Pharmaceutical RFID: From Mandates to Endorsements and Laws

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The healthcare industry’s motivation for adopting RFID can be attributed to a number of sources. These include concerns for patient safety, increased supply chain visibility, diversion reduction, retailer mandates and state pedigree laws.

Each of these motivators influences the decisions made by healthcare companies in regard to RFID. It is clear that Wal-Mart’s mandate, state pedigree laws, and the Food and Drug Administration’s (FDA) endorsement have forced the pharmaceutical industry to adopt a new point of view. Companies have moved from doing research and asking questions to beginning pilots and small-scale implementations. The industry has a specific timeline in order to meet set deadlines.

FDA: Prescription Drug Marketing Act

In 1987 the FDA passed the Prescription Drug Marketing Act in response to a series of counterfeit drug incidents. The final regulations were implemented in 1999. The PDMA requires prescription drug wholesalers to be state licensed and those that are not licensed must provide drug pedigrees. The FDA placed a stay on the pedigree requirements of the PDMA, which will expire in December 2006. The stay was issued due to significant concerns raised by the industry.

The stay was issued to provide time for wholesalers to implement electronic track-and-trace technology. But at this stage in the game it doesn’t appear that the FDA’s goal of having an electronic pedigree system implemented by December 2006 will be met. The FDA has said it will need to reevaluate its plans regarding the stay before December.

FDA: RFID Endorsement

The FDA released a report in February 2004 entitled “Combating Counterfeit Drugs.” The report includes conclusions from a study carried out by an FDA Task Force, and a series of guidelines for pharmaceutical companies. The report recommends the implementation of electronic track-and-trace systems in order to combat counterfeit drugs in the supply chain.

The FDA did not specify RFID as the only technology capable of performing track/trace responsibilities. It does, however, state that RFID is one the best methods for achieving the goal of supply chain visibility and preventing the sale of counterfeit drugs. It is encouraging pharmaceutical companies to experiment with RFID and provide feedback to the FDA.
A working group has been established by the FDA, responsible for monitoring the adoption of RFID. It is also responsible for clearing any roadblocks that may prevent companies from experimenting with RFID. To demonstrate its commitment, the FDA announced in November 2004 that it will overlook label-change violations for companies testing RFID. Many manufacturers were hesitant to pilot the technology due to strict regulations on label changing. A pilot would also require the purchase and integration of an inline tagging or labeling system which can be expensive. The FDA previously would not allow a supplemental RFID label to be placed on pharmaceutical products. The FDA is allowing RFID tags to be applied to drug containers, secondary packaging, shipping containers and pallets of drugs entering the supply chain.

The FDA set out a specific schedule that it believes pharmaceutical companies should use as a guideline. It believes pharmaceutical companies should have begun experimenting with RFID technology during 2004 and should have begun very few implementations in 2005. In 2006 implementations should increase, and by 2007 adoption of RFID should be widespread. Pharmaceutical companies are expected to start with drugs most likely to be counterfeit and gradually expand to all drugs by 2007 which will coincide with the end of the PDMA stay.

![Total RFID Life Sciences Revenue](image)

**State Pedigrees**

Florida has passed a law requiring all drugs to be tracked with pedigrees by July 2006. Similar laws have been passed in California and Nevada, and are being considered in other states. Some pedigree laws exist today but affect only a small number of companies. Florida has gained a great deal of attention because its deadline is the earliest. California follows, with its requirement beginning in January 2007. Once the California law comes into effect it will implicate not only the wholesalers/distributors and pharmacies but also the manufacturers.

A pedigree is a legal document that contains details of a drug’s history. It tracks the drug’s chain of custody throughout its life cycle starting with the manufacturer and
ending with the dispensing pharmacy. The Florida law does not specify if the pedigree should be electronic or paper and a particular technology is not recommended to satisfy the law. The California law requires an electronic pedigree (e-pedigree) meaning they will not accept a paper pedigree. While many companies understand that RFID will enable them not only to comply with the pedigree laws but also to better manage inventory, they plan to use barcodes in order to meet state pedigree requirements.

**Counterfeiting and Patient Safety**

Drug counterfeiting has become a worldwide problem, estimated to cost $30 to $40 billion per year. Counterfeit drugs usually enter the supply chain mid-way through, or shortly before reaching a pharmacy or hospital. The drugs are often sold by a smaller unknown distributor or wholesaler. Pharmaceutical supply chains are very complicated since one shipment can change hands ten times and shipments are often repackaged by distributors. Without a universal record-keeping system it is difficult to authenticate shipments.

The FDA has seen an increase in the number of counterfeit drug cases since 2000. In the United States the number of lawsuits filed against the three major drug wholesalers (Cardinal Health, McKesson Corp., and AmerisourceBergen) for supplying counterfeit drugs has increased. This appears to be a growing problem not only in the United States but around the world. The United States is the first country to have a government initiative to combat this problem.

There are a number of tools used to prevent counterfeit drugs from entering the supply chain. These tools include holograms, color shifting inks, fingerprints, taggants and chemical markers. RFID is seen as a powerful tool to combat the rise in counterfeit drugs.

RFID tags that are embedded in labels or molded into bottles will be difficult for counterfeiters to notice, let alone copy. Each RFID tag has a unique number stored in its memory that is used to identify the item to which it is attached. The tag can be scanned throughout the supply chain and the unique number will be used to verify the product’s authenticity. RFID is such a powerful tool in combating counterfeit drugs because it is very difficult to replicate.

**Supply Chain Efficiency**

Pharmaceutical supply chains are very disjointed; as stated earlier, a shipment can change hands many times. For the most part they are also not automated, meaning that a great deal of record-keeping is being done on paper. Many companies are slow to adopt newer technologies due to the cost, even though they provide benefits. Over time, this leaves their business processes more and more outdated. RFID will help pharmaceutical companies take control of their supply chains and their business processes.

In contrast to other RFID markets such as the consumer packaged goods and retail supply chain, RFID is primarily being used for authenticating drugs and preventing counterfeiting in the pharmaceutical market. While this is the primary agenda, most
companies involved in the pharmaceutical supply chain recognize that RFID can bring them other benefits. They can utilize the technology for supply chain efficiency too.

As manufacturers consider their RFID business plans, the question arises: when will they achieve a return on investment (ROI)? This has been a point of concern for manufacturers since they are the ones purchasing and applying the tags to the bottles. Using RFID to prevent counterfeiting and increase patient safety is compelling but it does not bring an ROI. Pharmaceutical manufacturers are struggling to with an ROI timeline, which has increased their interest in supply chain enhancements. If they are able to use RFID for both authentication and supply chain efficiency then an ROI may be achievable. Today these results focus on efficiencies within the manufacturer’s facilities. If a data sharing model similar to the EPC Network takes shape in this market, then they will be able to gain supply chain visibility as well.

**Diversion**

Diversion is often the reason counterfeit drugs enter the supply chain. Diversion pertains to any pharmaceuticals that are obtained illegally. Often counterfeiters will replace real drugs with counterfeits and sell the originals illegally at much higher prices.

Organizations such as hospitals are entitled to discounts on pharmaceuticals. Often an organization will state that it is purchasing drugs for hospitals in order to get the discount. The company will then turn around and ship the order to a commercial location and receive an increased profit margin. The pharmaceutical company loses that profit and has no way of realizing this fraud has occurred.

RFID alone cannot combat diversion. A central repository of information or pedigree system is necessary so that companies are able to verify their shipments’ authenticity. This will enable a distributor to verify whether its drug shipment is authentic. More important, retailers and pharmacies will also be able to verify if shipments are authentic so patients will not be dispensed counterfeit products. If people are caught selling drugs illegally, the original bottles will allow investigators to determine exactly where the drugs were stolen. Retailers will also be able to track each step of their purchase’s history. They would be able to see whether the company they purchased the pharmaceuticals from received an inappropriate discount.

**Overstocking, Expiration, and Out of Stocks**

Drugs are often delivered to pharmacies or hospitals and end up sitting on shelves until they expire. Overstock and expiration cost the industry over $2 billion annually. Once a shipment is placed on the pharmacy shelf, it is usually not tracked. If a pharmacy has ordered too much of one drug it may not realize it until the drug has expired.

If the retailer had a way of knowing that it had a large amount of one drug in inventory, it could take a number of actions. It could return some to the company from which it was purchased, for a credit. If the pharmacy had multiple branches it could send the drug to a branch that may have run out. At the very least if it could not make use of the medication
it would know in the future to order smaller quantities. All of these solutions would be possible with an inventory tracking system. Applying RFID tags to all the medications at the item level, installing a reader infrastructure, and using a software program that can monitor the system would all serve as a complete inventory management system.

Out-of-stocks are an issue with any business providing off-the-shelf products. Just as a pharmacy may not realize it has too much of one drug, it may not realize that it has run out of another. However, since most customers are loyal to their pharmacies this does not cause as much of a problem. The same inventory control system would combat any out-of-stock issues as well.

**Where the Industry is Today**

While there are a number of reasons pharmaceutical companies should be adopting RFID, the market has been moving slowly. It appears that the FDA’s endorsement in the “combating counterfeit drugs” report was not as strong a motivator as they had hoped. Most companies understand the benefits of the technology but they are taking a slow and measured approach to implementation.

The industry is able to comply with pending state laws by using barcodes causing those deadlines to be insignificant in RFID planning. Since barcodes are already being used on most if not all drugs, this solution is easy to implement and low in cost. ABI Research expects that during 2006 no more than 10 drugs will be tagged at the item level on a wide scale comparable to the Pfizer Viagra pilot. The market should pick up more significantly in 2007 once companies have completed pilot projects.