Drug Pedigrees and Distribution Dilemmas: FDA’s New Requirements May Disrupt Pharmacy–Wholesaler Relationships

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Pharmacists may feel a little bit like bouncers in a bar on December 1, 2006. On that day, the Food and Drug Administration (FDA) will begin requiring that pharmacies obtain a “drug pedigree” from any pharmaceutical wholesaler who approaches the pharmacy counter and who is classified as an “authorized distributor of record” (ADR).

The requirement that all retail, institutional, and hospital pharmacies obtain a pedigree from non-ADRs, primarily secondary wholesalers, is intended as an anti-counterfeiting measure. The FDA has actually had the authority to impose a pedigree requirement since 1999, but it held off, hoping that drug manufacturers would adopt electronic track-and-trace technologies. An example is radio-frequency identification (RFID), which would be much more effective against drug counterfeiting than pedigrees, which will most likely be just pieces of paper.

The FDA is not worried about primary wholesalers (e.g., Cardinal, McKesson, and AmerisourceBergen). Those companies buy their products directly from manufacturers and sell directly to pharmacies; these distribution chains are thought to be secure.

Secondary wholesalers, however, are not household names. They buy from all types of sources, and some of these can be shady. That is how counterfeit products are introduced into the U.S. drug-distribution chain.

Although no one believes that this new requirement will be the definitive solution to counterfeiting, the failure of drug manufacturers to adopt the track-and-trace technology essentially forced the FDA to adopt this less attractive method.

Pedigrees can be electronic, but they will probably be paper. They must contain the proprietary and established name of the drug; the dosage; the container size; the number of containers; the drug’s lot or control number; the business name and address of all parties to each previous transaction; and the dates of those transactions.

The FDA has not yet decided which drugs will need a pedigree. The Compliance Policy Guide, issued by the agency issued last summer, mentioned risk factors that the distributor is supposed to use to determine whether a pedigree is required. Of course, this leaves a lot to the imagination. The original concept was that the agency might supplement that information by publishing a list of drugs that would be susceptible to counterfeiting so that only those drugs would require a pedigree.

Yet some think that the list should be more complete. Tom McPhillips, Vice President of the U.S. Trade Group at Pfizer, says that his company thinks paper pedigrees should be required for all medications leaving the normal distribution channel.

Regardless of the number of drugs that are eventually subject to the pedigree requirement, pharmacies will be facing several challenges. It is not clear whether these problems will be large or small.

To begin with, non-ADRs will be smaller wholesalers, and some of these will be legitimate. They have been in the business of distributing niche drugs, which are important to pharmacies. However, if they do a small amount of business with any one drug manufacturer, given the cost of maintaining that niche wholesaler on its ADR list, the manufacturer might decide not to keep the wholesaler on the list.

This situation raises the question of how the niche wholesaler would get the pedigree information that must be passed on to the pharmacist. It is possible that the manufacturer would not want to voluntarily pass pedigree information to any wholesaler who is not on the ADR list.

It is unlikely that a manufacturer or authorized distributor would voluntarily produce a pedigree for a drug product, especially after considering time, manpower, and cost restraints. If manufacturers and authorized distributors do not voluntarily provide a pedigree to unauthorized distributors, unauthorized distributors would effectively be prevented from reselling the product—or [would be] forced to construct a pedigree.

This situation could cause that distributor to go out of business as well as result in a loss of the supply of products to pharmacies.

From the standpoint of the pharmacists, they must be able to quickly determine whether a secondary wholesaler who arrives at the pharmacy door is on the manufacturer’s ADR list for a given product. Some niche distributors might be on Pfizer’s ADR for one product but not for another. The pharmacist must be able to go to the computer and view Pfizer’s updated ADR list. But the FDA hasn’t made it clear how manufacturers will make those lists public or how they should maintain them.

Anita T. Ducca, Senior Director of Regulatory Affairs and Health Care Policy at Healthcare Distribution Management Association (HDMA), says, “There is a need for greater clarity regarding the FDA’s expectations of manufacturers and/or how the agency will enforce this requirement.”

With the December 1 start date fast approaching, pharmacists are hoping that the FDA will provide detailed guidelines to participants up and down the distribution chain—and soon. They’re less likely to have to flex their bouncer muscles that way.