

Pharma Groups Respond to FDA RFID Report

Although eager to adopt the technology, the drug industry says obstacles still hinder widespread implementation.

By Beth Bacheldor

June 20, 2006—Pharmaceutical industry associations have thrown their support behind the recently released U.S. Food and Drug Administration's report on RFID's use in the pharmaceutical industry.

The June 9 report, "FDA Counterfeit Drug Task Force Report: 2006 Update," contains high-level recommendations for building a more secure and safe pharmaceutical industry supply chain (see FDA Issues New 'Counterfeit Drug Task Force' Report). The task force consists of senior staff from the agency's Office of the Commissioner (Office of Policy and Planning, Office of the Chief Counsel), Office of Regulatory Affairs, Center for Drug Evaluation and Research, and Center for Biologics Evaluation and Research. For more than two years, the group has been investigating RFID technology and the concept of an electronic pedigree (e-pedigree), a procedure that records where a drug is manufactured and how it is distributed.

Industry associations such as the Pharmaceutical Research and Manufacturers of America (PhRMA), the American Pharmacists Association (APhA) and the Healthcare Distribution Management Association (HDMA) all agree that the task force's recommendations, endorsed by FDA Commissioner Andrew C. von Eschenbach, are a good step toward securing the pharmaceutical supply chain. In particular, the organizations praise the FDA's decision to end a temporary hold on regulations related to the Prescription Drug Marketing Act (PDMA) of 1987. That act requires drug distributors to document (via a pedigree, though not necessarily in electronic form) the chain of custody as drug products move through the distribution system. According to the FDA, the hold—initiated because there were concerns that pedigrees would have a negative impact on small wholesalers—will expire in December and not be extended.

The three groups also agree with the FDA's decision not to mandate RFID's use within the pharmaceutical industry. In its report, however, the FDA did recommend the industry "move quickly to implement this technology."

At this point, it's considered premature for the FDA to issue an RFID mandate because standards and technologies are still being worked out for item-level tagging, according to Alan Goldhammer, associate vice president of regulatory affairs for PhRMA, which represents pharmaceutical research and biotechnology companies. Case in point: The pharmaceutical industry, he notes, is still debating two differing RFID technologies—ultrahigh frequency (UHF) and high frequency (HF) (see RFID Vendors Unite to Promote UHF for Items and Study Says HF Rules for Pharma Items).

"If you look at what other industries are doing with mandates, particularly if they are in the consumer products industry, there are not quite the same issues," says Goldhammer. "It is very different if you are looking at putting RFID chips on blue jeans or DVDs, where you are just using RFID to identify the product in question."

The HDMA, an association representing distributors of health-care products, agrees that there are still obstacles to RFID's widespread adoption within the pharmaceutical industry. In particular, real-time systems that allow for the sharing and management of RFID data have to be designed, and companies have to integrate new technologies into current business practices and legacy systems. "These changes and processes take time to implement," says Scott Melville, HDMA's senior vice president.

To help advance implementation of RFID and other track-and-trace technologies, the HDMA Foundation (the HDMA's research affiliate) has launched an initiative with the Rutgers University Center for Supply Chain Management to study the key issues of data sharing and data management in the health-care supply chain, Melville says.

Although the FDA stopped short of requiring the pharmaceutical industry to use radio frequency identification, it did call RFID "the most promising technology for implementing electronic track and trace in the drug supply chain," expressing disappointment that the industry had not made greater progress on using the technology in its supply chain.

In early 2004, the FDA stated its hope that by 2006, the supply chain would be using RFID tags at the individual item level for all drugs likely to be counterfeited. It also wanted the industry to be able to tag all drugs at the pallet, case and unit levels the following year (see FDA Endorses RFID Technology).

According to Goldhammer, the industry's slow uptake of RFID shouldn't be a surprise because the obstacles have not yet been overcome. He adds, however, that the FDA's decision to enforce the PDMA may encourage RFID's use. "I think, actually, the pedigree announcement may do more to spur [RFID] because no one wants to be pushing paper pedigrees around," he says. "I don't think there is any shortage of commitment to RFID on the part of the industry, but there is a lack of standards, the infrastructure is still uncertain and the return on investment is still somewhat complex."

Susan Bishop, director of regulatory affairs with the APhA's policy group, agrees that RFID may make it easier to implement a drug pedigree system. The organization's 57,000 members include practicing pharmacists, pharmaceutical scientists, student pharmacists and pharmacy technicians.

"There are some challenges with the paper [pedigree] system," Bishop says. "APhA has been concerned with the way the FDA has defined an authorized distributor, and that authorized distributors are not required to pass along the pedigree." Authorized distributors are only those that have written agreements with manufacturers; all other distributors are considered unauthorized.

Authorized distributors often sell drugs to unauthorized distributors, which then move the drugs further down the supply chain. Unauthorized distributors are required to produce a pedigree. "But if it wasn't provided by the authorized distributor, how do they get that information?" Bishop asks. "If the industry moves to RFID, it could eliminate that problem because the information would be attached to the product at the point of manufacture."