

Ethical Marketing of Veterinary Pharmaceuticals

G.L. Upham, DVM, MPVM, Diplomate
American College of Theriogenologists
Veterinarian's Outlet, Inc.
2400 South "K" St., Tulare, CA 93274

Marketing is the total activities by which the transfer of goods from seller to buyer is effected. Veterinarians have a wide range of feeling about marketing of veterinary pharmaceuticals as it relates to food animal practice. Some veterinarians embrace pharmaceutical sales as part of their practice and routinely dispense both legend and over-the-counter (OTC) products to their clients. Others attempt to distance themselves from any phase of the marketing process, but if a veterinarian is involved in food animal practice and authorizes the use of legend drugs, they are involved and assume the liability associated with their use. The Federal Food, Drug, and Cosmetic Act mandates this involvement by requiring legend veterinary drugs be dispensed only by or on the order of a licensed veterinarian in the course of their professional practice.

Since the food animal practitioner is mandated to be involved, at least in legend drug sales, how are the majority of veterinary pharmaceuticals marketed to the food animal industry, particularly dairy producers, in California? Producers are inundated on a routine basis with all kinds of salespeople; grain, supplement, hay, chemical, equipment, and not the least of which are pharmaceutical. These pharmaceutical salespeople are usually commissioned, lay salespeople who promote the use of drugs, provide testimonials, suggest diagnoses, and sell drugs. Their primary training is selling and what scientific information they possess is supplied by the manufacturers of the products they promote. The sale and transfer of OTC pharmaceuticals to the producer does not require veterinarian involvement even if the product is later used in an extra-label fashion. If a commitment by the producer is made to purchase legend drugs, a veterinarian with a veterinarian-client-patient relationship is contacted to authorize the delivery of the legend drugs. The veterinarian is then pressed by the producer to provide labels for all legend and extra-label drugs in order to satisfy the insistence of the milk inspector. While this system may be considered legal, I do not believe it lends itself to responsible drug usage and residue avoidance. The food animal practitioner is left with the nagging responsibility to do something about drug labeling, and all the liability he assumes when he places a drug withdrawal time on a product that he had limited input in selecting for use on the dairy.

California food animal practitioners have reacted to this scenario in many different ways. Some have refused to authorize legend drug purchases after some distributors have abused their authorization by routinely selling more than authorized or substituting one legend product for another. These practitioners have attempted to maintain some control and limit their liability by selling the legend drugs required by their clients directly to them. In some cases, this stance has cost them clients when they are approached by commissioned, lay salespeople with lower prices if they switch veterinarians to one who authorizes their purchases.

Other veterinarians have attempted to maintain a pharmaceutical sales portion to their practice by "mixing" or manufacturing such products as intra-mammary infusion treatments to antibiotic solutions that are not available from commissioned, lay salespeople. Besides the inherent problems with purity, stability, and increased liability associated with these products, the Food and Drug Administration considers them new animal drugs, requiring New Animal Drug Approval (NADA).

The opposite approach to this situation has veterinarians authorizing almost any purchases from any distributor who makes a "sell" to their clients. In this situation, the veterinarian usually gives only oral authorization. This lack of a willingness to provide a "paper trail" may be due to his sense of frustration with the large number of requests for signed authorization forms or an attempt to limit his liability in the case of a problem since he didn't sign anything.

How should a veterinarian be involved in marketing of veterinary pharmaceuticals? I don't think there is one answer for every situation with the exception that the marketing process should begin with the veterinarian. Only he/she has the education and training in pharmacology, diagnostics, and preventive medicine necessary for proper diagnostic workups needed to assist the producer in preventative management, drug selection, treatment protocols, and adequate withdrawal times. More veterinary involvement reduces the danger of drug residues and therefore lower risks of residue violations.

Practitioners who wish to market drugs directly to their clients should, with the stipulation that the prod-

Paper presented at the Fourth Annual Symposium on Advances in Clinical Veterinary Medicine, School of Veterinary Medicine, University of California, Davis, November 23-24, 1991.

ucts are licensed and manufactured by reputable companies. Veterinarians must remember that most pharmaceuticals in California are sold with low gross margins and they must be competitive in price in order to compete. Producers will not pay a premium price just to buy from the vet. There are also many costs not immediately apparent such as inventory maintenance, increased billing, and collection of appropriate sales tax. Many manufacturers and licensed wholesalers view the veterinarian as the same end user as the producer resulting in the same prices to both. This philosophy severely hinders the veterinarian's ability to compete. Few manufacturers do sell directly to veterinarians but buying from only these limits the product lines available to them. Not all licensed wholesalers are the same. Some sell only to veterinarians, others only to producers, while some sell to both veterinarians and producers. A few of these do recognize the veterinarian's importance in the marketing chain and sell to veterinarians at a lower margin than producers. A viable alternative is to work out an arrangement with a wholesaler who will maintain the inventory and supply you with the products when needed at a low margin allowing you to compete.

The veterinarian who does not wish to handle the physical transfer of pharmaceuticals to his clients should be totally involved in the marketing process. This involvement should begin before legend drug requests are made. Ask your clients what drugs they are using to treat specific conditions. Sit down with them and help them decide what drugs they actually need. Fill out a written legend drug authorization form to that assure an adequate "paper trail" exists. This form should specifically state the products and the amounts that can be delivered in a specific time period. The veterinarian, producer, and wholesaler should sign this document with all receiving a copy. Any wholesaler who abuses this authorization should not receive further authorizations in the future. With this approach to pharmaceutical marketing, the veterinarian may receive nothing for the liability they assume by authorizing the legend drugs. This increased liability may be written off as a cost of doing business with some producers. Veterinarians might propose a retainer fee to their clients for drug authorizations which might include the service of labeling their drug purchases in order to satisfy the milk inspector. One distributor in California offers veterinarians a 5 to 7% margin on all legend drug purchases made on their authorization. In both these situations the veterinarian could receive some compensation for their liability in drug authorizations.

I would like to address two problem areas that veterinarians faced with in the state of California. One is the subject of legend drug authorization, the other is drug labeling on the dairy.

There is no agreement in the state of California on

the type of authorization that is required for legal legend drug purchases. Three regulatory agencies have input in this area, the FDA, the State Board of Pharmacy, and the State Board of Examiners in Veterinary Medicine. The FDA states that legend drug authorizations can be written or oral, but they bow to state regulations when they are more stringent than the federal. The Board of Examiners, who have jurisdiction over the professional conduct of veterinarians, declare that legend drug authorizations used for large or food animal medicine must be written. The Board of Pharmacy, who has regulatory control over licensed wholesalers, state that authorizations may be written or oral. Who are you going to listen to? The FDA has no interest in running around enforcing a state position which at best is unclear when they themselves have a magnitude of other problems to contend with. The Board of Examiners do not have the financial resources or personnel to run around the state ensuring veterinarians sign written authorizations. The Board of Pharmacy lack a full understanding of large animal veterinary practice and see very few differences with the relationship between the physician - patient - pharmacist and the veterinarian - client - wholesaler. I believe that ethical marketing of veterinary pharmaceuticals should have as its goal, a written form. I do not mean that every single purchase has to have a form signed. This would be ridiculous for the practitioner. At the same time, it is ridiculous for your client to have the wholesaler call a practitioner for an oral authorization every time they need a gross of dry cow tubes or a case of cal-dextrose solution. A good compromise in the spirit of ethical marketing, in my opinion, would be to fill out a written authorization form in advance with their client listing the legend drugs that they routinely use. If the situation arises that your client needs some other legend product, an oral authorization can be made which can be followed up with an amended written form at a convenient time when the veterinarian and client are together, such as a routine herd check. Some veterinarians write all authorizations to expire on a specific date, so that they know exactly when it's time to re-evaluate with their clients, their legend drug needs.

The Pasteurized Milk Ordinance requires legend and extra-label drugs to be stored on the dairy with proper labeling. This must include the name and address of the authorizing veterinarian, adequate directions for use, and any cautionary statements. The FDA does not mandate who should actually dispense legend drugs or who should affix the necessary label information, but for the purposes of the PMO, the producer is responsible for assuring that the specific label information is present. State regulations apply as who may dispense and who may apply labels. The California Board of Pharmacy requires that only a licensed veterinarian or registered pharmacist can affix a label to

legend veterinary pharmaceutical. A licensed wholesaler in California can only sell to a veterinarian, physician, dentist, podiatrist, pharmacist, or other wholesaler. Even though producers routinely pay the bills for the legend drugs directly to the wholesalers, all legend veterinary drugs in the state are legally sold to the veterinarian who authorized the purchase, the pharmaceuticals are only shipped to the producer. Therefore according to state law, the authorizing veterinarian is responsible for all drug labeling.

How are drugs labeled in the market place? From my observations, a large portion of the legend drugs on dairies are not properly labeled but kept concealed from the milk inspectors. Some veterinarians do apply their own labels but this can be a time consuming task which the producer resists paying for. Some licensed wholesalers have attempted to affix labels for authorized legend drugs until the scrutiny of the Board of Pharmacy have persuaded them to desist. One veterinary practice that I am aware of is supplied a locked cabinet by some of their clients for placement of legend drugs when delivered by the wholesalers. Only the wholesalers and the practice has keys. Someone from the practice removes the drugs, properly labels them, and places them on shelves for use by the producer. Technically this is only legal if a licensed veterinarian applies the labels. Some practitioners have encouraged their clients to purchase computerized label programs to be used on the farm computer to produce their own labels. The labels are applied by the producer when the drugs are delivered.

How should labels be applied? In some states, licensed wholesalers are allowed to affix labels to legend products delivered to producers if the wholesaler has an

authorization on file that states how the labels are to read. There is a movement in the California Veterinary Medical Association to push for allowing licensed wholesalers to apply labels for practitioners. Until the law is changed only a veterinarian or pharmacist can legally apply labels.

A veterinarian can simplify the labeling requirements for legend drugs by giving the first priority to authorizing drugs whose manufacturers list indications, dosages, and withdrawal times for meat and milk on their label. In these situations, the only cautionary statements needed is USE ACCORDING TO LABEL. This removes the added liability that a veterinarian assumes when they state a withdrawal time for a product which they have no hard information on. This practice also provides an excellent example to your clients about attempting to use pharmaceuticals which are approved for food animals. An example would be authorizing Azium which has an indication and dosage for cattle when a corticosteroid is needed verses Dexamethasone approved for horses.

By being involved in ethical marketing of pharmaceuticals, the veterinarian has a unique position to assist the livestock industry with responsible pharmaceutical usage. It must also be remembered that the majority of residue violations are not from legend drugs but from readily obtainable OTC products. The biggest problem, as I see it, is commission, lay salespeople whose very livelihood is dependent on the amount of drugs sold and used. The veterinary profession should not leave the marketing of veterinary pharmaceuticals unchallenged to them.