# RFID: Keeping America Safe from Counterfeit Pharmaceuticals

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# RFID: Keeping America Safe from Counterfeit Pharmaceuticals

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Abstract: This paper looks at the use of a new technology, RFID tags (radio frequency identification) to assure the American public is kept safe from counterfeit pharmaceutical drugs

Keywords:
RFID (radio frequency ID), counterfeit, PDMA (pharmaceutical drug marketing act), track and trace, UPC, safety, EPC (electronic product code), GTIN (global trade item number), Auto ID Center

This paper looks at the use of a new technology, RFID tags (radio frequency identification) to assure the American public is kept safe from counterfeit pharmaceutical drugs. The World Health Organization (WHO) defines a counterfeit pharmaceutical as one that is "deliberately and fraudulently mislabeled with respect to identity and/or source.[1]

Counterfeit pharmaceuticals pose a significant problem in the world economy:

1. because of lost sales and depressed prices counterfeits represent an economic loss to the company whose product is being counterfeited.
2. counterfeit pharmaceuticals pose a health risk to the patients taking the counterfeits;
    1. they may not be getting the drug recommended by their physician in the recommended quantity, and
    2. taking less than the recommended dose of an antibiotic may assist in the evolution of drug-resistant microbes..
    3. counterfeit drugs may include contaminants that are harmful.
    4. counterfeit drugs may not have been handled, packaged, or labeled properly.
    5. counterfeit drugs could cause a loss of faith in the healthcare system which results in patients not seeking appropriate care.
3. the pharmaceutical industry will divert funds from research to anti-counterfeiting measures.
4. as a consequence of counterfeiting the pharmaceutical industry may not fund research to create new drugs to the same extent it has in the past..

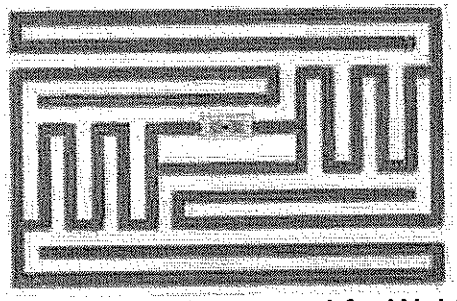
The World Health Organization (WHO) reports that approximately $34 billion in counterfeit medical products, including pharmaceuticals, was produced in 2001, accounting for 15 percent of the total market. . FDA reports that counterfeit pharmaceuticals may make up more than half of some countries' drug supply. For example, up to 50 percent of anti-malarial medication in Africa is counterfeit. [2] The WHO reports that approximately 8% of the drugs sold in the United States are counterfeit.[3]

**Prescription Drug Marketing Act (PDMA) of 1987 and Prescription Drug Amendments of 1992**

Congress passed PDMA in 1987 "because there were insufficient safeguards in the prescription drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs and that a wholesale drug diversion submarket had developed that prevented effective control over, or even routine knowledge of, the true sources of the drug." [4]

A key element of PDMA is a legal requirement of drug traceability back to the manufacturer. Every pharmaceutical drug dispensed to a patient must have a pedigree; it must be traceable back through the distribution system to the manufacturer and a particular manufacturing batch. " [The] FDA has concluded that an electronic pedigree should accomplish and surpass the goals of PDMA and is potentially a more effective solution to tracing the movement of pharmaceuticals than a paper pedigree." [5] The FDA has identified RFID (radio frequency identification) as the most likely technology to meet the requirements of PDMA. The FDA believes that RFID technology can be implemented for pharmaceutical drugs by 2007. For pharmaceutical drugs, the track and trace requirement will involve

- Assigning serial numbers to individual packages purchased by consumers and
- An information infrastructure of tags and readers.



An EPC RFID tag used for Wal-Mart

## How RFID Works

The Electronic Product Code (EPC) was created as an eventual successor to the bar code (UPC). The aim was to create a low-cost method of tracking goods using RFID technology. The benefits of RFID EPC for pharmaceuticals are:

1. the EPC is larger than the UPC, making it possible to identify each unity of a product with its own EPC.
2. the product can be scanned without an individual products being scanned, generating a savings in labor
3. both the product and the RFID tag can be inside a tamper proof container on a pallet containing many SKUs with their own RFID tags.

As of 2005 the smallest such devices commercially available measured 0.4 mm × 0.4 mm, which is thinner than a sheet of paper; such devices are practically invisible. Passive tags have practical read distances ranging from about 10 mm up to about 6 meters . Because passive tags are cheaper to manufacture and have no battery, the majority of RFID tags in existence are of the passive variety. As of 2004, these tags cost from US$0.40 at high volumes. Universal RFID tagging of individual products will become commercially viable at very large volumes of 10 billion units per year, driving production cost to less than US$0.05 according to one manufacturer[6]

### *What is an EPC?*[7]

A UPC (***U***niversal ***P***roduct ***C***ode) is the sequence of numbers in a U.S.-standard barcode today. An EPC (***E***lectronic ***P***roduct ***C***ode) is a standard for data formats in RFID tags that is meant to replace that for barcodes. For example, an EPC-96 code has four components:

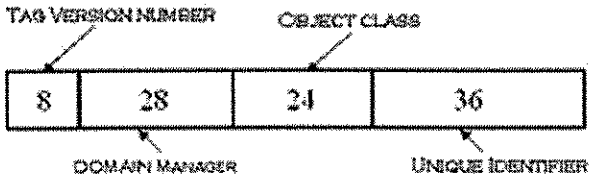
(1) A version number, indicating the tag type (e.g., 96-bit EPC Class 1);

(2) A domain manager, i.e., a number specifying the entity that administers the tag code, e.g., "Acme Products Co".;

(3) An object class, i.e., a number specifying the type of product the RFID tag is attached to, e.g., "Model L rocket "

(4) A unique identifier, a number that, in combination with the other EPC components, uniquely specifies the tag (and object).

The following diagram summarizes the EPC structure. Numbers here are bit lengths for the various EPC components.




96-bit EPC™ structure

In addition, a tag contains two non-readable data elements: A 16-bit checksum (cyclic redundancy code) used to identify transmission errors, and a PIN, used for such operations as "killing," i.e., permanent disablement of the tag for privacy enforcement.

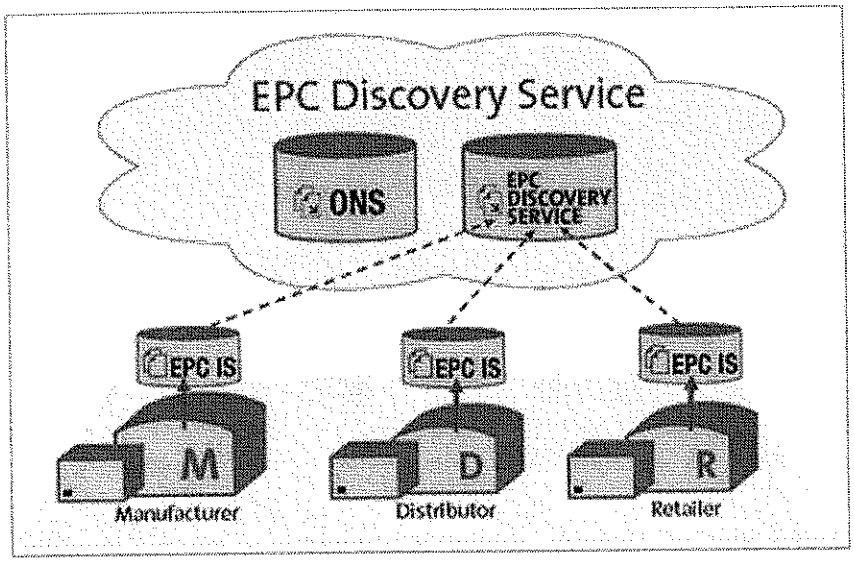
**Tracking and Tracing[8]**

To realize the tracking and tracing potential of RFID and EPC technology, retailers, distributors and manufacturers need access to comprehensive, real time product information. Verisign Corporation has been chosen to host the EPC network for the global exchange of EPC information. The EPC Network is composed of three key elements:

EPC Information Services (EPC-IS)
EPC Discovery Services
Object Name Service (ONS)

When an RFID tag is manufactured with an EPC, the EPC is registered within the ONS. The RFID tag is attached to a product and the EPC becomes a part of that product as it moves through the supply chain. The particular product information is added to the manufacturer's EPC-IS, and the knowledge that this data exists within the manufacturer's EPC-IS is passed to the EPC Discovery Service.

When the product leaves the manufacturer's facility, its departure is automatically registered with the EPC-IS. Likewise, when the product arrives at the next point in the supply chain (e.g., a distributor site) it is automatically read and registered with the distributor's EPC-IS and with the EPC Discovery Service.




When the distributor needs product information, it asks the ONS for the location of the manufacturer's EPC-IS. The root ONS provides the location of the manufacturer's ONS, which in turn provides the location of the manufacturer's EPC-IS. This query process is transparent to the supply chain member and takes only milliseconds to execute. With the manufacturer's EPC-IS location, the distributor's application can request specific product information.

As products progress through the supply chain, they are in constant communication with the EPC-IS. T The ONS is the "glue" that holds the EPC Network together; this service tracks every EPC-IS and EPC Discovery Service. Authorized users have access to complete, up-to-the minute intelligence about any product. The ONS will run on the same infrastructure as the Internet's Domain Name System (DNS), which routes domain names to specific Web servers around the world.

The result is real-time full visibility of the supply chain.

## Drivers of RFID Adoption

Large purchasers of pharmaceutical drugs including the Department of Defense, Walmart, and Target plan to require RFID tags on the pharmaceuticals they purchases. The State of Florida has a pharmaceutical drug pedigree requirement similar to PDMA. There will be significant savings associated with the implementation of RFID for pharmaceuticals, that is, benefits in

- inventory control,
- theft prevention,
- diversion prevention,
- efficiency in recalls, and
- reduction in medication errors.

As the volume of RFID tags increase, the cost of the tags, readers, and the rest of the infrastructure is expected to decrease. The development of interoperable readers that can read both RFID tags and barcodes will simplify the transition from UPC bar codes to RFID codes.

For years, drug manufacturers have sold their drugs to distributors like AmerisourceBergen and Cardinal Health. These wholesalers buy large quantities of drugs in hopes that manufacturers will increase drug prices. Large purchases by the wholesalers help consumers pay less for drugs, but the practice makes it difficult for pharmaceutical companies to forecast demand accurately. The result? Reports that Pfizer and Merck took revenue hits upward of $300 million to reduce their wholesaler inventories in 2003.[9]

The drug distribution market has undergone significant consolidation over the past five years. Currently, three companies, McKesson, Cardinal Health, and AmerisourceBergen distribute 90% of US pharmaceuticals. To avoid disintermediation, these companies must make their services more valuable. An immediate area of innovation is in the handling of controlled substances, which require extra security, and the handling of cold chain drugs, such as some vaccines that need to be stored at temperatures between two and eight degrees Celsius.

FDA Action

The FDA has delayed implementation of the PDMA until December 2006 in order to allow industry to study the feasibility of track and trace with RFID. So far RFID looks like the most feasible way, both economically and technically, to meet the requirements of PDMA. The FDA has indicated a willingness to work with the industry to ease the implementation of RFID by reducing or streamlining its regulations. The expectation is that RFID standards will emerge from the ongoing tests and that the pharmaceutical drug industry is following these studies and will be ready to implement the standards promptly.

Some Technical Problems

- Obtaining 100 % read rates
- Assuring that the RF readers have no affect on the chemical compounds or biological substances in pharmaceutical drugs.
- Assuring that RFID does not violate the privacy rights of individuals.
- Making appropriate arrangements for the ownership, security, and access to the RFID database.

One consequence of the implementation of RFID is the participants in the pharmaceutical drug industry are likely to be unwilling to partner with firms that have not implemented RFID. A similar phenomena happened earlier with EDI technology. Companies refused to partner with companies that could not provide an EDI interface. In the case of EDI, it was relatively easy for a company to obtain access to the technology. RFID demands a significantly higher level of sophistication and probably a higher level of financing.

**Many a Slip Betwixt Cup and Lip**

Implementing RFID EPC tags involves much more than just putting RFID tags on products. Retailers buying the merchandise (Walmart) have performance requirements. Thus it is appropriate to experiment with tag encoding, tag placement, pallet configuration, etc. The manufacturer needs to plan for the RFID scanning configuration at the distributors and retailers. Product can be exposed to humidity, heat, abrasion, etc. in transit. The manufacturer needs to plan his RFID tag placement in the light of the transit environment.

Implementation of RFID EPCs for pharmaceuticals is complicated by the regulation of the pharmaceutical industry by the FDA and other government agencies in the area of product packaging, product labeling, and information privacy. A trial of RFID in the pharmaceutical industry, conducted by Accenture in 2004, led to series of recommendations.

> The project team identified and brought to the attention of EPCglobal and the FDA the need for standards and business practices relating to the use of RFID and EPC technologies that address the unique requirements of the pharmaceutical industry.[10].

A research study by USA Strategies, Inc [11] explains the adoption of the UPC code and uses this information to predict the adoption of the current RIFD/EPC technology. Even though the UPC was first envisioned by Wallace Flint in 1932, the introduction of the UPC we use today took place in 1974. Because of understanding of the hexadecimal code used by UPC, technical issues and economic issues it took fifteen years to become efficient. Because today's business environment is more receptive to new technologies and standardized EPC (Electronic Product Code) already exists they predict it will take 7 to 10 years to see widespread adoption at the unit level.

On the other hand, Zaheerudin Asif, and Minir Mandviwalla [12] suggest that the diffusion of RIFD technology could be compared with the adoption of EDI (Electronic data Interchange) in the automotive industry. They base their reasoning on the assumption that technology users enjoy freedom of choice and that RFID technology should be studied in IS (Information Systems) context. Among other things, it will produced terabytes of data resulting in the need of re-structuring current data management techniques. It will impact the supply chain allowing for information to flow together with the product through the entire chain. [13]

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