Veterinary Prescriptions and Drug Distribution: Who's in Charge?

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Abstract

Veterinarians have come to expect reliable and predictable services from wholesale drug distributors. Due to valid concerns regarding counterfeit human medications and the security of the drug supply chain, changes at the federal and state levels have directly affected veterinary wholesale drug distributors. This manuscript will highlight state and federal regulations that influence production animal medicine business models where veterinary prescription drugs are sold/delivered to end users upon the valid order of a veterinarian within the context of a veterinarian-client-patient relationship (VCPR).

This presentation will review federal acts and state statutes and regulations that affect the sale and distribution of prescription drugs used in production animal medicine. Additionally, it focuses on regulatory affairs and regulatory compliance issues that impact practicing veterinarians and veterinary drug distributors.

Résumé

Les vétérinaires s'attendent à des services fiables et réguliers de la part des distributeurs grossistes de médicaments. En raison de craintes fondées concernant la contrefaçon de médications humaines et la sécurité de l'offre en médicaments, les gouvernements fédéral et des États américains ont apporté des modifications qui ont directement affecté les grossistes en médicaments. Ce manuscrit trace les grandes lignes des règlements des États et fédéraux qui influencent la médecine des animaux d'élevages commerciaux où les médicaments sont vendus et livrés à l'utilisateur sur ordonnance valide du vétérinaire, dans le contexte d'une relation vétérinaire-client-patient (RVCP).

Nous verrons dans cette communication les lois et règlements fédéraux et des États qui affectent la vente et la distribution des médicaments d'ordonnance prescrits par les vétérinaires aux animaux destinés à l'alimentation. Également, cette communication mettra l'accent sur les affaires et la conformité réglementaires qui ont un impact sur la pratique vétérinaire et les distributeurs de médicaments pour animaux.

Introduction

Due to valid concerns regarding counterfeit human medications and the security of the drug supply chain, changes at the federal and state level have directly affected wholesale drug distributors that supply human prescription drugs and veterinary prescription drugs.[1] While most of these changes have been invisible to practicing veterinarians, this manuscript provides an explanation of the impact of new regulations on veterinary wholesale drug distributors and the veterinarians that purchase prescription drugs from them, as well as provide practical advice to veterinarians on how to help assure the safety and integrity of prescription drugs.

Prescription Drug Marketing Act

The Prescription Drug Marketing Act (PDMA) of 1987 established requirements related to the wholesale distribution of prescription drugs. A primary purpose of the PDMA was to increase safeguards to prevent the introduction of counterfeit drugs in the United States drug supply chain.[7,8] Although PDMA was passed in 1987 and later amended, its implementation was delayed until December 1, 2006. Due to PDMA and the requirement for stricter standards for obtaining a wholesale drug distributor license, the large majority of state boards of pharmacy redefined the term "wholesale distribution". It is now defined by most states as "the distribution of prescription drugs to a person other than a consumer or patient."

Who Regulates Veterinary Drug Distributors

Regulatory oversight for wholesale drug distributor licenses is often the responsibility of state boards of pharmacy or departments of health. States have moved forward with their own wholesale drug distributor licensing requirements which often contain requirements in addition to those in the PDMA.[2,6] Confusion has resulted from the fact that not all states have identical wholesale drug distributor licensing requirements. While they are similar in many regards, they are not identical from state to state.

The most significant requirement of PDMA as it applies to veterinary drug distributors is that wholesale drug distributors must be licensed in the state where they physically reside. Additionally, they must also obtain licenses in the states where they distribute prescription drugs. Historically, practitioners have always had the clinical responsibility for all aspects of prescription drug use in food animals, but new regulations on the distribution of said drugs have placed new responsibilities on practitioners. Veterinarians who prescribe or sell prescription drugs incident to their food animal practice are responsible for knowing the rules and regulations that govern the sale and distribution of prescription drugs.

Distributor's Point of View

The new, stricter requirements for obtaining or maintaining a wholesale drug distributor license have due diligence and recordkeeping procedures in place that must be documented. One of many requirements is that the wholesale distributor must verify who they purchase prescription drugs from, and who they sell prescription drugs to. The licensing requirements typically include duty to report rule language. This means if a licensed wholesale drug distributor knows or suspects that prescription drugs are being diverted, they must report their suspicions to the licensing agency. Failure to do so can result in the wholesale drug distributor's license being disciplined if an inquiry proves they had knowledge of, or suspected diversion of, prescription drugs or any other illegal activity regarding the distribution of prescription drugs.

Compliance with the new licensing requirements by veterinary wholesale drug distributors is likely to be expensive and consume significant personnel resources. Many distributors have already implemented new business practices, policies and procedures in efforts to meet licensing requirements.

Impact on Veterinary Practitioners in Food Animal Medicine

A few states have special licenses or exemptions in state pharmacy practice acts that accommodate production animal medicine business models where veterinary prescription drugs are sold/delivered to end users (feedyards, stocker operations, cow/calf operations) upon the valid order of a licensed veterinarian within the context of a veterinarian-client-patient relationship. Examples of states that have accommodated food animal distribution models are Oklahoma, Kansas, Texas, Colorado, Nebraska, and New Mexico. In the author's experience, the farther removed one is from the south/southwest area of the United States, the noticeably fewer accommodations are made for the needs of veterinary drug distributors and production animal medicine at the state level.

PDMA and state wholesale distributor licensing requirements have significant repercussions for veterinarians who may purchase large quantities of human or veterinary prescription drugs only to turn around and re-sell them to internet/mail order pharmacies, catalog outlets, other veterinarians for resale, or to a business that is functioning as an unlicensed wholesale drug distributor. Such activities would place the purchasing veterinarian in the position of being a wholesale distributor without the proper wholesale distributor license, which is a criminal offense. Such transactions are now defined as "wholesale distribution" and require a state-issued wholesale distributor license to legally participate in those types of sales. These types of sales have been termed "grey market, sideways, or lateral" drug sales because they were often conducted between one or more unlicensed parties and were intended to bypass traditional wholesale distributor licensing requirements.

Relationships (contractual or otherwise) between veterinary drug distributors and practicing veterinarians have historically focused on product costs. However, given the new landscape of veterinary drug distributor licensing requirements, veterinarians should expect, and receive, support from the regulatory affairs department within a distributor. There is a shared responsibility on behalf of both parties to comply with licensing requirements, drug labeling requirements, and recordkeeping requirements. Practitioners should be confident in the regulatory knowledge base and practical application of rules and regulations by a distributor in any state where a veterinarian has authorized their client to acquire prescription drugs.

Conclusions

Increased state and federal oversight of veterinary drug distribution in the United States has the potential to affect how veterinarians acquire, dispense and prescribe drugs. The veterinarian's role in the safety of the prescription drug supply chain became more pronounced and visible with the implementation of regulations that govern the sale and distribution of prescription drugs.

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