Sponsors

University of Minnesota
College of Veterinary Medicine

College of Agricultural, Food and Environmental Sciences

Extension Service

Swine Center

Editors
W. Christopher Scruton
Stephen Claas

Layout
David Brown

Logo Design
Ruth Cronje, and Jan Swanson;
based on the original design by Dr. Robert Dunlop

Cover Design
Sarah Summerbell

How do we comply with AMDUCA?

Lisa J. Becton, DVM

Premium Standard Farms

As debates increase regarding the use of antibiotics in food animal production, individual consumers and consumer advocacy groups—as well as various government officials—will increasingly be looking to veterinarians for assistance. In 1996 the final AMDUCA document was presented to the veterinary community. This document gave veterinarians legal authority to use extra-label products for target species in order to alleviate pain and suffering. The AMDUCA document and the "Judicious Use Guidelines for Swine Practitioners" provide guidelines for appropriate handling of medications for food animals.

Complying with AMDUCA is a professional obligation and privilege that accompanies our veterinary licensure. As a veterinarian for a large production company, the pressure and sense of urgency to have all programs in order is extremely daunting. Large systems provide a unique challenge for medication management and compliance. Breaking down AMDUCA into its basic components makes it easier to have the appropriate documentation available to justify actions. Compliance can be a very complicated issue that requires a fair amount of time and action. We as a profession often like to be the "first to...", however, each of us needs to be aware of the implications of using antimicrobial products in food animal production. Listed in this paper are some of the basic areas on which our veterinary group focuses and the documentation that we feel is needed to support the decisions that we make.

The original AMDUCA rule focuses on four main areas:

- VCPR
- requirements for use
- records
- label requirements

After further evaluation, these areas were divided into more detailed components:

- documented VCPR
- documented, careful diagnostic work-up
- justification for ELDU
- prescription records
- labeling requirements
- record requirements
- knowledge

What is required for AMDUCA compliance?

Documented VCPR

- vet scheduling routine visitation
- records of visitation
- records indicating that the vet is readily available for follow-up
- records that the caretaker agrees to follow instructions and/or records of noncompliance and actions taken

Documented, careful diagnostic work-up

- diagnostic accessions
- current and historical diagnostic work for the target animal flow
- routine frequency of visitation
- use known references for diagnostic support

Justification for ELDU

- is there a labeled product for the target species?
- dose available?
- culture and sensitivity support use?
- documented withdrawal time or database to support decision?

Prescriptions

- no >12 month duration (vet dependent)
- scripts for stages of production
- copy of the scripts located at the target farm(s)
- copies at main vet office and distributor (if different from vet)
- proper content

Labeling requirements
- include both vet and distributor name/address when applicable
- proper content
- contact FARAD for withdrawal
- individual versus package labeling?

Record requirements
- ALCOA (attributable; legible; contemporaneous; original; accurate)
- proper storage (two years)
- available for audits: internal and external
- accompany additional training records

Knowledge
- spirit of the law: remember cost is *not* a deciding factor for ELDU!
- know what products are banned
- no feed additives may be used ELDU
- compound (mixing) of drugs?
- use of production drugs in an extralabel fashion is illegal (i.e., Estrumate)
- use other references (CPG 608.400) and www.fda.gov/ora/compliance

In order to make record keeping more effective for our system, we developed a comprehensive veterinary database that helps to track the vital information needed to make the correct decisions regarding the use of any medication. Dr. Kelley Meyers (PSF, Texas) developed a Microsoft Access database that tracks all farm visitations, diagnostics (to include serology and tissue submissions), and farm memos. This provides an easy route to look up past farm history without having to go through each record manually.

How we comply with AMDUCA at PSF?

Documentation kept for these activities (VCPR)
- vet visits to all farms at least once per annum
- vet staff is readily available for consultation (phone/fax/email)
- vets follow-up on action plans and audit compliance
- vets provide training (PQA, residue avoidance, injection technique)

Diagnostic work-up
- herd database (contains both past and present herd health history)
- use acceptable treatment standards (Diseases of Swine. 8th Edition)
- see **Chart 1** for decision tree

Justification
- is there an acceptable product available?
- use Green Book as product guideline
- clinical efficacy? response of target animals; past history of culture/sensitivity
- feedback from farm manager/production supervisor

Prescriptions
- write scripts by system
- "general" script good for up to one year
- "special scripts" good for limited amount and period
- copies kept on-farm and at main office
- distributor maintain scripts at locations

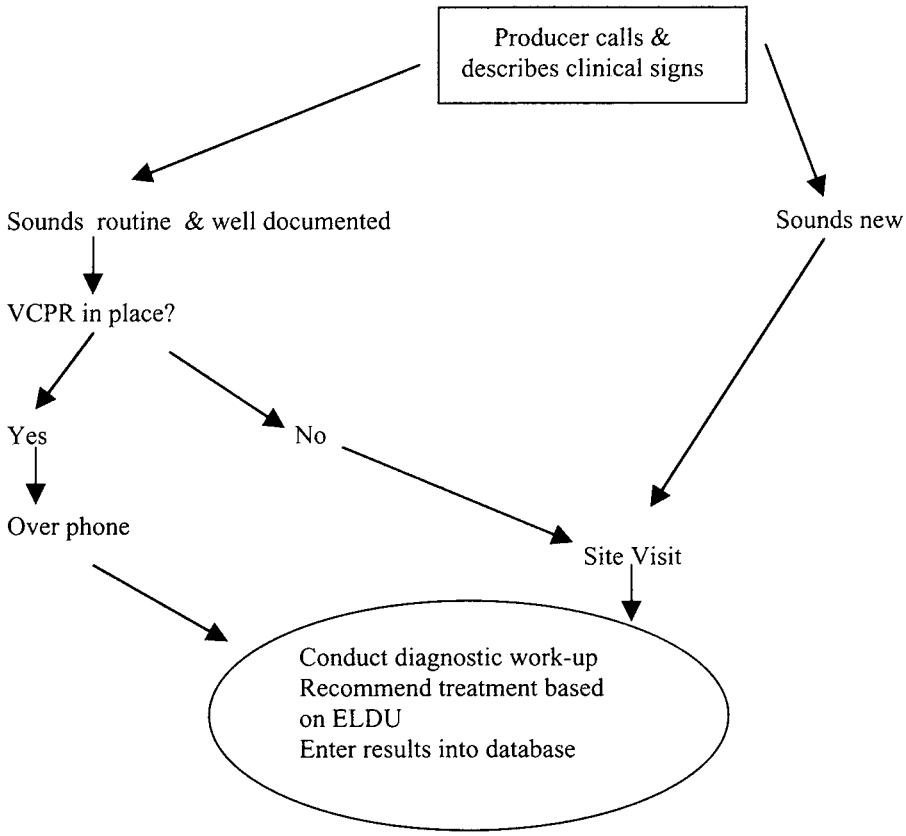
Labeling requirements
- label by case/bulk order
- "special script" to accompany every order to the farm
- script is discussed before implemented on-farm (farm manager)

Record requirements
- sow and piglet treatments recorded on cards (kept with animals through production)
- nursery and grow-finish have individual door charts
- supply invoices are kept a minimum of two years
- all herd health records are stored a minimum of two years

Knowledge:
- use common sense for timing of medications
- know what you can and *cannot* prescribe
- use other available references for additional technical support
- documentation, documentation, documentation!

The process of evaluating medication use in a large system can be a frustrating task. However, with the current herd health database, this tracking can be made manageable. We as veterinary practitioners have an obligation to follow guidelines like AMDUCA in order to preserve our ability to have medications to prescribe. One adverse ac-

Chart 1: Decision tree for ELDU within a similar system



AND:
Assess (regularly) procedures / policies
Audit compliance

tion could jeopardize the few interventions that we do have. It is our responsibility to use all medications in a judicious manner. AMDUCA has set reasonable guidelines that can be followed in any practice or system.

Acknowledgement

I would like to thank the following individuals for their time and contribution:

Dr. Eric Neumann, Dr. Tim Kniffen, Dr. Angela Baysinger, Dr. Robyn Fleck, Dr. Tom Burkgren, Dr. Bob Morrison, and Dr. Kelley Meyers

With their help, AMDUCA has been made easier to follow!