

RFID systems for pharmaceutical distributors to meet the new FDA regulations on drugs.

Abstract : The US FDA has decided to implement the “Pedigree provisions” of the Prescription Drugs Marketing Act after December 2006, when the current stay on it expires. There is a lot of concern that many pharma supply chain participants, may not be able to meet this deadline and hence risk non compliance with the provisions of the act. This White Paper attempts to present a solution to ensure timely compliance and get added side benefits in the process.

Background :

The Prescription Drug Marketing Act (PDMA) was signed as a law, as far back as 1998 but a number of amendments introduced later, finalized the pedigree requirements only in 1999. It would have been implemented in that year itself, were it not for several representation received by the FDA from the pharmaceutical industry, essentially requesting them to the act “put on hold” , citing several reasons for this, one of them being “the technology required for this system is unproven and not in place.” The FDA then issued a stay on the implementation not once but for several times since 1999.

Meanwhile the counterfeit & illegal prescription drugs menace continued to grow. In 2004 there were 58 cases filed by the FDA against counterfeiters. If this appears low, consider the fact that in 2001, there were hardly 10. Though the number of cases is lower than for other goods, the implications for public health and safety are enormous.

The FDA patience finally wore thin. Therefore it was decided that they will allow the current stay on this act, to expire in December 2006. This means that by this time, the pharmaceutical business will have to get its act together and implement a “pedigree” system for all prescription drugs in the supply chain. This may not be a big problem for the drug makers, but it could be a really big problem for supply chain intermediaries like distributors, wholesale suppliers and traders, who may not know much about “electronic track and trace” technology, which is necessary for the compliance. This White Paper attempts to explain how this pedigree system can be implemented and how it will be beneficial in the long run to all sections of society— pharma companies as well as intermediaries and ultimately the end users.

Understanding the Pharma Supply Chain

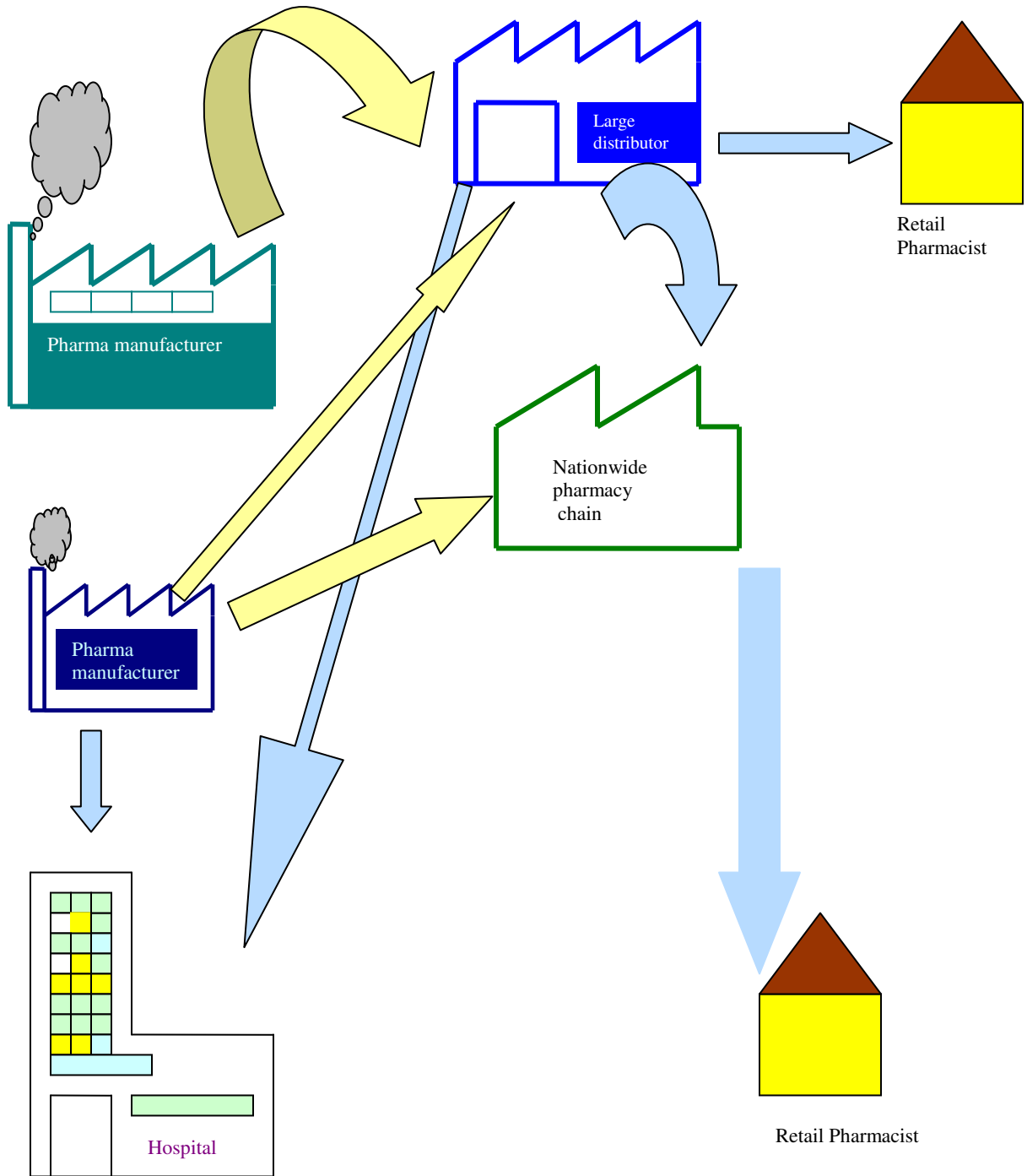
Before attempting to explain the whys and hows of the pedigree system, it will be worthwhile to examine how the pharma supply chain works. The lay reader may assume that it is like any other supply chain, which brings goods from the manufacturers’ factories to the retail shelves, but it is not so. The pharma supply chain is inherently different in its organization. To start with, you have the big pharma companies who manufacture prescription drugs. Then the next stage in this distribution chain are the large wholesalers who buy in bulk quantities. They then supply these drugs at varying prices to big traders, regional distributors, national level pharmacy chains and large retailers like Wal-Mart, as well as to hospitals. Between these entities, there are the large logistics service providers, warehousing companies and transporters who physically ship these drugs. Hence your corner pharmacy may have received its stock through at least two or

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three intermediaries with plenty of stops in between, where the drugs may be handled. Upto now, this is similar to the movement of consumer goods.

This is where the similarity ends. For the pharma business, the pricing for each end user is different. Therefore a typical hospital gets these drugs at lower rates than does a corner pharmacy. There are programs like Medicare and Medicaid where the procurement prices are different than for someone who buys the same drug at a corner pharmacy. The diagram on the following page shows some of the various flows of prescription drugs through the supply chain.

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Problems with the present pharma supply chain.

There are two major problems with the present supply chain model of the pharma business, as it exists today. The first one is not of counterfeiting, but of diversion.

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i) Drug diversions can be of two types. The first one is where cheaper priced drugs meant for Medicare or Medicaid programs, public hospitals or charitable institutions, are diverted to the open market.

The second type of diversion, is where unscrupulous persons sell prescription drugs or “controlled” substances to consumers, without proper prescriptions. The end users are habitual drug abusers. The incidences of diversion may be far more than counterfeiting, but, many of these cases may not come to notice, since the whole system is quite complicated and opaque.

ii) Counterfeits

The second problem in this existing pharma supply chain is of course, counterfeiting. The counterfeiting problem is not of just some dummies or placebos being sold instead of the “real stuff”. The FDA definition of counterfeiting includes the following.

- a) Dummies/ Placebos, which means that there is no active ingredient at all
- b) Products with a lesser quantity of active ingredient than stated
- c) Products with the wrong active ingredient
- d) Products with a packaging that wrongly suggests that it was made by an FDA approved manufacturer

These cases not only cheat the consumer, they may also endanger her health. Last year about 4 billion prescriptions were filled, which shows that a very large number of drugs is moving through the US supply chain every year, with corresponding high risk of counterfeiting or diversion.

The 58 cases filed by the FDA in the year 2004, does not mean that it discovered 58 counterfeit drugs, each case may involve several drugs and various dosages. To give you an idea of the scale of the counterfeiting just one of these cases involves \$42 million of counterfeit Lipitor. Other high value cases include a case involving a \$200 million nationwide drug diversion conspiracy and a \$45 million Medicaid fraud involving diversion of blood products. Other cases include wholesalers and pharmacists illegally importing counterfeit drugs (Viagra and Cialis) from China.

All this gives a perspective of the current problem.

The FDA’s solution to the problem.

The FDA’s vision of a safe and secure supply chain is based on transparency and accountability by all participants in the (prescription drugs) pharma supply chain. Therefore to implement this vision, the FDA wants a drug pedigree scheme which is an electronic “track and trace” system. Each participant in the supply chain would not accept any drugs from any supplier unless assured of its pedigree.

The FDA had nominated a task force to study whether this system could be implemented with the currently available state of the technology. The committee held several hearings from the general public as well as interested parties like the pharma companies and other intermediaries like traders and wholesalers. They received several representations, mostly asking for more time. The committee however recommended that the current stay, which was to expire in December 2006, not be extended. They came to this conclusion after studying the various technologies currently commercially available, which could meet the

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pedigree requirements, including RFID or Radio Frequency Identification technology. Amongst all technologies studied including bar coding, RFID seemed to be the most promising and the committee felt that the pedigree requirement could be met by easily leveraging something that is readily available. Big pharma companies had already implemented RFID in various pilot trials and in some cases, for high value drugs like Viagra, begun implementation of RFID based track and trace technology already. Hence the pharma business already has some experience with RFID implementations. All they have to do is to increase the present scope to include all prescription drugs and all participants in the supply chain.

How the pharma companies can approach this issue

Big pharma seems reluctant to jump into full scale RFID implementations, even with successful pilot projects, because of several reasons, the major one being of cost. The million dollar question is “Who can ensure an ROI on this RFID technology, especially after millions have already been spent?” Even if a full scale RFID implementation were done now, how can it be done fast, before the December 2006 deadline? Is the second question.

To answer the first question, of course implementing RFID in the entire pharma supply chain does provide a very good ROI, but the problem is one of calculating it correctly. Many companies make the mistake of treating an RFID investment as more of a necessary evil, rather than as an investment in an asset. However if one calculates the losses that result to the industry as a whole, then the RFID investment seems reasonable. Counterfeit drugs annually cost pharma companies in the millions, an RFID investment is definitely worth it.

However the current buzz is that no company wants to invest more money in RFID than what is already committed, people are already talking about paper trail based pedigree systems. While a paper record may satisfy the “pedigree” requirement, it will not comply with the “electronic track and trace” mooted by the FDA. Then one hears of bar codes being used, with nobody sure how the whole mixture of paper and bar codes will operate. Rather than resist implementation of RFID based pedigree system, pharma supply chain participants must realistically estimate the costs of investment in the technology, the real cost of counterfeits and the returns on a foolproof RFID based “track and trace” system. An RFID based system will virtually eliminate the counterfeit market at one go. Secondly, it can ensure that drug recalls can be done swiftly without any ambiguity. This has been demonstrated many a times. Thirdly, an RFID based system need not cost too much. Here’s the reason why.

Many pharma companies assume that they will need to not only spend money on tags and on the added labor of affixing them, but also invest in middleware and dedicated web based information systems. It is not only wasteful but also troublesome to the retailers.

For example consider the case of Viagra. To know whether a bottle of Viagra pills is genuine, the pharmacist needs to scan it with a reader and connect to Pfizer’s secure website, where the tag number links to a database which has all the information (when produced, at which location, batch number, date of manufacturing, expiry date, etc) .This

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validates the bottle. But this system has a flaw, in that the pharmacist has to log on to a different system to access information for pills from different manufacturers.

Thus a pharmacist, who has two brands of the same drug in his store, may need to log on to two different web servers and systems (of the two different companies). Imagine what would happen if he were to access something like 20 company sites at once. It would be a nightmare.

An easier solution would be to have one single system, that would encompass all pharma manufacturers and suppliers, so that the pharmacist needs to log on to a common system.

Before you start imagining how much complex it would be, to put such a system together, you should know that there is such a system in place already, for retail consumer products, why not use the same one for pharma too?

What we are referring to here is the EPCglobal system. They currently have a system in place, to issue electronic product codes for retail consumer items, this same system can be used, with some minor changes for the pharma industry. If all pharma companies became a part of the EPCglobal system, then any pharmacist who is interested in knowing the source of his bottle of pills, needs to log on to only one site to confirm this, irrespective of the manufacturer.

This would reduce the cost of implementation for everybody.

How wholesalers and traders can implement track and trace

Ditto for other supply chain intermediaries. They can simply join the same EPCglobal system currently in place and implement the electronic pedigree system easily. The only investment would be in the RFID readers and middleware. Even these can be bought in bulk by their associations at negotiated prices and implemented. This solves the issue of standards too, since all participants would be using similar kinds of readers and software.

Beneficial Side effects of the implementation

In addition to combating counterfeiting and diversion, wholesalers, traders and retailers, get the added benefit of looking into their businesses and track the movement of prescription drugs with full transparency. This will no doubt yield added benefits of inventory optimization, demand forecasting and increasing their knowledge of what is selling and how fast.

Besides, since RFID usage is expected to grow many times the present usage in the years to come, it is better that the pharma businesses implement this right now, in one go rather than delay the inevitable. There is a school of thought which prefers stage wise implementation (which means first paper trail pedigree, then bar codes and then RFID) but going for such a multi stage system will only cost more. Going all ahead and implementing an RFID based system will cause no doubt a bump in capital spending this year, but it will pay back its implementers handsomely in the long run.

Implementation issues

To implement this system fast, before the deadline of December approaches, it is essential to train all stakeholders (pharma company personnel, wholesalers, traders, retailers and others) fast but, at a competitive cost. However, the present cost of

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classroom based training is expensive, besides having other related costs like travel and hotel stay. A better system would be to go for a vendor-neutral e-learning program, which can be deployed immediately and across several locations simultaneously.

See: http://www.bin95.com/BarCode_RFID.htm

This has the effect of bringing up all staff, to a level necessary for them to implement an RFID based pedigree system. The [e-learning program](#) should cover all aspects of the technology including the history, advantages over traditional automatic identification like bar codes, practical RFID systems, standards and middleware as well as other issues like RFID privacy and RFID security. It should ideally also offer a self assessment and a glossary.

We believe, that deploying such a program, across many companies is the only option to effectively train hundreds of people, in a cost-effective manner, so that the actual implementation of the system can be done smoothly. It is essential to bring all people on board, make them understand this technology better and only then talk of implementing it.

Conclusion

RFID track and trace is a technology whose time has come. It not only will meet the FDA requirements for compliance but also prevent counterfeiting (lost opportunity sales of genuine drugs), prevent diversion, optimize pharma supply chains as well as fulfill social responsibilities of the pharma fraternity. Rather than resist this it is in the interest of all pharma supply chain participants, to whole heartedly embrace this technology and improve their bottomlines, in the long run the existing EPCglobal system can be used by the pharma supply chain so that the cost of implementation becomes reasonable as well as manageable. Training large numbers of people in a short time, is not a problem at all since a vendor-neutral, technology and implementation focused e-learning program is now easily available.

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