Work-A-Day Drug Use on the Farm-Your New Responsibilities

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Over the years, many veterinarians expressed concerns that the use of drugs in an extralabel manner in the course of bovine practice could lead to their prosecution by the Center of Veterinary Medicine (CVM) for violation of the Food, Drug and Cosmetic Act. The passage of the Animal Medicinal Drug Use Clarification Act (AMDUCA) has changed that possibility to some extent and yet the expression "the more things change, the more they stay the same" applies very nicely to this situation of extralabel drug use by bovine practitioners. For the most part, bovine practitioners are still bound by the very same rules that the CVM used for "regulatory discretion" before the passage of AMDUCA. The following points regarding what is "allowed" under the new law follow:

- Extralabel drug use is legal within the context of a valid veterinarian-client patient relationship. Extralabel use is the administration of a drug via a dose, route, duration, frequency, species, or indication that is not found in the drug's labeling.
- Metaphalaxis is now permitted (the use of a drug - usually an antimicrobial in an animal that has been exposed to conditions that are likely to lead to a diseased condition i.e. shipping of cattle through a sale barn).
- Labeling and storage requirements still apply under the provisions of extralabel use as well as the PMO (Pasteurized Milk Ordinance).
- The livestock owner and veterinarian still must ensure that no violative residues occur in foods derived from treated animals.
- In general, human labeled pharmaceuticals may NOT be used unless there is no animal drug approved for use in food producing animals that might be used in an extralabel manner. Additionally, if the use of non food animal or human labeled drugs are contemplated, scientific information regarding the human food safety aspects of such use must be available or the owner must take steps to ensure that foods derived from treated animals do not enter human food supplies.
- Use in water medications.

What is NOT permitted:

- Extralabel use for production purposes.
- Compounding for large scale purposes (outside the scope of normal practice).
- Mixing of drugs into animal feeds.
- The same list of prohibited drugs exists so that they are not to be used under any circumstances-Chloramphenicol, Clenbuterol,
- Diethylstilbesterol, Ipronidazole, Dimetridazole, the nitro furans specifically not labeled for topical use in food animal species, and the Sulfonamides not labeled for specific lactating dairy cow purposes.

What is NEW under AMDUCA is the requirement that veterinarians must make available to the CVM when requested copies of records of extralabel drug use for a period of up to the past two years. These records must contain the following information:

- The name and active ingredient of the drug used.
- The species treated.
- The condition treated.
- The dosage and duration of treatment.
- The number of animals treated.
- The specified withdrawal times for foods derived from any animals treated.

As of the time of the writing of this paper, many rules are being written and in the process of revision so **the reader of this paper is cautioned to check with some degree of regularity to see if there have been changes in the final rules and regulations that are published and in effect at the time a question may have arisen.** One of the areas that has been a source of common misconception to most practitioners is that of drugs in animal feeds. As stated in the preceding points above, this is not allowed even under AMDUCA. There is, however, a new provision under CVM's rules that will allow for a new category of drug approvals. This is to be called the Veterinary Feed Directive (VFD). At the time of writing this article, no new compounds labeled

for cattle that fit this category have received a New Animal Drug Approval (NADA), however reputedly there are some bovine products in the NADA pipeline.

Bovine practitioners should understand that the new rules that apply to them and their practices are surprisingly similar to the old days of regulatory discretion that was the *de facto* policy of CVM with regard to enforcement actions. Practitioners and practices must now understand the new rules as they apply to them. **Probably the most important one is the records requirement.** CVM has set up a clear set of principles regarding their requirement to make such records available to them. Their stated purpose is to use such records to determine the extent of and potential for public health impact of drugs that are being used in an extralabel manner in food animals, not for specific enforcement actions against a practitioner or practice. As proposed, a practitioner would be notified by mail or by a phone call appointment regarding the request for records information. It then would be the practitioner's requirement to provide the information to the CVM via a form that could be filled out and mailed in or to make such records available to an inspector on clinic premises during regular business hours. A finding of fact that extralabel usage constituted a threat to public health might then become the basis for an outright ban on a pharmaceutical that was of potential harm. Practitioners will find that they already have most of the tools that they need to be in compliance with the new rules already in place.

For Bonnie Bargstedt's paper please turn to page 195-196

Abstract

Percutaneous ultrasound-guided abomasocentesis in cows

U. Braun, K. Wild, M. Merz, H. Hertzberg
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The goal of this study was to determine the optimal location for ultrasound-guided centesis of the bovine abomasum and to assess the safety of the procedure. In the first part of this study, the technique was applied to 50 clinically healthy cows which were slaughtered within two hours of the procedure. The abomasum and peritoneum were then examined for lesions. In all but one cow, the location for abomasocentesis was 10 to 27 cm caudal to the xiphoid and on the ventral midline or up to 10 cm to the right of it. No peritoneal lesions were observed in any of the cows. In all cases, the site of centesis was visible as a localised haemorrhage on the serosal surface of the abomasum. In 41 of the cows, a haematoma was visible on the mucosal surface of the abomasum. In the second part of the study, 10 cows were monitored clinically for 10 days after abomasocentesis, to assess the safety of the procedure. The appetite, general behaviour, attitude and rectal temperature of the cows remained normal. The haematocrit, total and differential leucocyte counts, and the concentrations of total solids and fibrinogen were determined daily and remained within their normal ranges. At slaughter minimal changes, such as localised reddening and adhesions between the site of the puncture in the abomasum and the abdominal wall, were visible in three of the cows.