Veterinarians have come to expect reliable, efficient, and predictable service from the wholesale drug distributors they contract with to obtain prescription drugs for use in clinical practice and dispensing. For the most part, obtaining prescription drugs on behalf of a veterinary clinic or hospital has been a routine task. However, because of concerns regarding counterfeiting of human prescription drugs and the security of the drug supply chain, federal and state agencies have adopted new regulations for wholesale distributors of human and veterinary prescription drugs. Although most of these changes have not been apparent to practicing veterinarians, some have an effect on veterinary wholesale drug distributors and the veterinarians who purchase prescription drugs from them.

**Federal and State Regulatory Considerations**

The 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 into the US drug supply chain.² Although the PDMA was originally passed in 1987, its implementation was delayed until December 1, 2006.

One important provision of the PDMA is that it requires pedigrees be maintained on prescription drugs, documenting the movement of those drugs from the plant where they were manufactured through the US drug supply chain to the final dispenser.² Pedigree requirements are complex, and a complete discussion of them is beyond the scope of the present article. In addition, pedigree requirements do not apply to veterinarians in their daily use of prescription drugs within a clinic or when dispensing to clients.³

Regulatory oversight and licensing of wholesale drug distributors are often the responsibilities of state boards of pharmacy or departments of health. States have moved forward with their own wholesale drug distributor licensing requirements, which often contain provisions beyond those stipulated in the PDMA.⁴⁻⁸ Confusion has resulted from the fact that wholesale drug distributor licensing requirements for the various states are similar in many respects, but not identical.

For veterinary wholesale drug distributors, the most important requirements of the PDMA are that they must be licensed in the state where they physically reside if they distribute any human prescription drugs and must obtain licenses in all states where they distribute prescription drugs. This requirement applies to virtually all full-service veterinary wholesale drug distributors because most also distribute human prescription drugs. A few states have provided for special licenses or exemptions in their state pharmacy practice acts to accommodate production animal medicine business models under which veterinary prescription drugs are sold or delivered to end users, such as feed yards, stocker operations, and calf-calf operations, on the valid order of a licensed veterinarian within the context of a veterinarian-client-patient relationship. Examples of states that have accommodated production animal medicine distribution models include Oklahoma, Kansas, Texas, Colorado, and New Mexico.

**Potential Effects of Federal and State Regulations**

The new federal and state regulations for veterinary wholesale drug distributors affect not only those distributors, but also the veterinarians who purchase drugs from them. As an example, there has been a trend to establish stricter standards for obtaining wholesale drug distributor licenses. As a result, most state boards of pharmacy have redefined the term wholesale distribution as “the distribution of prescription drugs to a person other than a consumer or patient” and require that individuals and companies involved in wholesale distribution obtain a valid state-issued wholesale distributor license prior to participating in these types of activities. Importantly, although some states have limited this definition only to human prescription drugs, a few have also included veterinary prescription drugs. As a result, this change has important implications for veterinarians who purchase large quantities of human or veterinary prescription drugs with the intent to subsequently resell them to Internet or mail-order pharmacies, catalog outlets, other veterinarians, or businesses functioning as unlicensed wholesale drug distributors. Such activities would put the purchasing veterinarians in the position of being wholesale drug distributors without the proper wholesale drug distributor license, which is a criminal offense. These types of transactions have been called gray market, sideways, and lateral drug sales because they have often involved unlicensed parties and were intended to bypass traditional wholesale drug distributor licensing requirements.
The new regulations for obtaining and maintaining wholesale drug distributor licenses contain a requirement that proper record-keeping procedures be in place so that wholesale drug distributors can verify who they have purchased prescription drugs from and who they have sold those prescription drugs to. This will have an effect on veterinarians because wholesale drug distributors can be expected to request proof that veterinarians attempting to buy prescription drugs have a current veterinary license and current Drug Enforcement Administration registration number. Veterinarians who have allowed their veterinary license to lapse may not be able to purchase prescription drugs until they can furnish proof of current licensure.

Under the new pharmacy regulations, policies related to the return of human prescription drugs will likely be tightened or eliminated because returning drugs to a distributor is seen as a potential way to reintroduce counterfeit drugs into the supply chain. Therefore, veterinarians should take this into account when ordering large quantities of human prescription drugs.

New pharmacy licensing requirements typically include duty-to-report language, meaning that licensed wholesale drug distributors who know or suspect that prescription drugs are being diverted must report their suspicions to the licensing agency. Failure to do so can result in disciplinary action against the wholesale drug distributor. This is similar to current requirements that wholesale drug distributors must report the purchase of large amounts of controlled substances or certain chemicals such as pseudoephedrine, phenylpropanolamine, and iodine solutions and tinctures ≥ 2.2%. Veterinarians may become frustrated with the increased vigilance of wholesale drug distributors but should be aware that such measures are not personal and are simply a cost of doing business.

Compliance with the new licensing requirements by veterinary wholesale drug distributors is likely to be expensive and may consume substantial personnel resources. Many distributors have already implemented new business practices, policies, and procedures in efforts to meet licensing and pedigree requirements. Unfortunately, the cost of compliance is likely to be passed on to the purchaser in the form of an increase in costs of human prescription drugs sold to practicing veterinarians.

**Veterinarians’ Role in the Safety of the Prescription Drug Supply Chain**

Veterinarians are uniquely positioned to assist in protecting the safety and integrity of the prescription drug supply chain by reporting suspect counterfeit prescription drugs and other drugs of questionable quality or origin. In particular, veterinarians should be wary of online pharmacies that do not list a physical address on their Web site. Offshore pharmacies mailing counterfeit drugs into the United States are a top-level concern for the FDA and the Drug Enforcement Administration.

Veterinarians should purchase drugs only from licensed, trusted, wholesale drug distributors and should avoid gray market, sideways, and lateral drug sales because such sales are intended to circumvent new wholesale distributor licensing requirements and can be viewed as illegal. In addition, veterinarians should not purchase any human or veterinary prescription drugs from countries outside the United States, including Canada and Mexico, because these drugs have not been approved by the FDA.

Importantly, veterinarians should not purchase any drugs compounded by a pharmacy with the intent of relabeling and reselling the drugs to other entities, such as other veterinarians, drug distributors, or their clients. Such activities are normally associated with drug manufacturing, and compounded drugs are not the same as generic drugs. Generic drugs are FDA approved, originate from licensed manufacturers, and are sold through licensed distributors.

Finally, veterinarians should report any prescription drugs that appear to have an altered label, a label printed in a different language, different colored or altered packaging, or an altered appearance. Reports should be directed to the FDA Counterfeit Alert Network (www.fda.gov/oc/initiatives/counterfeit/qa.html) or MedWatch, the FDA Safety Information and Adverse Event Reporting System (www.fda.gov/medwatch/how.htm). In addition, the originating source of the suspected drugs should be notified.

**Conclusion**

Increased state and federal oversight of wholesale drug distributors in the United States has the potential to affect how practicing veterinarians acquire, administer, and dispense prescription drugs. Veterinarians are uniquely positioned to offer guidance and counseling to clients seeking to obtain veterinary prescription drugs from Internet pharmacies and should be watchful for suspicious or questionable prescription drugs. Full-service wholesale veterinary drug distributors are knowledgeable on the plethora of new laws, rules, and regulations affecting their licensing status and should be able to counsel veterinarians who might have additional questions on this topic.

**References**


8. States adopt legislation to tighten licensing requirements for wholesalers. National Association of Boards of Pharmacy Newsletter 2007;Sep:140.