

Pfizer Prepares for Viagra E-Pedigree Trial

Later this year, the drugmaker says it will use SupplyScape e-pedigree services to document RFID-tagged bottles of Viagra as they move across the supply chain.

By Beth Bacheldor

Feb. 14, 2007—Now that it has gained more than a year's experience with radio frequency identification, Pfizer is preparing its first electronic pedigree (e-pedigree) trial for a launch this year. The trial will document the movement of individually tagged bottles of Viagra as they leave Pfizer's facilities for delivery to distributors, wholesalers and other partners. Favored by the U.S. Food and Drug Administration (FDA), as well as lawmakers and other organizations, drug pedigrees (whether paper or electronic) are intended to improve the security of the country's pharmaceutical supply chain and help fight drug counterfeiting.

The drug manufacturer plans to use e-pedigree services provided by SupplyScape, a creator of pharmaceutical supply chain software based in Woburn, Mass. SupplyScape's software will create secure files that will store the RFID tags' unique ID numbers, along with shipping and transaction data, lot number and other information pertinent to each specific bottle.

This system is expected to comply with EPCglobal's newly ratified e-pedigree protocol, developed to provide the pharmaceutical industry with a common format for supply chain partners to use in collecting pedigree information (see EPCglobal Ratifies E-Pedigree Standard). Pfizer will share the Viagra e-pedigree files with trading partners yet to be identified.

The e-pedigree trial broadens Pfizer's RFID initiatives already underway. In the past year, the drugmaker has successfully affixed high-frequency (13.56 MHz) tags to more than 2 million bottles of Viagra, while applying passive EPC UHF tags to 55,000 cases and 400 pallets containing the drug. This year, it plans to affix EPC Gen 2 UHF RFID tags to all cases and pallets of Celebrex—a pain reliever and anti-inflammatory—bound for the U.S. market (see Pfizer to Tag Celebrex).

Pfizer has also been using SupplyScape's RxAuthentication Service, designed to allow wholesalers and pharmacies to use SupplyScape's service in verifying the authenticity of RFID tags on the drugs they receive (see Pfizer Using RFID to Fight Fake Viagra). Since it began using the authentication service, more than 300,000 authentications have been performed on RFID-tagged Viagra bottles, according to Peggy Staver, the firm's director of trade product integrity. Staver detailed the company's RFID initiatives during a recent webcast sponsored by Brady Corp., a maker of identification solutions.

Peter Spellman, senior VP of products and services for SupplyScape, says e-pedigrees go beyond authentication measures because they do more than verify a tag number. "The issue with pedigrees is that they require very specific definitions and specific data elements," he says. "It isn't enough to document that you saw a particular serial number on a specific bottle at a specific time."

E-pedigrees can contain ship-to addresses, ship-from addresses, transaction numbers, transaction types, expiration dates and more. Collecting that data to create the e-pedigree file often requires software able to

interface with multiple information systems, including order processing, manufacturing execution and warehouse management systems.

Presently, 15 states have laws requiring drug pedigrees, Spellman says, while seven states have legislation pending, with five more expected to introduce legislation this year. A California law calling for e-pedigrees takes effect in 2009; originally, the state's e-pedigree legislation was supposed to take effect in January 2007, but Spellman says that law has been pushed back two years. Drug manufacturers, wholesalers and distributors must comply with the requirements outlined in the various laws.

Although Pfizer is satisfied with its use of HF tags on bottles, Spellman states, the company is still working out the details of its e-pedigree project. A number of other companies are finding themselves in the same situation as well. "Across the market," he notes, "pharmaceutical manufacturers are engaging with us to figure out fundamentally what their e-pedigree strategy is, to get experience with their supply chain. And they all want to make sure they are ready for the California 2009 date."

According to Staver, Pfizer's aggressive stance on RFID and e-pedigrees is spurred by an increase in drug counterfeiting. As of Dec. 31, 2006, the drugmaker had found counterfeits of its products in at least 69 countries. "This is a significant issue for all of us in our industry," she told webcast attendees.

Counterfeit drugs pose serious health threats, Staver said. "The [counterfeit] drugs are often manufactured in unsanitary conditions, in unregulated and unlicensed sites, and the packaging methods are drastically different." In some cases, she added, the drugs don't contain any active ingredients, such as the counterfeit versions of Norvasc—a drug used to treat high blood pressure and the chest pain of angina—that Pfizer found in the fall of 2005 in a pharmacy in Hamilton, Ontario. At other times, dangerous additives are used—in one case of counterfeit Viagra, Staver said, traces of boric acid and brick dust were found.

RELATED_ARTICLES "Our mission and our vision, as our starting point, is to enhance patient safety by implementing effective U.S. channel security strategies that protect our products and reduce the threat posed to the channel by diverters and counterfeiters," Staver told attendees. "This is an internal mission for Pfizer, but clearly this is of interest to other manufacturers."

Pfizer, she said, is very committed to looking at using RFID in other aspects of Pfizer's supply chain, including shipping and receiving.

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