

VFD and Prescription Compliance in Poultry: Lessons Learned

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Regulation Changes

With implementation of FDA Guidance for Industry (GFI) #213 on January 1, 2017, food animal veterinarians had to develop or change their processes for managing Veterinary Feed Directives (VFDs), as well as veterinary prescriptions. Over 13 drugs for poultry transitioned from over-the-counter (OTC) to VFD status.^{1,2} Prior to 2017 no drugs specifically for turkeys required a VFD.

Implementation Challenges

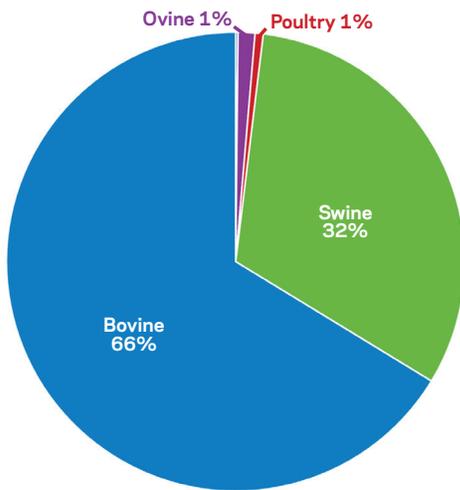
A primary challenge to implementation was stakeholder knowledge and understanding of the new regulation. Common stakeholder questions involved clarifying that:

- ▶ Production classes, indications of use, dose, and duration were taken directly from FDA approved drug labels.
- ▶ Extralabel Drug Use (EDLU) is not permitted for feed medications.

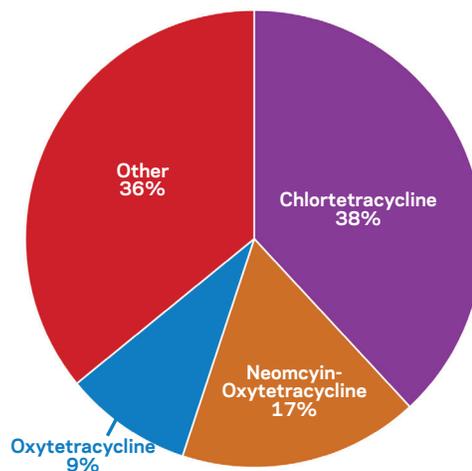
- ▶ The two-year VFD retention requirement for veterinarians, clients, and feed distributors increases the need for collaboration and communication.
- ▶ A valid Veterinary-Client-Patient Relationship (VCPR) is required for VFDs and prescriptions.^{3,4}

2017 GlobalVetLINK VFDs and Scripts - Poultry

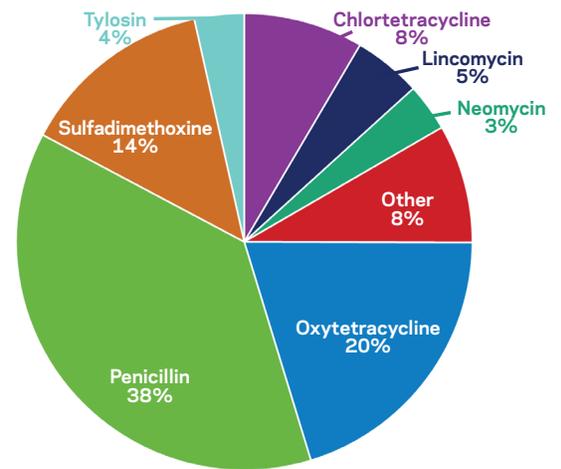
1. VFDs by Species



2. Poultry VFDs by Active Ingredient



3. Poultry Scripts by Active Ingredient



Key Learnings

Of the approximately 150,000 FeedLINK VFDs written in 2017, 1% were written for poultry (Figure 1), with an average group size of 3.5 million head.

Of the VFD drugs which transitioned to VFD status in 2017, chlortetracycline (CTC) comprised 38% of the FeedLINK VFDs for poultry (Figure 2).

ScriptLINK prescriptions for poultry in 2017 were primarily written for penicillin, oxytetracycline, and sulfadimethoxine (Figure 3). Note that a prescription or VFD does not necessarily confirm fulfillment or usage of the drug by the indicated animals.

Primary Concerns

Stakeholder concerns documented by GVL in 2017:

- ▶ Producers labeling use of medicated feeds and water solubles
- ▶ Awareness of drug status (VFD, prescription, OTC)
- ▶ Ability to attach pictures to VFD or prescription to prove VCPR
- ▶ Location accuracy (premise ID, etc.)
- ▶ Need for customized script templates

FDA's "Ask CVM"^{5,6}

Commonly addressed poultry questions⁷:

1. State law governs all prescriptions, thus inquiries are referred to the state board of veterinary medicine, board of pharmacy, or other appropriate authority for any state prescription requirements.
2. Federal policy does not prohibit an on-farm inventory of medically important antibiotics authorized for use by the client's veterinarian.
3. Federal law sets forth certain minimum labeling requirements for prescription drugs that are dispensed by a veterinarian and must bear a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner.
4. State law will have precedence and may demand additional labeling requirements.

Administered In-Feed (VFD) FDA Approved Medications⁸

VFD MEDICATIONS*	CHICKEN	TURKEY
Albamix (Novobiocin) [^]	✓	✓
Aureomycin [®] (Chlortetracycline)	✓	✓
ChlorMax [®] (Chlortetracycline)	✓	✓
Hygromix [®] (Hygromycin B) [^]	✓	
Inteprity [™] (Avilamycin)	✓	
Lincomix [®] (Lincomycin)	✓	
Neo-Oxy [®] (Neomycin + Oxytetracycline)	✓	✓
Neo-Terramycin [®] (Neomycin + Oxytetracycline)	✓	✓
Pennchlor [®] (Chlortetracycline)	✓	✓
Pennox [®] (Oxytetracycline)	✓	✓
Pharmastatin (Nystatin) [^]	✓	✓
RofenAid [®] (Sulfadimethoxine + Ormetoprim)	✓	✓
Stafac [®] (Virginiamycin)	✓	
Terramycin [®] (Oxytetracycline)	✓	✓

[^] Not currently marketed. ^g Includes label claim for improved weight, gain and feed conversion. [®] All trademarks or trade names are property of their respective owners. *CAUTION: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. Extralabel Drug Use (EDLU) is not permitted. Species can vary, observe label indications.

NON VFD MEDICATIONS	CHICKEN	TURKEY
Albac [®] (Bacitracin Zinc) ^{^g}	✓	✓
Amprol [®] (Amprolium)	✓	✓
Avatec [®] (Lasalocid)	✓	✓
Aviax [®] (Semduramicin) [^]	✓	
Bio-Cox [®] (Salinomycin)	✓	
BMD [®] (Bacitracin Methylene Disalicylate) ^g	✓	✓
Clinacox [®] (Diclazuril) [^]	✓	✓
Coban [®] (Monensin)	✓	✓
Coyden [®] (Clpidol) [^]	✓	✓
Deccox [®] (Decoquinatate)	✓	
Flavomycin [®] (Bambermycin) ^g	✓	✓
Maxiban [®] (Narasin + Nicarbazine)	✓	
Monteban [®] (Narasin)	✓	
Nicarb [®] (Nicarbazine)	✓	
Pennitracin [®] MD 50 (Bacitracin Methylene Disalicylate)	✓	✓
Robenz [®] (Robenidine HCl)	✓	
Sacox [®] (Salinomycin)	✓	
Safe-Guard [®] (Fenbendazole)		✓
Stenorol [®] (Halofuginone) [^]	✓	✓
Topmax [™] (Ractopamine) [^]		✓
Zoamix [®] (Zalene)	✓	✓

Administered In-Water (Script) FDA Approved Medications⁸

PRESCRIPTION MEDICATIONS*	CHICKEN	TURKEY
Aureomycin [®] Soluble (Chlortetracycline)	✓	✓
Di-Methox [®] (Sulfadimethoxine)	✓	✓
Gallimycin [®] PFC (Erythromycin)	✓	✓
Lincomycin Hydrochloride Soluble (Lincomycin HCl)	✓	
Neo-Sol [®] (Neomycin)		✓
NeoMed [®] (Neomycin)		✓
Oxytet [®] Soluble (Oxytetracycline)	✓	✓
PenAqua Sol-G [®] (Penicillin G Potassium)		✓
Pennchlor 64 [®] (Chlortetracycline)	✓	✓
Pennox 343 [®] (Oxytetracycline)	✓	✓
PoultrySulfa [®] (Sulfamerazine, Sulfamethazine, Sulfaquinoxaline)	✓	✓
R-Pen [®] (Penicillin G Potassium)		✓
TetraMed [®] 324 HCA (Tetracycline)	✓	✓
Tetroxy [®] HCA Soluble (Oxytetracycline)	✓	✓
Tet-Sol [™] 324 Soluble (Tetracycline)	✓	✓
Tylan [®] Soluble (Tylosin Tartrate)	✓	✓
Tylovet [®] Soluble (Tylosin Tartrate)	✓	✓

NON SCRIPT MEDICATIONS	CHICKEN	TURKEY
Amprol (Amprolium)	✓	✓
BMD [®] Soluble (Bacitracin Methylene-Disalicylate)	✓	✓
Safe-Guard [®] AquaSol (Fenbendazole)	✓	

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Species can vary, observe label indications.



Clark, Steven. VFD and Prescription Compliance in Poultry: Lessons Learned. Poster presentation and Bulletin. Prepared by Devenish Nutrition, LLC (Fairmont, MN)/GlobalVetLINK (Ames, IA). AVMA-AAAP, Denver, CO. July 13-17, 2018.

¹<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482107.htm>; ²<http://feedstuffs.com/mdfm/Feeess50/author/427/2016/7/37263-1%20Antibiotic%20Quick%20Reference%20Guide%20v4a.pdf>; ³<http://www.ecfr.gov/cgi-bin/text-idx?SID=99550a83c97103df1503d4e34b99b26b&mc=true&nnode=pt21.65308r&gndiv5#se21.6530.13>; ⁴AVMA Veterinarian-Client-Patient-Relationship VCPR. <https://www.avma.org/KB/Policies/Pages/Veterinarian-Client-Patient-Relationship.asp>; ⁵Guidance for Industry #120: Small Entity Compliance Guide, Veterinary Feed Directive Regulation, Questions and Answers [Q&A]. September 2015. <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf>; ⁶FDA Disclaimer for Q&A and Ask CVM *Please Note: This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed"; ⁷Ask CVM. AVMA AAAP Questions from May 2016 Meeting. Email dated October 23, 2017; ⁸Clark, Steven. VFD and Prescription Compliance and Solutions for Poultry Veterinarians. Poster presentation. AVMA-AAAP, Indianapolis, IN. July 21-25, 2017. Devenish (Fairmont, MN)/GlobalVetLINK (Ames, IA) Bulletin. Updated version November 19, 2018.