Drug Pedigree: Does it Matter to Manufacturers?

The U.S. Food and Drug Administration (FDA) announced it will be taking new steps to strengthen existing protections against the growing problem of counterfeit drugs. In addition, a growing number of regulatory efforts at the state level will compel drug manufacturers and/or distributors to provide drug pedigree information at each stage of distribution. In fact, beginning in December of 2006, wholesalers were required to supply pedigrees unless they are designated an “Authorized Distributor” from a manufacturer.

Life science companies face significant challenges in effectively designing, optimizing and managing product supply and demand throughout their entire life cycle. They must develop specific brand security plans that meet the FDA’s requirements and prepare for future regulations.

Securing the pharmaceutical supply chain is one of the most critical issues facing both manufacturers and distributors today. For manufacturers, counterfeiting and diversion pose grave risks to brand integrity, business reputation and patient safety. Legislation requiring chain of custody documentation throughout the distribution system has been around since the late 1980s, when Congress passed the Prescription Drug Marketing Act (PDMA). These “pedigrees” require all parties that subsequently resell a drug at the wholesale and retail level to authenticate each transaction preceding it in the chain. In response, the FDA in 1999 subsequently issued its own regulation requiring pedigrees. While the means of recording (paper or electronic) are not specified, it is widely believed that due to the sheer volume of transactions, manual paper-based pedigrees are unsustainable, and electronic means of pedigree are encouraged.

However, implementation of pedigree requirements by the FDA has been delayed by a series of stays, designed to allow the industry time to adopt suitable electronic technologies. Subsequently, in June of 2006, the FDA, on the recommendation of its Counterfeit Drug Task Force, announced its disappointment with the lack of progress from the industry, and declared it is allowing the stay on enforcement to lapse.

In the absence of active federal enforcement over the past several years, states have seized the initiative. Pedigree laws have been passed and are now on the books in several states, including Florida, California and Indiana. While similar in intent, there are significant differences in how the states view pedigrees as well as their requirements for the information contained in them. Variations exist in requirements such as invoice number and “ship-to” state license number. Additionally, the state pedigree laws differ from the industry-oriented EPCglobal standards for pedigree information requirements.

As a result, there is a great deal of confusion in the market today. What is the “superset” of pedigree requirements? Who do the pedigree laws apply to? And perhaps most importantly to our manufacturing clients, does any of it matter to the manufacturer?”

It does. While most laws are focused on the wholesale distribution chain, securing the drug supply chain can’t be accomplished by starting in the middle of the chain. Pedigree is not just a wholesaler issue, but as the license holder for drugs at risk of counterfeit and diversionary practices, it is critical for manufacturers as well. Pharmaceutical and Biopharmaceutical manufacturers should consider the following:

- California is first - While the Florida and Indiana laws focus on the distribution chain, beginning with the wholesaler, California became the first state to mandate that the pedigree documents be initiated by the manufacturer, and so bears the most relevance for pharmaceutical manufacturers. While a stay in enforcement has recently been granted, beginning January 2009 manufacturers will be required to provide a pedigree to any wholesaler or pharmacy acquiring a drug that is shipped into the state of California.
- Broad reach - While the law is clearly focused on products shipped into the state, as a result of typical supply chain practices across the industry, it
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has implications reaching far beyond California. For example, it is not unusual for manufacturers to not know which units will ultimately be shipped to California. In many cases, drugs are shipped to regional distribution centers that can ship to customers in a number of states. Where the final destination is not known, pedigrees may be needed for all manufactured product going into that distribution center.

- Manufacturers’ Agents - There is a great deal of uncertainty regarding significant portions of the California pedigree law. For example, there are conflicting opinions on the legal interpretation of the California requirements, and therefore on the necessity of a pedigree for situations involving so-called “agents” of a manufacturer, such as contract manufacturers (CMOs), 3rd Party Logistics providers (3PLs), and Returns services providers. Interpretations – or future developments – requiring pedigrees for these transfers may eliminate the option of manufacturers relying on their partners to generate and certify pedigrees on their behalf.

- Operational Burden - Most pedigree regulations mandate that a customer can not receive a shipment of product without a matching pedigree. As a result, quickly and effectively generating, certifying, and transferring pedigrees will become an integral part of doing business. Considering the volumes of pedigrees likely to be required, if this process is not managed and executed well, pedigree delays may quickly become an operational constraint for manufacturers. This may also guide the determination of what is the appropriate level for a manufacturer to generate a pedigree. For example, if pedigrees are generated at the order level and an under or over shipment occurs, the entire order may not be available for receipt until the pedigree is decommissioned and a new pedigree is generated. As additional states look to mandate drug pedigrees, several things are clear:

- Even with the existing federal and state regulations focused on wholesalers and pharmacies, the information required to generate the downstream pedigrees will need to be created and communicated. This includes manufacturer information, lot numbers, shipment information, and other requirements as regulations evolve. The mechanisms may take the form of expanded Automated Shipment Notifications (ASNs), ePedigree solutions, or some other means, but one way or another; manufacturers will need to provide the extended pedigree information.

- While the pedigrees themselves may or may not be initiated by the manufacturer, the information required from the manufacturer to produce the pedigree will certainly continue to grow.

- Finally, with the level of activity occurring at the state levels, it’s very likely that further pedigree requirements are coming. And while the recent FDA decision to lift the stay on pedigrees does not focus on manufacturers, it is significant in raising the administration’s role as an active, rather than passive participant in ensuring the security of the pharmaceutical supply chain. For manufacturers, it’s not a question of if, but when, requirements will reach back earlier in the supply chain.

With the large amount of uncertainty likely to persist in the near-term, manufacturers should regard any investment in pedigree-specific solutions as an interim step toward a longer-term track and trace infrastructure. They should also maintain flexibility through partnerships with robust solutions providers, and focus on developing strategies for utilizing pedigree and future serialization technologies not only for meeting regulatory requirements, but also for realizing better overall management and control of their supply chains.

Manufacturers, and particularly those producing drugs meeting certain counterfeiting risk factors, cannot afford to ignore current and upcoming developments in pedigree regulations. After all, it’s the manufacturer, along with patients, who is most at-risk from counterfeit drugs stemming from an unsecured supply chain.

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