Making AMDUCA Work in Your Practice

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Introduction

The Animal Medicinal Drug Use Clarification Act (AMDUCA), which established conditions for legal extralabel use of approved drugs by licensed veterinarians, took effect December 9, 1996.

The act recognized that veterinarians need to use drugs in an extralabel fashion to alleviate pain and suffering. It contains sufficient safeguards to protect public health and food safety.

In December 1997 the Wisconsin Veterinary Medical Association (WVMA) executive board established a task force of 6 dairy practitioners, a University of Wisconsin veterinary clinician and pharmacist, 2 veterinary office practice managers, the WVMA office staff and the American Veterinary Medical Association (AVMA) staff person responsible for AMDUCA. The task force studied the act and gathered available information that would be needed by practitioners to comply.

The focus of the task force was the adult dairy cow. While AMDUCA affects all species, concentrating on 1 species was more manageable. Dairy was chosen because of public health concerns about milk and dairy beef residues.

Goals of the task force were:

- gather available scientific information in 1 stand-alone report
- organize withdrawal times on drug applications
- develop prototypes of record systems
- distribute the AMDUCA report to all dairy practitioners

Contents of the act and regulations are available from many sources, the most concise being the AVMA's Extralabel Drug Use (ELDU) guidance brochure. A laminated brochure can be found in the February 15, 1998 issue of the Journal of the American Veterinary Medical Association. The WVMA AMDUCA Task Force combined information from several sources to produce its final report, aimed at creating an easy-to-follow guide for all dairy practitioners.

AMDUCA Requirements

It is important to remember that ELDU is supposed to be the exception, not the rule. AMDUCA is not an encouragement to use ELDU.

- ELDU is permitted only by, or under supervision of, a veterinarian.
- ELDU is allowed only for FDA-approved animal and human drugs.
- A valid veterinarian/client/patient relationship (VCPR) is required.
- ELDU is for therapeutic purposes only, when the animal's health is suffering or threatened.
- Rules apply to dosage-form drugs and drugs administered in water. (ELDU in feed is prohibited.)
- ELDU is not permitted if it results in a violative food residue or any residue which may present a risk to public health.
- AMDUCA does not provide for extralabel drug use of non-approved drugs.
- The FDA has prohibited certain drugs.

FDA-prohibited drugs for use in food animals:

- Chloramphenicol
- Clenbuterol
- Diethylstilbestrol (DES)
- Nitroimidazoles (including but not limited to dimetridazole, ipronidazole and metranidazole)
- Nitrofurans (except for approved topical use of nitrofurazone and furazolidone)
- Sulfonamides in lactating dairy cattle (except for approved uses of sulfadimethoxine, sulfabromomethazine and sulfaethoxypyridazine)
- Fluoroquinolones (except for approved uses including enrofloxacin in beef cattle and sarafloxacin in poultry)
- Glycopeptides (including but not limited to vancomycin)

Record-keeping Requirements

The veterinarian bears responsibility for producer records. Record requirements are:

- Identify the animal as an individual or a group
- Animal species treated
- Numbers of animals treated
- Condition treated

- Name of drug and active ingredient
- Dosage prescribed or used
- Duration of treatment
- Specific withdrawal or withholding of animal-derived food

Additionally, records must be kept for 2 years (3 years in Wisconsin) and the FDA may have access to these records for 2 years.

The task force developed 3 prototypes for records:

- Individual case records
- Daily treatment log
- Individual animal lifetime record

Label Requirements

Each label must include:

- Name and address of prescribing veterinarian
- Established name of the drug
- Any specified directions for use including the class/species; identification of the animal or herd, flock, pen, lot or other group; the dosage frequency and route of administration; and the duration of therapy
- Any cautionary statements
- Veterinarian-specified withdrawal or withholding for meat, milk or any animal-derived food

Extralabel Drug Use Algorithm

The AVMA ELDU guidance brochure included an algorithm for the order of extralabel drug selection. The following was extrapolated from the algorithm.

As you will notice, the ELDU algorithm seems pretty straightforward and logical, so where are the challenges that must be addressed? Here are a few thoughts:

1) The only door into ELDU is clinically ineffective.

2) Records of clinically effective label treatments are needed to meet prescription drug usage guidelines.

3) Lay people diagnose and treat sick animals, calling for professional help on the most severely sick.

4) People want to emulate the treatments they see used by professionals on cases they diagnose, but we treat the most severe and the clinically ineffective.

5) Endemic pathogens on farms are in an ever-changing state, dependent on a variety of factors; therefore, on-farm treatment protocols must be current.

6) Animal identification needs improvement.

7) Varied sources of advice on treatment are available on a daily basis.

8) There are multiple drug sources.

9) A valid VCPR requires work.

10) Both the veterinarian and producer are in business. AMDUCA does not address business, but business must be a consideration.

Valid VCPR is the Cornerstone

A VCPR exists when the following conditions have been met (AVMA Model Veterinary Practice act, section 2):

1) The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the veterinarian's instructions.

2) There is sufficient knowledge of the animal(s)

The decision has been made to treat a food animal

Label drug application for the condition	⇒	**Clinically effective**	⇒	Use the drug Keep the records
⇓				
Clinically ineffective				
⇓				
Food animal drug ELDU	⇒	**Clinically effective**	⇒	Extended withdrawal Label the drug Keep the records
⇓				
Clinically ineffective				
⇓				
Approved human or non-food animal drug ELDU	⇒	**Clinically effective**	⇒	Meet the requirements Label the drug Keep the records
⇓				
Clinically ineffective				
⇓				
Drug application doesn't meet the food safety requirement.	⇒	**Clinically effective**	⇒	Label the drug Keep the records **No longer food animal**

by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition. This means the veterinarian recently has seen and is personally acquainted with the keeping and care of the animal(s). The veterinarian is acquainted through an examination of the animal(s) or by medically appropriate and timely visits to the client's premises.

3) The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the therapy regimen.

The challenge is to reach a mutually agreed-upon course of treatment. The VCPR is an exercise in communication, with listening skills being the most underestimated.

Records are the Tools that Validate the VCPR

Records are the main way of listening to the producer, and the source of current information on disease incidence and prevalence for medical decision making.

The task force developed 3 record prototypes that meet the AMDUCA requirement: the daily log, the lifetime record, and an individual case record. In our practice we continue to re-work these to meet our producers' record-keeping style. The factors to remember when you re-work these for yourself are:

- They must be user-friendly for the recorder.
- They must capture the information you use for treatment supervision.
- They record a measure of clinical effectiveness / ineffectiveness.
- They meet regulatory requirements (prescription drug and AMDUCA).
- They aid in assuring food safety and judicious use of antimicrobials.

Making AMDUCA Work in our Practice

This is not finished work, but is work in progress. AMDUCA gives us the guidelines for ELDU. Our practice uses the law to structure our treatment surveillance.

1) We continually review treatment protocols.

2) We stress recording the data we need for medical decision making.

3) We use the records to monitor treatment protocols and effectiveness.

4) We reference dosage, route, duration and withdrawal times of the farm drugs.

5) We monitor endemic and epidemic situations.

6) We are translating this information into on-farm economics.

7) We are committed to the amount of ongoing work and nurturing required for getting this right.

Conclusion

Finally or perhaps first, this program has to be good business for both the producer and the veterinarian while meeting the therapeutic needs of the patient, the food safety requirements of the consumer, the judicious use of antimicrobials for society, and the regulatory requirements of prescription drug use and AMDUCA.

That sounds simple enough.

In actuality, we believe we are developing a simple approach that will achieve our needs.

We favor a manure-splattered, hard-copy, cow-side record for each treated animal. We want enough symptomatology recorded to monitor treatment decisions, drugs and dosages given so we can review appropriate medical rationale. Finally, we want a measure for clinical effectiveness that can stimulate change in treatment protocols, illustrate the need for diagnostics or a review of treatment expectations.

The veterinarian in the VCPR can use these in a medically appropriate and timely manner to reach medical decisions for the farm. Then a mutually acceptable course of action can be worked out with the client. There are some i's to dot and t's to cross, but we are most of the way home. We have achieved my interpretation of the intent of AMDUCA and judicious use of antimicrobials.

We have no more abandoned the computer for the pencil than we could abandon the pencil when we computerized. A cow-side record stands on its own merit for supervising therapies, then serves as a tool to summarize information for computer entries.

Achieving the record compliance we need is an unfinished task, but it is changing the way we practice. It is fun, challenging, and we are making progress.

Reference

1. AMDUCA: Meeting the Challenges. Wisconsin Veterinary Medical Association, 301 Broom Street, Madison, WI 53703 (608) 257-3665.