestock Drug Program



Prior to 2018

CA already had a Restricted Livestock Drug Program in place



- In California, a ***Restricted Livestock Drug (RLD)*** is any livestock drug sold in a form that could be used by humans or any livestock drug which, if improperly administered to livestock, is dangerous to the health of those livestock or to humans who consume products from those livestock.
- Requires retailers selling RLDs to be licensed by the CA Dept of Food and Agriculture
- Excludes federal prescription drugs
- Includes MIADs (OTC antibiotics, non-VFD Type A medicated articles), other non-medically important antibiotics, coccidiostats, dewormers, hormones, etc.

How did California approach OTC-to-RX?

(cont.)



2017 – 1 year prior to full CA law change

- CA already had a state Restricted Livestock Drug Program
- Widely announced pending changes
 - Meetings, presentations, flyers, posters
 - Veterinarians
 - Retailers
 - Offered posters announcing changes that they could post in stores
 - Suggested to stop ordering affected products



How did California approach OTC-to-RX?

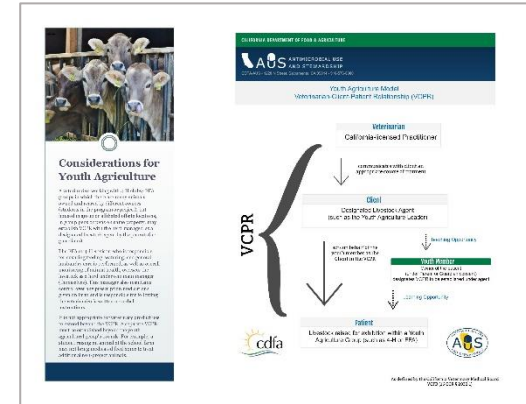
(cont.)



2018 – once CA law in full effect

1. Focus on VCPR

- Developed a practice model for youth agriculture
- Expand veterinary access through promoting federal financial support
 - Veterinary Medical Loan Repayment Program (VMLRP)
 - Also participated on the national VMLRP Review Panel
 - Veterinary Services Grant Program (VSGP)



How did California approach OTC-to-RX?

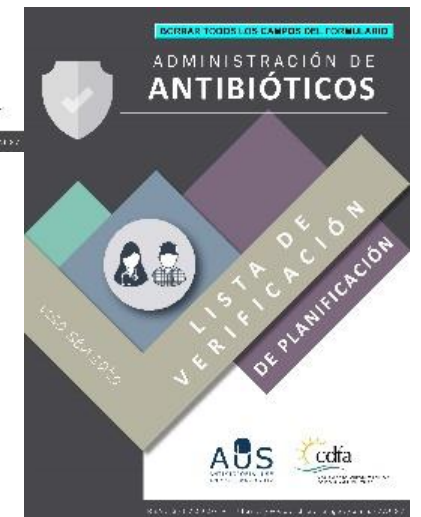
(cont.)



2018 – once CA law in full effect (cont.)

1. Focus on VCPR (cont.)

- Survey form for owners / producers to report lack of veterinary access
- Assess producer awareness of VCPR in data-gathering activities
- Ready-to-use tools supporting AM stewardship in context of VCPR
 - Antimicrobial Stewardship checklist & workbook in English, Spanish



How did California approach OTC-to-RX?

(cont.)



2018 – once CA law in full effect *(cont.)*

2. Drug sales and distribution

- Established regulations
- Provided education for retailers



How did California approach OTC-to-RX?

(cont.)



2018 Regulations

- Developed regulations to allow RLD licensed retailers to sell “CA-prescription” drugs (MIADs previously OTC in CA) with a veterinarian’s prescription when used *ACCORDING TO LABEL DIRECTIONS ONLY*
 - NOTE: Veterinarians can still write prescriptions according to ELDU regulation, but these prescriptions must be filled by a licensed pharmacy.
- Developed Qualified Individual training for RLD licensed retailers to meet these new regulations
- No retailers fulfilled the requirements to do this



Lessons learned in California



VCPR and Veterinary Access

- Most producer reports were anecdotal
 - Outrage, frustration
 - Almost none documented a true veterinary shortage – more often, people did not have a VCPR and hadn't really looked effectively for a veterinarian to fill their needs
- CDFA's approach to the VMLRP program needed to be overhauled
 - Focus was on pleasing reviewers instead of attracting applicants
 - Didn't update nominations to reflect changing or worsening conditions



Drugs and Drug Sales

- Few retailers went to the trouble to develop a Qualified Individual program to continue selling MIADs
 - Interest now growing – unclear why (Gas prices? Hoarded drugs running out?)
- ‘Loophole’ for non-food-producing species, such as pigeons and ornamental fish (BTW – these products are not FDA-approved, anyway!)
- Drop shipping makes drugs fairly accessible with regards to geography
 - Some therapeutic delays still possible – i.e. VFD feeds for aquaculture species
- Illegal drugs occasionally continue to be reported, intercepted, and, very rarely, found on shelves



What do you need to know about this transition?



VCPR

- Producers who **previously did not use a veterinarian** may be more likely to seek one in the few years after 2023
- Veterinarians may / are likely to see **increased demand** (and animal owner frustration) around and after this transition
- **Demand may exceed available veterinary resources**, especially for underserved populations
- A lack of veterinarians' familiarity with treating **(pet) livestock and exotics** could leave these animals especially vulnerable to lack of professional care

What do you need to know about this transition?

(cont.)



Drug Access

- Drug access is less likely to be an issue than veterinary access
- All MIAD products – including those used OTC for exotic species – will become RX
- **ENFORCEMENT** is likely to be a challenge in many places, especially for online sales
 - CA had a unique program already in place, facilitated enforcement
 - FDA cooperative agreements??
- Hoarding and illegal trade of pharmaceuticals are likely (certain)

What can practitioners do to prepare?



Practitioners

- Develop clear expectations for what is a VCPR with your practice and stick to them
- Notify support staff (vet techs, front desk, etc.) of this change and discuss how it may impact your practice
- Inform current clients of coming changes and how your practice may (and/or may not) be adjusting
- Consider how your practice might be able to include serving livestock and/or exotics, if not done already



What can practitioners do to prepare? *(cont.)*



Practitioners

- Remember that FDA determines food animals by species, not by purpose or lifestyle!
- If looking for a change in your practice and clientele, consider serving an area of need and applying for VMLRP



What can you do to prepare?



Organizations & Government

Promote and facilitate the VCPR

- Educate producers/owners on VCPR
 - Many producers/owners seem unaware of the legal requirements / structure of this relationship
- Review state-specific regulations on VCPR, provision of care, and telehealth
 - Are updates needed to safely facilitate expanded services?



What can you do to prepare?



Organizations & Government

Provide outreach and CE opportunities for veterinarians looking to expand their practice

- Refresh on livestock and/or exotics
- Drug regulations – ELDU, VFDs
- Include business training to help support expanded and alternative, sustainable practice models



What can you do to prepare? *(cont.)*



Organizations & Government



Enhance efforts to advertise VMLRP / VSGP nomination and application processes

- Get to know local stakeholders – they may not know who can help address their shortage
 - Request concrete examples of shortage effects
- Don't assume there is no need because you are not hearing anything
- Check back on nominated areas to see if anything has changed
- Consider providing assistance for completing applications / forms
 - i.e. A DUNS number is needed to receive VSGP award \$

What can you do to prepare? *(cont.)*



Organizations & Government

Outreach on other funding resources / opportunities that may be available to assist a veterinarian or practice in expanding their services



Education and outreach to local retailers who sell MIADs intended for use in animals

- Alert to upcoming change
- Consider offering printed outreach materials for public posting
- Help them avoid unsaleable stock by awareness of deadline
- Plan to follow up – may try to continue selling stock after deadline

What is next in the antimicrobial space?



In late 2020, FDA published a 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”*

- Updating ranking process used in 2003 (GFI #152)
- One Health, broader approach
 - Non-foodborne exposures; non-enteric pathogens; “serious infection”
- Increases importance of several drugs / classes
- Adds ‘tiers,’ which encompass drugs not currently considered medically important in humans



What is next in the antimicrobial space? (cont.)



In early 2021, FDA sought public comments on its concept paper, *“Potential Approach for Defining Durations of Use for Certain Medically Important Antimicrobial Drugs for Food Animals”*

- Would work with drug sponsors to change labels to establish appropriately defined durations of use
 - Applies only to certain products used in or on **feed**
 - Expected to impact approximately 89 drug applications
 - FDA reports these make up 28% of MIADs approved for feed



<https://www.fda.gov/animal-veterinary/judicious-use-antimicrobials/list-approved-medically-important-antimicrobial-drugs-administered-feed-food-producing-animals-lack>

Any questions?



Acknowledgements:

CDFA AUS Team

- **Stewardship**
 - Dr. Marissa Silva
 - Dr. Catherine Lorenz
- **Inspection Services**
 - Rachelle Kennedy
 - Shelly King



Thank you!

Antimicrobial Use and Stewardship Contact Information



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