RFID in the Pharmaceutical Supply Chain: A future prognosis

A Report for BT

HenleyCentre + BT
Working together
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BT has been investing in radio frequency identification technology (RFID) for many years. This started an internal research programme in 1994 focusing on the practical application of the technology both in terms of business benefit and implementation issues. Building upon the research legacy, BT has established a full commercial offering - BT’s auto-ID platform.

BT understands there are significant benefits when utilising RFID technology in support of commercial activities. These encompass, but are not limited to:

- Greater efficiencies within/along the supply chain
- Release of resources, allowing a greater focus on delivered product quality
- Real-time proactive security measures and
- Full authentication of critical and high-value products.

Early RFID adopters have been the retail/FMCG sector, where leading players on both sides of the Atlantic are utilising the RFID technology for “track & trace” purposes. The benefits they are achieving have been made very public - an increase in supply chain visibility, lowering of costs and faster/more efficient fulfilment to the point of purchase.

To date, adoption within the pharmaceutical supply chain has been ‘patchy’. Whilst some drivers have been widely reported - such as the proposed legislation by the Food & Drug Administration within the USA to require the tagging of all pharmaceutical products - much less activity is apparent within Europe, with seemingly less consistent approaches to adoption and utilisation.

BT commissioned this independent research to:

- Understand the issues faced by the pharmaceutical industry
- Provide informed knowledge to the wider healthcare community and
- Ensure future investments meet the needs of the industries supported

… for the benefit of all interested parties.

BT accepts that for companies to adopt this technology - and more importantly to reap the rewards - the compelling benefits have to be better understood and more widely communicated.
According to the media, we are ‘on the verge of an RFID revolution’. However, as yet there is little evidence of this impacting the pharmaceutical industry. Trials have been conducted in tracking drugs along certain supply chains, and RFID has been employed in some hospital applications, but adoption of the technology is by no means ubiquitous within the healthcare industry.

The pharmaceutical supply chain in the UK is complex and fragmented. In some cases, pallets of drugs change hands more than five times between leaving the factory and reaching the patient, crossing national borders more than once along the way. Consumers and providers often turn to secondary distribution channels (the ‘grey market’) to acquire cut-price pharmaceutical products, which has added to the complexity of the supply chain and increased the risk of insertion of counterfeit drugs.

The track-and-trace systems employed at present vary in terms of sophistication and level of adoption. In some cases, members of the same supply chain use different tracking techniques (for example, batch numbering and barcoding), meaning that multiple systems run concurrently for tracking just one drug. There is little consistency in the information required to accompany each drug along the supply chain, or in the methods by which data is stored.

Implementation of a drug pedigree (or ‘mass serialisation’) would considerably reduce the risk of counterfeits entering the pharmaceutical supply chain. It would also control parallel trading (‘grey market’ trading), improve the accuracy of drug administration in hospitals, facilitate more efficient product recalls, improve drug availability and prevent dispensation of out-of-date medicines. These are all benefits that RFID might bring in terms of patient safety.

In addition to these there are supply chain efficiency benefits that could be attained using radio frequency identification. Manufacturers, distributors, wholesalers and retailers would profit - to varying extents - from improved inventory accuracy, reduced paperwork, better visibility, shorter turnaround times, lower labour costs and better stock replenishment. There are also large financial incentives (particularly for manufacturers) in cracking down on drug counterfeiting and parallel trading.

A key message that came out of this study was that the killer application for RFID is different for every party. While supply chain efficiencies make a strong business case for large general retailers, wholesalers and distributors, the case is less obvious for manufacturers, hospitals and small pharmacies, who are more likely to pursue a patient safety or supply chain security business case. Even within the manufacturing industry, there are mixed opinions about where RFID could drive the most value: for manufacturers of high-risk prescription drugs (particularly ‘lifestyle’ drugs such as Viagra), the appeal of RFID lies in anti-counterfeit/brand protection potential, whereas for manufacturers of over-the-counter products such as cough medicines, the attraction is on the supply chain efficiency side. There are ‘push’ factors and ‘pull’ factors driving the adoption of RFID. Wal-Mart in the United States is pushing the technology by issuing a mandate to its

Executive Summary
suppliers enforcing the use of RFID tags on pallets and cases. Similar ‘pushes’ have been seen from retailers around the world, with Tesco in the UK, Metro in Germany and several US chains following in Wal-Mart’s footsteps. Also pushing adoption is the FDA (Food and Drug Administration) in America, which released guidelines in February 2004 on the tracking of drugs in the supply chain. No equivalent European legislation looks imminent, however. Potential ‘Pulls’ for RFID include: multinational pharmaceutical manufacturers (either under mandate from retailers or otherwise), major retail pharmacists and - in the UK - the National Health Service (NHS).

Even with the ‘push’ and ‘pull’ factors at work, there are logistical hurdles to overcome. Firstly, the technology does have limitations: the radio waves can be absorbed by water and reflected by metal - a major issue when considering water-based drugs and foil-coated blister packs. The introduction of a drug pedigree in the pharmaceutical supply chain would also bring about serious database issues. Ownership, control, access, data protection and global standards would have to be born in mind, and the industry would need to think carefully about where to source their RFID solutions. Global standards in data format, spectrum usage, and tag-reader interface would address some of the criteria for a successful roll-out; at present, there are still several different standards in place, despite the extensive work being carried out by international bodies such as AIM (Association for Automatic Identification and Mobility), ISO (International Organization for Standardization) and EPCglobal.

By far and away the most common issue cited by executives from the pharmaceutical supply chain was the cost of RFID tags. Unless it falls dramatically within the next few years, most manufacturers will need to be convinced of the business case for adoption, especially for low value, item-level tagging.

However, the European Commission’s ongoing DRIVE 2 trial has indicated some cost savings associated with RFID compared against barcoding. Other trials have been (and continue to be) conducted and media interest is intense, but full-scale implementation remains to be seen. Most RFID activity is taking place in the United States, largely because of the FDA’s anti-counterfeit guidelines and Wal-Mart’s supplier mandate. Europe will be heavily influenced by what is happening in the US, but is likely to follow a different adoption path.
It is likely that Europe will opt for a two-stage approach, starting with an alternative form of mass serialisation. RFID should not be considered the ‘golden bullet’: barcodes - both standard and 2D - seem most likely to play a part in the migration, and the option of a barcode-RFID hybrid solution should not be ruled out. While this approach may have some cost advantages at the current time, organisations should bear in mind that an open infrastructure would allow easier migration to RFID at some time in the future.

The industry anticipates that RFID ‘will become a reality’ sometime over the next eight years, but is currently locked in a stalemate. Every member of the pharmaceutical supply chain is waiting for something to happen, and no one is willing to make the first move. In order to kick-start the industry into action, some form of ‘trigger’ is required, such as new legislation, a high profile drug counterfeit incident, a breakthrough in the technology employed (reducing the cost of tags) or a mandate from a large organisation such as the NHS.

The key to successful implementation is to have an intelligent back-end network and database to hold the information; RFID tags and readers are simply the facility to enable efficient capture of data.

RFID will most likely be rolled out as a supply chain solution at first, deployed by the multinational pharmaceutical companies and large general retailers. As the new technology proliferates and companies start to reap the rewards, adoption will escalate and mass serialisation will become a feasible prospect for the pharmaceutical industry.
1. Introduction

In June 2004, BT Major Business commissioned a report from Henley Centre about the future role of Radio Frequency Identification (RFID) in the healthcare industry. This investigation was to be set within the broader context of understanding the industry’s requirements in tracking and tracing drugs through the supply chain from manufacturer to patient.

Henley Centre, a strategic futures and marketing consultancy, has sought to provide an objective, realistic assessment of the current state of the industry, and its readiness for RFID adoption. This report does not attempt to make firm predictions for the future, but instead identifies the opportunities for RFID in the pharmaceutical supply chain, and explores different ways in which these may be realised over the next five to ten years.

The findings are based upon new research in the form of thirty in-depth interviews conducted by Henley Centre with key players in the pharmaceutical sector. Those interviewed included representatives from drug manufacturing companies (across a wide range of job functions), pharmacists, retailers, government and regulatory bodies, as well as RFID equipment manufacturers, industry experts and RFID opposition groups. Interviews took place in the US as well as the UK, and consideration was given to the UK’s position within a wider European framework.

In addition, Henley Centre undertook an extensive review of secondary sources, including a critical analysis of previous reports on RFID. Structured brainstorming techniques were then used by the project team to develop scenarios for the future of the pharmaceutical supply chain and the key influences within it.

Acknowledgements
Henley Centre and BT would like to thank all those who agreed to be interviewed for this project for their valuable contribution. While these people were identified as authoritative representatives of their company or organisation with regard to RFID strategy, it should be noted that their statements may not reflect views held elsewhere within the same company or organisation; nor will they take into account any official policies developed subsequently.
2. RFID: what’s it all about?

RFID is one of the most eagerly-anticipated technologies to have emerged during the last twenty years. It has been billed as “the technology of the future” and, according to the media, we are “on the verge of an RFID revolution”.

So what exactly is RFID? A typical definition states that: “RFID (radio frequency identification) is a technology that incorporates the use of electromagnetic or electrostatic coupling in the radio frequency (RF) portion of the electromagnetic spectrum to uniquely identify an object.”

In simpler terms, it is a method of remotely storing and retrieving data from small electronic tags that can be attached to objects. As such, it is a form of Auto-identification (AutoID).

RFID is not actually a new technology. It was first used more than sixty years ago during World War II to distinguish between friendly and enemy aircraft as they flew overhead, and it has been employed ever since in a variety of different ways including tagging of cattle and other livestock, prevention of theft in high street stores, warehouse management, car keys and high-speed motorway toll booths.

However, it is the new application of RFID as a track-and-trace technology which has generated heightened interest in recent years. Tags are placed on products (or batches of products) and monitored from manufacture through to sale or administration. This can bring greater efficiencies to supply chain operations, as well as helping to guarantee the authenticity of drugs, thus guarding against counterfeit goods.

Other track-and-trace technologies currently being used or developed for these purposes (which therefore provide a ‘competitive’ context for RFID) include:

- **Batch numbering** - The simplest form of tracking, used by a minority of companies interviewed. It is generally considered unreliable and vulnerable to human error. The system involves noting down the number printed or embossed on the packaging at each stage of the supply chain.

- **Barcoding** - Currently used at various levels in pharmaceutical (and other) supply chains, mainly to check when batches arrive at each stage. An advantage is that barcodes can be printed directly onto packaging (and hence are cheap to use), but because of this, barcodes are easily forgeable.

- **2D barcoding** - More sophisticated than normal barcodes, capable of holding many times more data, but operating in the same way. Again, these barcodes are printable but easily reproduced.
Similarly, a range of other technologies exist for guaranteeing the authenticity of drugs:

- **Tamper-proof packaging** - A fairly standard packaging technique, sometimes involving holograms, complex packaging designs and unique fonts to reduce risk of counterfeiting.

- **Inert chemical signature** - Compounds are injected directly into the medication. The presence of this chemical signature can be checked with a small handheld device.

- **Drug pedigree** - Currently a paper-based system used to keep track of all drugs manufactured and distributed throughout supply chains. It is not 100% secure.

We will see later in this report that RFID is not necessarily ‘the golden bullet’ for the pharmaceutical industry in terms of track-and-trace methodologies. It represents one option, whose merits can be considered alongside other alternatives or perhaps combined with these in a hybrid form.

So far, take-up of RFID in the pharmaceutical industry has been limited. One of the reasons for this is the perception that RFID is a technology-led development, which is being pushed upon the pharmaceutical industry by the technology suppliers, consultants or other parts of the industry supply chain; the idea that RFID can deliver solutions or direct benefits to the pharmaceutical industry itself is not always sold very persuasively.

“If there was a tailored solution for which you could actually do a return on investment, that could and would save money, then, yes we would be very happy to hear about it. But that’s not how RFID solutions have been put forward to me. They have been presented as this very grandiose thing - scanners, software, record keeping, databases, administration etc.”

**Pfizer**

“The fact that our supplier says, ‘Well, I’ve got this fantastic technology that will tell me exactly why we’ve let you down’, probably doesn’t help me out that much.”

**Moss Pharmacy**

As with any new application, in order for successful adoption to occur, the technology must evolve to suit the needs of the customer - not the other way round. Manufacturers, retailers and other members of the pharmaceutical supply chain do not expect to have to change how they operate to fit within the scope of what RFID can deliver. Adoption should be user-driven, not technology-driven. Trials are now being undertaken both in the USA and Europe to test the technology in the field and to better understand the fit between technology and process.
3. The structure of the supply chain

The pharmaceutical supply chain is highly complex. Retail pharmacists and hospitals purchase the majority of their drugs through pharmacy wholesalers, and source most of their remaining needs directly from the manufacturer. Pharmacy wholesalers obtain a large number of medications directly from pharmaceutical manufacturers, but some from secondary wholesalers or distributors who participate in an alternative distribution channel, often outside the country of origin.

There is very little uniformity, either within or between pharmaceutical supply chains in terms of processes, standards and systems employed.

The executive interviews highlight, among other things, how different one supply chain is from the next. For example, in one case the chain consists of two members only: the manufacturer and the hospital. The supplier uses barcodes to track pallets between the two.

“At the moment our products have a relatively simple barcode on them.”
Eli Lilly & Co.

At the other extreme, another chain consists of five main parties, located in different parts of Europe. In this instance, batch numbers are printed or embossed on the outside of the packaging, and separate manual, paper-based systems are employed at each stage to check that the goods arrive correctly.

“At currently, our products aren’t tracked at all through our supply chain.”
GlaxoSmithKline

“We rely on the batch number, and a one-forward, one-back, kind of daisy chain approach to traceability.”
AstraZeneca

There is great variation in the extent to which technology is adopted within each supply chain. Some companies fully embrace it whilst others employ almost none.

“We’re primarily an SAP company.”
AstraZeneca

“We’re putting in our first EPOS system as we speak”
Moss Pharmacy
4. Benefits of RFID: the theory

There are extensive potential benefits to be obtained from implementing a drug tracking system in the pharmaceutical supply chain. These can be split roughly into two categories:

1. Improving patient safety/service
2. Improving supply chain efficiency/security

**Improving patient safety/service**
The fundamental goal of the medical industry is to provide patient care and safety. The public wants peace of mind - to know that the risks of drug tampering, drug shortages, incorrect medication and inaccurate dosages have been kept to a minimum.

A recent survey by Cap Gemini Ernst & Young found that 65% of the 1,000 consumers questioned in the US felt that better prescription drug security was extremely important, and 61% would buy tagged items to attain that benefit.

The pharmaceutical industry is quick to recognise that patient safety is a fundamental issue.

“As a body, we are primarily concerned - entirely concerned, in fact - with patient safety.”
*Association of British Pharmaceutical Industry (ABPI)*

“We felt that the patient safety, brand protection, the customer-facing side of things was the most important area to develop, and that the logistics, efficiency, cost-savings side of things would come along eventually.”
*AstraZeneca*

There are seven main aspects of patient safety in which RFID could play a part:

- 1. Administration of drugs
- 2. Drug availability
- 3. Improved product recalls
- 4. Use-by dates
- 5. Counterfeit drugs
- 6. Parallel trading

**1. Administration of drugs**
Betsy Lehman died from an overdose during chemotherapy. Will King had the wrong leg amputated. Ben Kolb was eight years old when he died during ‘minor’ surgery due to a drug mix-up. More lives are lost in a given year as a result of medical errors in the United States than from motor vehicle accidents, breast cancer or AIDS.

Patients all around the world expect the four Rs:
- Right drug
- Right patient
- Right dose
- Right time
Yet in the UK, 1,100 people died in hospital from medication errors and adverse effects from drugs in 2000. These kinds of problems are estimated to cost the National Health Service £500 million a year in longer hospital stays.

In the United States, 125,000 deaths are caused each year by medication errors (in hospitals and at home). This equates to a loss of $100 billion. These figures were some of the reasons behind the FDA’s guidelines (see Section 5) on electronic drug tracking. The FDA estimates that the bar-code rule, when fully implemented, will help prevent nearly 500,000 adverse events and transfusion errors over 20 years.

At present there is no equivalent legislation outside the United States. However, the UK’s NHS is committed to the greater use of ‘e-prescribing’, which would help to link the correct drug to its prescription in community-based pharmacies.

2. Drug availability
Pharmacists and hospitals are under constant pressure to deliver safe, effective medication to patients. They are sensitive to the potential impact on patient care, and to the increased costs caused by the difficulty and inability to source products when required. Drug shortages, product substitutions, and secondary distribution channels all pose potential threats to patient safety.

A shortage of critical medication means finding an alternative product source, which adds to the complexity and expense of patient care. Pharmacists and providers face the continual dilemma of whether or not to access medications that are in short supply through secondary or alternative distribution channels, which could lead on to the problems associated with parallel trading (on page 16).

A drug tracking technology (be that RFID, barcodes or some other technology) would streamline the process of getting medication to patients, thereby reducing the risk of drug shortages in hospitals and pharmacies.

3. Improved product recalls
When a pharmaceutical product is found to be defective, contaminated, tampered with or otherwise not safe for consumption (or infringing licensing rules), an immediate recall is necessary. As well as being time-critical and important from a patient safety point of view, recalls are harmful to the manufacturer’s reputation and revenue stream.

In the event of a product recall, suppliers often find it difficult and costly to track down the product. An electronic identification system for drugs would significantly ease and speed up this process, whilst enhancing patient safety.

“We from a product recall point of view it’d be a benefit, in terms of patient safety.”
Eli Lilly & Co.

“I think RFID would certainly give us a more focused approach to recalls.”
AstraZeneca
4. Use-by dates
From a patient safety point of view it is imperative that pharmaceuticals are consumed before they reach their use-by date. Currently the use-by date is printed or embossed on the packaging of the medication. Hospitals and retail pharmacies have no fail-safe mechanism for ensuring that patients do not receive out-of-date medication.

“Out-of-date medicine is currently a huge issue. Medicine expiration dates are hardly dealt with, and when they are, it has to be done visually, with the nurse checking each label.”
RFID equipment manufacturer

RFID tags would carry use-by date as part of the electronic code, thus alerting staff at administration/sale if the product is too old for use. Not only would this improve patient safety but it would cut down on wastage of out-of-date drugs and reduce the highly labour-intensive process of checking expiration dates.

5. Counterfeit drugs
The World Health Organisation (WHO) has been collating information about counterfeiting activities since 1984. Between this time and 1999, the majority of these reports came from developing countries. In recent years the trend has shifted, with nearly half of cases now coming from the developed world. Very few countries are willing to provide information about cases detected, which makes this a difficult issue to investigate.

WHO estimates that 5-8% of worldwide pharmaceuticals trade is counterfeit, and in some countries it could be as much as half. Tests on anti-malarial drugs for sale in Cambodia, Laos, Burma, Thailand and Vietnam showed that up to 33% of contained no active ingredient.

Figure 2. FDA Cases of Drug Counterfeiting in the US
In 2001 the number of counterfeiting cases open in the US leapt from 6 to 20. The Lipitor scare and consequent recall in 2003 illustrates just how vulnerable pharmaceutical companies are to the issue of counterfeited drugs.

Only weeks ago, a batch of counterfeit anti-obesity drug Reductil was recalled in the UK by the MHRA, shortly after fake Cialis capsules (used to treat impotence) were also discovered in the UK supply chain. Prior to this, the last case of counterfeit drugs in the UK had been in 1994. The MHRA, interviewed before the fakes were uncovered, claimed that counterfeiting of pharmaceuticals was not a major problem in the UK.

“The majority of counterfeit medicines found in the UK have been in the illegal supply chain. The last example of a counterfeit product entering the legal supply chain was counterfeit Zantac, approximately 20 years ago.”

MHRA

Despite the MHRA’s downplaying of the issue, some pharmaceutical companies are adamant that counterfeit drugs are a problem in the UK. Those companies which mainly produce high-value prescription drugs (or ‘lifestyle’ drugs) suffer greatly at the hands of counterfeiters. Those which make over-the-counter drugs, however, find it to be less of an issue.

“Counterfeiting is a big issue… We’re very transparent in raising the threat of this, especially with all these middle men who unpack and repack the product.”

Pfizer (80% prescription drugs)

“Counterfeiting is not a major problem for us.”

Wyeth Pharmaceuticals (largely OTC)

“Like any pharmaceutical company, we do suffer some counterfeiting, perhaps not as much as some because we don’t have retrovirals or lifestyle drugs like Viagra to concern us, but we do have some counterfeit going on.”

AstraZeneca

A further problem arises globally with ‘cloned’ products. India and China do not recognise European patent laws and therefore legally manufacture products that are illegal in the UK. The difficulty is that they are licensed products in the country of origin and can be legitimately imported into the UK for personal use but not traded.

In the light of these mixed messages, there is some debate in the industry as to whether drug counterfeiting should be considered a serious problem in Europe. Many governments are reluctant to acknowledge that counterfeiting occurs for fear that patients will be put at risk if concerns over fake drugs prevent them from taking the real product.
The European Commission has taken steps to deter counterfeiting by funding a €4.2 million project called DRIVE (Drug In Virtual Enterprise) with the aim of providing a safer, smarter and more trusted health care system for Europe.

The project, which trialled the use of 2D barcodes at the San Raffaele Hospital, Milan, ran for nine months and involved several pharmaceutical stakeholders from all around Europe including AstraZeneca and GlaxoSmithKline, as well as many research institutions. Its success led to the initiation of DRIVE 2, which will use the same system as applied to the DRIVE project but with RFID tags instead of 2D barcodes.

Preliminary results in March 2004 showed that using RFID at system level was more cost effective than the barcode system, even though the barcodes cost one tenth of the price of the RFID devices. The DRIVE 2 project is ongoing.

In terms of legislation, there has been no indication from European or UK regulators that new anti-counterfeit laws are imminent. It has been suggested that it would take some high profile deaths or serious illnesses to prompt UK legislators to take action.

The issue of counterfeiting should be addressed from a global point of view; it is not applicable to consider just one continent in isolation. Events and regulations in the United States may directly or indirectly affect parallel markets in Europe and the rest of the world.

The FDA guidelines recently issued (See Section 5) are intended to cut down on counterfeiting in the United States and, if successful, then parallel traders will look elsewhere for markets to exploit.

“If the US gets its act together and closes its borders to counterfeiters, then Europe will become an easy target.”
Auto-ID Labs, MIT
Some form of European drug tracking system similar to that enforced by the FDA in the United States might prevent this migration across the Atlantic and potentially a large growth of counterfeit drugs in Europe.

6. Parallel trading
Whilst not directly harmful to patient safety, the use of alternative distribution channels to access cheap medication increases the complexity of the pharmaceutical supply chain, creating more insertion points for counterfeited drugs (leading to the problems described above).

UK regulators are not greatly concerned by any such link between parallel trading and counterfeiting:

“There’s been no evidence of anything getting into the legal supply chain through parallel trading.”

MHRA

As outlined in the above section on counterfeit drugs, the MHRA recalled batches of fake Cialis and Reductil after this interview. This burgeoning crime racket, operated by organised gangs in India, has been putting counterfeit drugs into the official supply chain as well as distributing them by mail order and the internet.

The closure of ‘grey markets’ in the United States might drive parallel traders to other parts of the world (for example, to Europe), exacerbating the issue of counterfeit drugs entering the pharmaceutical supply chain.

Improving supply chain efficiency/security
Within the pharmaceutical industry there are plenty of opportunities to streamline the supply chain, and this is where certain key industry players see the value of RFID to lie.

“The main area where RFID can help us is supply chain efficiency.”

Boots

“GiaoxSmithKline think of RFID purely as infrastructure. It’s up to us to get the value from it.”

GiaoxSmithKline

There are eight main aspects of supply chain efficiency/ security in which RFID could play a part:

1. Improved inventory accuracy
2. Elimination of paperwork
3. Better visibility
4. Track-and-trace in transit
5. Reduced turnaround time
6. Lower labour costs
7. Parallel trading
8. Counterfeiting

1. Improved inventory accuracy
By moving to an electronic, paperless environment, suppliers and wholesalers will apparently be able to attain inventory accuracy of over 99.9% by cutting out human errors. Real-time information would be kept on a database about stock both in warehouse and in transit, and suppliers alerted automatically when stock levels reach critical levels.
2. Elimination of paperwork
Following on from above, the shift towards an automated, electronic tracking system would virtually eliminate paperwork for suppliers, distributors, pharmacists, hospitals and GPs. This will free up time and resources for other more important functions.

3. Better visibility
With up-to-the minute information on where each product is located, it will be possible for suppliers and wholesalers to predict future demand levels more accurately, and plan for fluctuations up the line.

“If you know you’ve got, of that particular line, this amount on your shelf, this amount in your store’s depot, this amount in your main depot and this amount at the manufacturer in crates for you, and if you’ve got all that visibility on a screen in front of you, then the confidence that that will give you in your supply chain is obviously going to be increased.”
Moss Pharmacy

4. Track-and-trace in transit
Liability during transit is a bone of contention between members of supply chains. If products go missing somewhere between the supplier’s warehouse and the distribution centre, who is to blame?

With an accurate drug tracking system in place, it will be impossible for items to ‘go astray’ during transit. This will cut down on shrink.

“We transport high-value low-volume products, so yes occasionally our carriers ‘lose’ things... Shrinkage is one of the main drivers for us.”
Wyeth Pharmaceuticals

This is particularly applicable to distributors, whose entire business is based upon efficient transport of goods.

5. Reduced turnaround time
In Marks and Spencer’s trial of RFID tags, the average truck unloading time went down from 23 minutes to 3 (still with almost 100% accuracy)\( \text{XIV} \), as there was no need to scan individual barcodes. This is a significant time saving, particularly when extrapolated across the whole pharmaceutical supply chain.

This burgeoning crime racket, operated by organised gangs in India, has been putting counterfeit drugs into the official supply chain as well as distributing them by mail order and the internet.
6. Improved stock replenishment
Retailers will attain value from RFID on two accounts. As well as being able to streamline their point of sale process with the use of tagged products and hence improve the speed and quality of customer service, they will benefit from the improved accuracy that RFID will bring over the barcode or manual system that they currently employ. Because retailers will know exactly which goods have passed through their doors, their stock replenishment will be more accurate, which will ensure that a full set of goods is on the shelves at all time.

7. Lower labour costs
Because of the automation at each stage of the supply chain, significant savings can be achieved through reduced labour requirements. In warehouses, there is no need for manual checking or counting of goods. Along the way, there are no delays while products are scanned, ticked off or signed for. In stores and hospitals, drugs continue to be tracked electronically up to the point of sale or administering, with far less need for manual intervention.

8. Parallel trading
The effects of parallel trading on supply chain security do not only pose a potential problem for patient safety; there are also financial costs for manufacturers which are associated with failure to secure the supply chain. Those manufacturers affected therefore tend to believe that parallel trading should be stamped on by the regulators.

“Sometimes 50% of our products are exported to another country then come back to the UK.”
Bayer Pharmaceuticals

“Diversion is a problem; 60% of our drugs sold in the UK are diverted.”
GlaxoSmithKline

The parallel trading of bona fide pharmaceuticals into Britain from Europe has been calculated to cost the UK industry more than £770 million a year. The net effect on the UK economy as a whole, taking into account the benefit to consumers of lower pharmaceutical prices, may be a loss of more than £290 million.”

Another estimate from the Association of British Pharmaceutical Industry (ABPI) claims that parallel trading costs UK companies £1.4 billion a year and threatens their ability to re-invest in R&D. The parallel traders dispute these figures, arguing that they save healthcare systems money - around £100 million per year in the case of the UK’s NHS”.

IMS Health, a pharmaceutical consultancy, has estimated that parallel traded medicines account for 20% by value of all medicines dispensed within the branded market “.

Outside the UK, parallel trading represents equally big business. Legal arbitrage is thought to be worth $12 billion a year in Europe. IMS Health estimates that parallel trading along the Canadian-US border was worth $1.1 billion in 2003, up 70% in a single year. After taking into account drugs coming up from Mexico and from North America’s free-trade zones, drug arbitrage in the US is believed to total $15 billion”.
It is difficult to put a value on this parallel trading business, since much of it takes place behind closed doors. Very few traders and wholesaler are prepared to talk about it on the record. But it is clear from the data available that the business of parallel trading is huge, and it is constantly growing.

“The NHS is going to find ways to buy drugs that are cheaper, so parallel trading will become more of a problem.”

Eli Lilly & Co.

9. Counterfeiting
Whilst counterfeiting is mainly an issue of patient safety, it also has an impact in terms of protecting the brand and corporate reputation. Pfizer is currently filing lawsuits against the operators of eighteen internet websites for selling unapproved and illegal copies of its cholesterol reducing medicine, Lipitor. The drug is patent-protected and no generic versions are legally available in the United States. According to Pfizer, tests performed on tablets obtained from two of the suppliers showed that they contained no active ingredient.

“Counterfeiting is a big issue more in terms of reputation than cost.”

Pfizer

The ‘Killer Application’
The ‘killer application’ for RFID is different for every party. While supply chain efficiencies make a strong business case for large general retailers, wholesalers and distributors, the case is less obvious for manufacturers, hospitals and small pharmacies, who are more likely to pursue a patient safety or supply chain security business case.

Push and Pull influences
In a ‘push’ market, adoption of technology is imposed or incentivised by authorities, regulators or providers. In a ‘pull’ market, adoption is driven by demand from (end) users. The distinction is sometimes subtle: for example, the NHS could create a stronger ‘pull’ for RFID as a customer of the pharmaceutical manufacturers and as a point of patient interface; if, however, the NHS or its government overseers issued a mandate for pharmaceutical suppliers to use RFID, this could be considered a ‘push’ factor.

The next section explores these different drivers more thoroughly.
5. The ‘Push’ factors

Retailers

Wal-Mart, US

Wal-Mart is the largest and most influential retailer in the world. In 2003 it announced that it wanted its top 100 suppliers (including those of the most tightly controlled prescription drugs) to use RFID tags on all shipments by the end of March 2004. By November 2003, 32 further suppliers asked to participate in the scheme, eager to be pacesetters in the new technology.

The March 2004 deadline failed to be met, and had to be revised to June 2004. The main hurdle for suppliers was the cost of tags. Wal-Mart has again extended its deadline, and is now making adoption compulsory by January 2005 for the top 100 suppliers (and by January 2006 for the rest). The intention is for all Wal-Mart suppliers to tag pallets and cases by 2007, with the end goal of a ‘no checkout’ scenario (i.e. where customers simply wheel shopping carts through barriers and purchase is carried out automatically) sometime in the next fifteen years.

Forrester Research estimates that fewer than 25% of suppliers will meet the retailer’s January 2005 deadline. Many analysts do not expect a full-scale rollout of radio tagging at Wal-Mart until well after 2005. However, Sanford C Bernstein & Co, a New York investment research house, estimates that Wal-Mart could save nearly $8.4 billion per year when RFID is fully deployed throughout its supply chain and in stores.

Although the Wal-Mart timeline has always been ambitious, there is no doubt that suppliers are making an effort to comply. Wal-Mart has tremendous influence in the United States.

Figure 3. Wal-Mart’s timeline for RFID adoption

2003
Announcement: top 100 suppliers to use RFID tags on all shipments by end March 2004

Further 32 suppliers willingly participate in scheme

March deadline not met, revised to June ’04

New FDA guidelines issued

2004
Case level barcoding Compulsory for top suppliers

2005
Case level barcoding Compulsory for all other suppliers

2006
2007
2008
The reaction to Wal-Mart’s mandate by the pharmaceutical industry is mixed, as suppliers are affected to varying extents.

“In comparison to companies like Pfizer and J&J, who have very large consumer product businesses and so are impacted by Wal-Mart, we don’t have any consumer products; we are purely ethical pharma, so we don’t expect to be impacted ‘til later than those guys. So you’ll find that they’re much more bullish, because they’re involved in it; they have to be, whereas we have the kind of privilege of being able to wait and see what happens in this space.”

AstraZeneca

Other retailers around the world are following in Wal-Mart’s footsteps, but because of their weaker global presence they have less influence over their suppliers than Wal-Mart.

Albertsons, Idaho
The US’s second largest food and drug retailer, Albertsons, launched its first RFID pilot in March 2004 and announced that it will require its top 100 suppliers to tag pallets and cases by April 2005.

Target Stores, Minneapolis
The fourth largest retailer in the United States, Target Stores, announced in February 2004 that its top suppliers will be required to apply RFID tags on pallets and cases sent to ‘select’ regional distribution facilities beginning late spring 2005. The company wants all suppliers to comply by the spring of 2007.

Metro Group, Germany
Germany’s supermarket chain Metro announced in 2003 that it wanted its top 100 suppliers to begin attaching RFID tags to pallets headed for the company’s 10 central distribution warehouses and 50 of its stores by November 2004. It is working with IBM and SAP to deploy RFID tags throughout its entire supply chain.

Tesco
In November 2003, Tesco, the UK’s largest retailer announced that it would put RFID tags on cases of non-food items at its distribution centres and track them through to stores in the UK. Its suppliers were expected to conduct their own RFID research, some of them tagging pallets and cases by September 2004.

Tesco has been using RFID to track trays and cases moving from one of its distribution centres to two of its UK stores, and claims that the trial is proving a success. It is, however, keeping quiet about its progress on enforcing the technology on its suppliers.
Tesco has joined with Carrefour (France), Metro Group (Germany) and Intel to form a European working group called EPC Retail Users Group, to accelerate the adoption of the technology.

**Asda**

Work is still underway to bring Asda’s ERP, EPOS and EFTPOS systems in line with those of Wal-Mart, following the acquisition by the American chain in 1999. This is one reason why research into new technologies such as RFID has been limited at ASDA over the last four years.

Many other smaller retailers are jumping on the radio frequency bandwagon, demanding that suppliers adopt the technology over the next 3 - 5 years. According to a study carried out by Deloitte, the ePC Group and the Retail Systems Alert Group, 28% of US and European companies with $5 billion or more in revenue will spend more than $500,000 this year on RFID.

“Most companies plan to spend less than $500k, but looking at large companies, we see some are spending up to $10 million this year, but that’s not a surprise, as they were caught out by the retailer mandates) and have to move quickly to meet them).”

Deloitte

The retailer mandates will drive up tag volumes, thereby helping to reduce costs, and also helping to lower the barriers to adoption.

**Legislation**

**The FDA’s guidelines**

In July 2003, the Food and Drug Administration (FDA) in the United States formed the Anti-Counterfeit Task Force as part of its initiative to curb fraud in the pharmaceutical industry. In February 2004 this task force brought out ‘guidelines’, stipulating that most prescription and some over-the-counter drugs should carry “bar codes or an encoded computer chip” to help
wholesalers and retailers confirm their authenticity. The FDA expects that in 2005, manufacturers will begin applying RFID chips to pallets, cases and packages of the pharmaceuticals most likely to be counterfeited, and that wholesalers, chain drug stores, and some hospitals will begin equipping themselves with RFID technology. An FDA timeline calls for these actions to be extended in 2006 to more products and for more pharmacists and hospitals to have a full RFID tracking system in place by 2007.

**Europe**

There is no European equivalent to the FDA in Europe or the UK, and no such legislation in place to monitor the movement of drugs. This is one of the reasons that adoption of RFID is less prolific in Europe than it is in the United States.

An investigation commissioned by the British government in 2003 entitled Safety, Quality, Efficacy: Regulating Medicines in the UK found that the Medicines Control Agency (now part of the MHRA) was not doing enough to ensure patient safety.

“The role of the MCA is not well understood by the wider public, and even many health professionals. This contrasts with the United States FDA, which maintains a high profile and targets safety information directly to consumers and patients.”

In the UK, the newly-formed MHRA (Medicines and Healthcare products Regulatory Agency) is responsible for regulating the safety, quality and effectiveness of medicine. The Department of Health said the new agency was now stepping up its efforts to inform patients and doctors about the risks of medication errors.

“There are a number of initiatives that MHRA already has in place to develop and improve all aspects of medicine safety, along with its work in Europe... Work is in hand to improve patient information leaflets and labels of medicines.”

Department of Health

The MHRA in the UK takes a different stance to the FDA in the States. Its view is that some good work is being carried out, particularly by the Anti-counterfeit task force within the FDA, but that RFID is not necessarily a feasible solution. No legislation equivalent to the FDA’s looks imminent in the UK.
“In the States, obviously they spent the best part of half a year with a counterfeit task force producing that report. There are some very good points in there and various things that need addressing. RFID is potentially a good recommendation, because if it delivers everything it’s supposed to. The potential in terms of track-and-trace would be huge, but in terms of set-up, practicability, etc., how deliverable that is remains to be seen.”

MHRA

As discussed in Section 4 (Parallel trading as a commercial issue), the tightening of US drug laws may lead to displacement of existing parallel markets and an influx of counterfeit medicines to Europe, particularly with the large variations in drug prices that exist between different parts of the EU. Some industry experts believe there is more urgency to act in Europe, though less is being done by the regulators.

The FDA’s guidelines will also affect drugs manufactured in Europe that are exported to the US. European suppliers will have to use tags on their pharmaceutical products, which may accelerate the take-up of RFID.

There are other European directives that may have an influence on RFID adoption:

- Italy has passed one of the strictest laws in Europe regarding drug pedigrees. With EU financial backing, the government in 2000 implemented mass serialisation throughout its pharmaceutical supply chain, through the Bollini Law. This requires unique serial numbers or barcodes to be attached to each unit of sale, and for all parties to record and archive each serial number. This has created enormous database issues for the government, in that existing infrastructure is unable to cope with the huge volume of data.

- In the EU, legislation is coming into force in January 2005 that will enforce food traceability through the supply chain. This will become a legal responsibility of manufacturers, and under the new laws, food producers must be able to identify products by batch, lot or consignment numbers. No pharmaceutical equivalent is imminent.
6. The ‘Pull’ factors

The potential benefits of RFID set out in Section 4 above can be considered as the main ‘pull’ factors which will encourage the pharmaceutical industry to fast-track adoption of track-and-trace technologies.

The persuasiveness of these drivers can be measured in part by progress up the RFID adoption curve.

**Pharmaceutical manufacturers**

RFID is still at an early stage on the adoption curve, at least within the pharmaceutical supply chain.

**Figure 5. The technology adoption curve**

The process of identifying suitable interview candidates from various parts of the pharmaceutical supply chain was revealing in itself. Responsibility for ‘looking into RFID’ cuts across many different areas of the companies we contacted. Most companies simply have one or two people responsible for keeping abreast of new developments in the technology, and they could be located in various departments, including Manufacturing, Trade, Supply Chain, Business Support, Commercial Development, Regulatory and Retail.

Within the industry there is great variation in the level of understanding of this subject.

“We’re at the starting point of our knowledge of RFID. But we can’t put our heads in the sand on this one.”

**Bayer Pharmaceuticals**

Most people interviewed during the course of this project had at least a superficial awareness of what RFID could do, gleaned either from the media or from what was happening inside their own firm, often in the United States. RFID was on their radar, albeit sometimes on the periphery. Some had attended RFID conferences, some had conducted research of their own and a few had been approached by RFID technology providers or strategic consultants. On the manufacturing side, only a small number of companies (all of them multinationals) were thoroughly well-informed, having participated in studies or trials.

“We’re trying to be at the forefront of what’s going on. We’re members of EPCglobal, we’re founder members of the EPCglobal Healthcare Action Group... we believe that anything in this industry needs to be developed as a consortium rather than as an individual company solution.”

**AstraZeneca**
Coming from America
Some multinationals (e.g., Pfizer, Eli Lilly & Co.) manufacture locally, which means there is no need to transport drugs across the Atlantic. If they implement RFID tagging in the States, their European counterparts are not necessarily affected. GlaxoSmithKline, however, maintains that 90% of its US drugs are shipped across from Europe, so rollout of any drug tracking system would have to be done on a global scale.

In the cases of Wyeth Pharmaceuticals, Eli Lilly & Co. and GlaxoSmithKline, the research and development on RFID tagging is happening in the States.

“To be honest, most of this work would have happened over in the States; being a US company, our UK side is really about manufacturing and research.”
Eli Lilly & Co.

“We’re aware of some projects they’re doing over in the US for Wal-Mart, but we don’t really know the details.”
Wyeth Pharmaceuticals

The UK Retail Pharmacists
The major players
The retail pharmacy market in the UK is restricted in size by government legislation, which controls the location and number of dispensing outlets across the country. Due to the limited availability of NHS dispensing licences, the number of retail chemists in the UK has remained almost static for the last 17 years, and chains have only been able to expand through the acquisition of existing outlets. This has led to consolidation of the UK market, where there now exist just three key players:

- Boots the Chemists
- Lloyds Pharmacy
- Moss Pharmacy

Almost half of retail outlets are owned by Lloyds and Moss Pharmacy, which in turn are owned by European wholesalers AAH and Alliance Unichem.

Following the abolition of the resale price maintenance (RPM) on over-the-counter pharmaceuticals in 2001, supermarkets have been able to offer increasingly competitive prices on these products, and in 2003 further changes were made to the legislation, extending the availability of NHS prescription contracts to non-pharmacy outlets. In-store pharmacies have proliferated, competing with chemists on prescription drugs as well as OTC products. There are four key multiples in the UK:

- Tesco
- Sainsbury
- ASDA (now owned by Wal-Mart)
- Safeway (now owned by Morrisons)
New pharmacy legislation
Recent changes to UK legislation have made it easier for one-stop primary care centres and shopping-centre pharmacies to obtain a licence to sell prescription drugs. This is in addition to over-the-counter products they are already able to offer.

The government has also given the go-ahead to internet-only pharmacies, which will further open up the competition in the retail pharmacy industry. Many claim that the new legislation will further increase the risk of counterfeits entering the supply chain - potentially reducing consumer confidence in the UK pharmaceutical industry.

It may be that increasing the number of internet-only pharmacies may push the drug counterfeiting debate up the public agenda, triggering a review of the existing controls on the pharmaceutical supply chain and possibly prompting further changes to the legislation (in line with the FDA’s guidelines in the States).

Progress of track-and-trace technology
The interviews with the major retail pharmacies brought out some interesting findings with regard to the ‘pull’ factors which are most influential in determining their current state of progress with RFID or other track-and-trace technologies.

The large multiples such as Tesco, Safeway and ASDA are all fully equipped with the latest EPOS (electronic point of sale) software, EFTPOS (electronic funds transfer) systems and electronic scanners, and have highly efficient, semi-automated distribution/stocking systems that help streamline their operations. These multiples are seen as the champions of new technologies such as RFID.

Boots the Chemist also employs EPOS software and uses a fair amount of technology both in-store and along the supply chain to improve efficiency.

“We’re on legacy ERP systems at the moment, and those systems already contain the means to track-and-trace.”

Boots maintains a good level of awareness of RFID, having conducted a trial 6 years ago. The trial was aborted when Boots decided that the technology was ‘not up to scratch’.

“Now, we’re working with a number of pharmaceuticals; we’re checking out what other people are doing, what the technology can do and we’re developing our own agenda.”

Boots
Moss Pharmacy, however, is still in the process of implementing its first EPOS system. Following the acquisition by Unichem in 1991, the company has evolved and grown such that EPOS has ‘become a necessity’. However, it believes that it would be too difficult to introduce another new technology (such as RFID) whilst it struggles to cope with EPOS.

Lloyds is also less involved, having explored the potential of several ‘new technologies’ last year but decided not to progress them any further for the time being.

There are varying degrees of scepticism among retail pharmacy chains about whether RFID is realistic. They recognise that there could be benefits to them, but they do not all share the bullish attitude of Tesco or Wal-Mart in the States.

“The main area where RFID can help us is supply chain efficiency. It’s about: can I actually make some of these processes possible, without involving so many operating people to deliver them?... However, there’s an awful lot of things you see being done at the moment with RFID that could actually be done using barcodes.”

Boots

Lloyds believes the main benefit of RFID to be security throughout the supply chain, but also sees applications in stock management, product recalls and on-shelf pricing. Although Lloyds is not actively pursuing an RFID programme at present, it sees implementation within the pharmaceutical market as “likely or inevitable” some time in the next few years.

The attitude at Moss Pharmacy, however, is that there are very few benefits to be gained from RFID, and that it is “a technology, not a solution”.

“At the moment, it looks like one of those things where somebody’s got some technology and they’re desperately trying to convince the marketplace that it is what the marketplace needs, and the marketplace is going, ‘mmm, looks very nice, but I’m not sure’... It reminds me of ten years ago, when people in the industry were first starting to talk about category management. It seemed like a trendy thing to do and everybody was looking into it, and then a lot of them died away and it never really happened.”

Moss Pharmacy

However, going against the grain of the usual retailer-to-manufacturer chain of influence, Moss believes that the pharmaceutical companies may exert a ‘push’ influence on retailers’ adoption of RFID.

“We’re expecting our suppliers to start banging on our door saying ‘we’re rolling out RFID’.”

Moss Pharmacy
The NHS

The NHS is increasingly aware of the need for a drug tracking technology, but is likely to opt for a barcode approach instead of RFID, at least initially.

Within the government’s £6 billion National Programme for IT (NPfIT) in the NHS, mass serialisation has been raised as an important issue. Barcoding already plays an important part in the UK National Health Service (for example in blood transfusions, drug labelling and administration), and is therefore considered the obvious choice.

RFID is complex, costly and a relatively new technology, so it is not seen as the number one choice with which to roll out mass serialisation - at this stage. However, this does not rule out RFID’s use at a later date, and studies are currently underway to investigate how it could play a part in the future of the NHS.

A white paper was recently published by UK healthcare research house Wireless Healthcare entitled ‘Wireless eHealth and the NpfIT’. According to this, the applications that make up the National Programme for IT, while regarded as revolutionary by the NHS, will merely provide the level of automation most large commercial organisations have been enjoying for almost a decade.

The report points out that, as new IT systems are rolled out and pressure builds for the NHS to use IT to cut costs, the NPfIT will encounter resistance from NHS staff. Technology such as RFID tagging of patients, blood plasma packs and medicine bottles (that reduce medical errors) should in theory be welcomed by medical staff, probably won’t be in reality, if used to identify the members of staff who are responsible for mistakes. The paper advises that, to avoid such retaliation, vendors should partner with companies who have experience of change management within the healthcare sector.

Bringing about change, however small, within such a large organisation (and particularly one as complex as the National Health Service) is slow and laborious. It has become apparent from research and from the executive interviews conducted that the various parts of the NHS do not always communicate effectively with one another, and that implementation of new strategies is a slow process.

“(The NHS) is starting to understand how IT can increase efficiency. It is becoming an integral part of strategies... If the chief executive of one of the biggest organisations in the world says more IT is needed it is good news for suppliers that provide both systems and services.”

National Programme for IT
Other applications

A joint venture between MIT scientists and Harvard medics at the Massachusetts General Hospital was launched in 2000 to find how RFID could help in surgery. The Operating Room of the Future (ORF) initiative involved the tagging of staff, patients and medical equipment in an attempt to speed up and streamline workflow.

RFID is also employed in other hospital applications, for example tracking of consumables, uniforms and apparatus outside the operating theatre.

The MD Anderson Cancer Center in Houston is tagging drugs from wholesaler through to administration, and is looking to implement RFID on a wider scale if trials are successful.

“We’re looking at RFID for inventory control after internal thefts of Procrit and Neupogen. But if you can do it for inventory management, you can do it for billing, for security, for matching dose and patient, or any other purpose. Preventing counterfeiting could be the factor that accelerates interest in RFID.”

Managing Director, Anderson Cancer Center

Several other hospitals around the world are using RFID as a track-and-trace technology. The Georgetown University Hospital in Washington DC is conducting trials to track blood products from donor to patient.
7. The logistical issues

While there are many research papers, media articles and conference presentations which speak in broad terms about RFID, very few actually manage to ‘go down to the next level of detail’ in understanding how it can be implemented and which logistical issues may impede its progress.

“There’s mass serialization, there are tags and readers, and then there’s this entire back-end network, which actually links the physical object to the information about the object, which is essentially where the EPC Network derives a lot of value.”

Auto-ID Labs, MIT

**Database issues**

Even with case- or pallet-level tracking throughout the pharmaceutical supply chain, a significant amount of data would accumulate as the tags pass through the readers. The issues around who stores this data, how they store it and what they do with it are very important.

“Where’s the data kept? What if it’s leaked?”

Auto-ID, Cambridge

Of course, with full-scale mass serialisation (i.e. product-level tagging) these problems would be accentuated.

**Industry standards**

Whether the industry adopts 128-bit product codes or 256-bit codes, whether it broadcasts at 867MHz or 915MHz and whether it uses a standard tag-reader interface are all matters to be addressed ahead of global roll-out. Because of the different radio spectrum restrictions around the world, the task of developing standards that suit all parties is a difficult one.

Much work is being carried out by international standards bodies such as AIM (Association for Automatic Identification and Mobility), ISO (International Organization for Standardization) and EPCglobal, the member-driven organisation whose role is to come up with industry standards for the Electronic Product Code, to support the use of RFID in trading networks. Because of the limited adoption of RFID, these standards have not so far come into play to any great extent.

“A standard only becomes a standard unless people use it. We recognise that, and we hope that as we’ve got the backing of EAN International and also some of the major retail players within the global supply chain community, and we hope that EPCglobal will become the standard.”

EPCglobal Consultant, e.centre (UK branch of EPCglobal)
More development is needed before they become as coherent and widespread as, for example, barcoding standards.

**Technical issues**
The radio waves used by RFID tags (Ultra High Frequency) are absorbed by water and reflected by metal. This is an issue for applications such as metal packaging or water-based products, both of which feature in the pharmaceutical industry. Readers also have problems dealing with thousands of tags in close proximity, which would be a problem when trying to implement drug tracking at item-level.

**Cost**
Extensive cost/benefit analysis has been carried out by various consultancies and industry players on radio frequency identification. Some findings from this analysis are as follows.

- **Forrester Research** found that tags currently make up more than 80% of a supplier’s cost. Based on today’s tag production processes and projected volumes, it seems unlikely that tag costs will drop any lower than $0.40, so suppliers should not build a near-term business case on the much-touted ‘5 cent tag’. Suppliers may actually have to add staff to their payroll when implementing RFID - at least in the beginning - because “vendors have yet to perfect solutions for automating tagging and embedding RFID in packaging material.”

- **LogicaCMG**, however, calculated that the average handling cost per pallet could be decreased by 8.5% with the introduction of RFID (assuming a tag cost of €0.50), which would lead to a return on investment within 2 - 3 years.

- **Soreon**, the independent German research house, believes that retailers can expect a return on investment of up to 187% within a year by using RFID, while suppliers will only recoup 37% of their investment within three years.

- **AT Kearney** looked at a low impact grocery manufacturer with $5bn turnover. The conclusion was a loss of $155m (assuming a tag cost of $0.15) over 10 years.

**Figure 6. RFID tag costs are expected to fall as sales rise**

<table>
<thead>
<tr>
<th>RFID tag and reader cost projected over time</th>
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</thead>
<tbody>
<tr>
<td>Purchase curve</td>
</tr>
<tr>
<td>2002</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Tag sales, mill. units</td>
</tr>
<tr>
<td>Tag price, high volumes</td>
</tr>
<tr>
<td>Reader sales mill units</td>
</tr>
<tr>
<td>Reader hw. price</td>
</tr>
</tbody>
</table>
According to AMR research completed in September 2002, the cost of tags will fall significantly as volumes rise.

• RFID tags can in fact be manufactured for the predicted $0.15, if made in large enough volumes. However, one alternative technology provider maintains that tags of the current design will never be priced below 15 cents because of the costly use of silver or aluminium to form the antennae on the tags.

ARC Advisory Group, a research firm based in Massachusetts, America, claims that the average price of a passive RFID tag will drop to only 16 cents by 2008.

The assumptions made and the conclusions drawn from the various cost/benefit analyses are mixed; there is no consensus on the likely future cost of tags, and no overall feeling as to whether RFID will bring a positive return on investment. The only certainty is that more research is required over the next few years.

Opposition Groups
Some consumer groups feel that tagging products through to point of sale (and beyond) would represent an invasion of people’s privacy. A US group called CASPIAN (Consumers Against Supermarket Privacy Invasion and Numbering) has been particularly outspoken in its opposition to RFID.

The Auto-ID Center in the States has worked with privacy groups since inception in 1999 and, in response to their suggestions, the centre has added a ‘kill switch’ to its microchip specifications, so that certain tags can be permanently disabled at a consumer’s request.

While these consumer groups do not always enjoy the highest levels of public support or credibility, there is always the potential for this issue to flare up within the media or a more mainstream audience in the context of growing concerns about ‘the surveillance society’.
8. The adoption path

The technologies hype cycle

The media coverage, hype and confusion surrounding radio frequency tagging are typical features of a technology in its infancy. Broadly speaking, there are five distinct stages in the emergence of a new technology.

Firstly, there is the ‘technology trigger’, when the product or system is launched into the marketplace. In the case of RFID, this was more of a gradual event than a single ‘trigger’. The technology was initially introduced over sixty years ago, and has since evolved to fit new applications, one of them being track-and-trace in the pharmaceutical supply chain.

Secondly, there is the flurry of media attention that occurs when the innovators and technology providers push the new concept into the spotlight, forcing the issue higher on the public or industry agenda. This is known as the ‘peak of inflated expectations’, and RFID would appear to sit at the top of this crest at the present time.

Following this spike of interest, it is usual for visibility to drop once again as the consumer (or in this case, the industry) becomes aware of the technology’s shortcomings and the media reduce coverage of the topic. This is known as the ‘trough of disillusionment’, and it is at this point that RFID technology providers need to be on their guard; a pragmatic approach will be sought by the industry. It is possible that RFID is heading for this ‘trough’ as retailers and manufacturers begin to explore their options and to realise the logistical obstacles they must negotiate in implementing RFID.
After a period of experimentation and industry trials (known as the ‘slope of enlightenment’), barriers are overcome and interest levels rise again. In the case of RFID, software and middleware solutions will be developed to help each member of the pharmaceutical supply chain to realise maximum benefits from the technology.

Finally, as the benefits are proved and accepted, adoption plateaus at some pre-determined level. The height of this plateau depends on whether the technology is broadly applicable or only benefits a niche market. It remains to be seen how widespread adoption of RFID will be.

**Barcoding as an intermediate technology**

It is fair to assume that radio frequency identification will not take effect overnight. Implementation will most likely occur gradually over the next few years, with the most likely adoption path being a two-stage process involving barcode technology running alongside RFID. Many of the benefits brought about by RFID can already be attained using barcodes:

- In retail, barcodes are employed throughout the supply chain up to the point of sale, with the data then being fed back into the ERP (enterprise and resource planning) system to help with stock control.

- Some suppliers and distributors use barcodes on pallets and boxes in their warehouses.

- In hospitals, barcodes are employed in supply chain management, inventory tracking, blood transfusion verification and asset management. However, many point-of-care applications such as administration and remote patient monitoring have had lower adoption levels to date:

<table>
<thead>
<tr>
<th>Application</th>
<th>Adoption</th>
<th>Patient safety focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply chain</td>
<td>Med</td>
<td>•</td>
</tr>
<tr>
<td>Positive patient ID*</td>
<td>Low</td>
<td>*****</td>
</tr>
<tr>
<td>Medication administration*</td>
<td>Low</td>
<td>*****</td>
</tr>
<tr>
<td>Specimen collection*</td>
<td>Low</td>
<td>*****</td>
</tr>
<tr>
<td>Blood transfusion verification</td>
<td>High</td>
<td>*****</td>
</tr>
<tr>
<td>Document management</td>
<td>Med</td>
<td>•</td>
</tr>
<tr>
<td>Remote patient monitoring*</td>
<td>Low</td>
<td>****</td>
</tr>
<tr>
<td>Dietary/food service</td>
<td>Med</td>
<td>•</td>
</tr>
<tr>
<td>Asset management</td>
<td>Med</td>
<td>•</td>
</tr>
</tbody>
</table>

*High value, low adoption

Many experts believe that barcodes still have a long way to go before ‘extinction’.

“(RFID) is unlikely to replace the barcode for a long time. Both these technologies will co-exist.”

Auto-ID Center, MIT

“Barcodes will remain the primary means of automatic data capture because they are a ubiquitous, inexpensive technology. It will be several years - perhaps decades - before barcodes are eliminated in the supply chain… Many organizations that need to comply with the Wal-Mart initiative could operate hybrid systems comprised of both barcodes and RFID in the short term. Then, as RFID evolves and has been proven out by the early adopters - both process and technology - more customers will make the investment to jump to RFID.”

Psion Teklogix

Industry representatives seem to be in agreement with this view.

“We’re behind barcode implementation, barcode standards… we see it as a technology that’s got further to go.”

Unilever BestFoods
Industry expectations

Pharmaceutical manufacturers have invested time and resources into their investigation of RFID, with the intention of formulating a business case. Most manufacturers interviewed found their business case to be weak, with mandates (either retail or regulatory) being the primary drivers for adoption.

“There is no business case for most suppliers in the short term. The technology is not ready, and there is a lack of deep expertise in the industry to help suppliers implement RFID.”

Forrester Research

Although it is generally accepted that RFID will play a part in the pharmaceutical supply chain at some point in the future, most industry players are reluctant to make the first move.

“We’re talking to lots of people, but nothing looks very realistic… If there are significant supply chain benefits, please tell me!”

European Director of Trade, Pfizer

“What would it really add to my life?”

Moss Pharmacy

The cost of tags was stated as a major stumbling block in many cases, particularly by the manufacturers who would bear most of this cost.

“The cost is horrendous. What’s the return for us?”

Wyeth Pharmaceuticals

“It is a huge cost, tagging our products”

Eli Lilly & Co.

Because of this general reluctance to act, the industry is locked in a stalemate. Everyone is waiting for someone else to act.

Figure 9. Perceived drivers of RFID

The pharmacists expect the pressure to come from suppliers who are complying with mandates from large retailers such as Wal-Mart, Metro and Tesco.

“Pressure from retailers is the main reason for adoption.”

Proprietary Association of Great Britain

The manufacturers are waiting to be pushed by large retailers or by the NHS.
“RFID is being driven by the sales arena, specifically large retailers, specifically Wal-Mart over in the US.”
Wyeth Pharmaceuticals

“The driver would more likely be the Department of Health or the NHS.”
Association of British Pharmaceutical Industry

The regulators believe that adoption will be driven by the pharmaceutical suppliers.

“It’s going to be largely industry-driven.”
Medicines & Healthcare products Regulatory Agency

The NHS is one party that could potentially break the loop, but making progress within such a large organisation is complicated and time-consuming.

“Within the NHS, there must be five or six people who feel strongly about AutoID. We’re trying to raise the profile - we’ve been trying to do this for over twelve months and slowly, slowly now it is percolating up to the right level, I think. It’s really been hard work.”
Pharmaceuticals NHS Purchasing and Supply Agency

First movers versus fast followers

There are obvious advantages to being a ‘first mover’ with any industry innovation, namely:

- Technological leadership
- Stronger differential advantage
- Early experience
- Potential to set standards

The advantages of being a fast follower are:

- Lower trial/development costs
- Less uncertainty of results
- Better idea of potential success
- Faster learning curve

From an RFID perspective, the first mover advantages are not as compelling as the fast follower ones. Pfizer and Johnson & Johnson are perceived by the other manufacturers as first movers within the industry, as they were keen to find improvements in the drug supply chain (following massive revenue hits from the unpredictable bulk buying of pharmaceutical products by distributors), but GlaxoSmithKline on the other hand sees itself very much as a fast follower:

“We’re not going to be stupid about this; we’re definitely a fast follower… A lot of pharma companies have gone out and spent a lot of money on this.”
GlaxoSmithKline

Case studies of technology adoption triggers

As is often the case with the introduction of a new technology, something needs to happen - a trigger from the government, from the consumer or from within the industry - in order to break the deadlock and kick-start RFID adoption.

Barcodes

After more than ten years of barcode development, two things in the 1960s finally made the technology a practical reality: cheap lasers were one, integrated circuits were the other.

On June 26, 1974, at a Marsh supermarket in Troy, Ohio, a single pack of chewing gum became the first retail product sold using a scanner. This was the trigger for adoption by the rest of the industry.

The use of barcodes grew slowly at first. A minimum of 85% of all products would have to carry them to achieve a positive return on investment, and when suppliers reached that level in the late 1970s, sales of the systems started to take off. In 1978 less than 1% of US grocery stores had scanners. By mid-1981 the figure was 10% and three years later it was 33%.
In October 1986 the National Mass Retailing Institute (NMRI) decided to endorse the Universal Product Code (UPC) for retail point-of-sale applications. While the UPC had been used in grocery and hard lines for several years, the incumbent technology in retail in the 1980s was optical character recognition (OCR), which scanned human-readable text printed in a special font.

Interestingly, only months previously, Wal-Mart (along with two other US retailers) had announced that it was forcing UPC onto its suppliers, and shortly moved across to barcodes.

Today more than 60% of US retailers are equipped with barcodes\textsuperscript{xxxviii}.

**International cash withdrawal**

The concept of the modern ATM began in 1968\textsuperscript{xxxix} and a working prototype came about in 1969. The first working ATM was installed in a New York based chemical Bank, but this was not networked to any other machine. By 1973 there were 2,000 ATMs in the United States\textsuperscript{xl}, but still none of them were linked.

When ATMs first appeared globally 20 years ago, not many people used them, and banks had to resort to promotional gimmicks to get anyone to try them\textsuperscript{xli}.

In 1974 the first linked machines were introduced, and this was the trigger for worldwide acceptance that led to the network of ATM machines we know today.

**Chip & pin**

Again, the UK government took the initiative in an effort to protect consumers and reduce credit card fraud by introducing ‘chip and pin’ to replace signature-stripe cards.

In 2003 a trial of ‘chip and pin’ technology was run in Northampton, concentrating on how consumers adapt to the new technology. The trial was successful with many major retailers participating. This was the trigger for chip and pin rollout.

In 2004, an intensive retailer/consumer education programme was rolled out, with the intention that by the end of 2004, all retailers will have upgraded their hardware to accept PIN authorisation at point of sale.

**Timescales predicted by the industry**

Whatever the trigger for RFID, there is an expectation that adoption will take place at some point over the next eight years.

**Figure 10. Anticipated timescales for adoption**

These timescales refer to ‘when RFID is expected to become a reality’ for each party interviewed. Unsurprisingly, retailers gave the most ambitious predictions, with RFID implementation seen as likely to begin within the next 1-2 years and to be complete by 2008. Manufacturers were more conservative in their estimates, feeling that a 3-8 year timeframe was more realistic.
Formulating future strategy

Predicting the future is a hazardous occupation, especially where a high number of uncertain variables are interacting together to drive change. However, companies and organisations from all different sectors are increasingly realising the necessity of developing ‘future-proofed’ long-term strategy, which attempts to anticipate possible changes in their operating environments, to maximise the associated opportunities and minimise the potential threats.

“Whilst the future is uncertain and much of it is beyond our control, we can control many aspects of it. We choose our future: we create it by what we do or fail to do. Visions and strategies linked to a clear sense of trends and scenarios make us better able to shape the future we prefer.”

Wendy Schultz

Henley Centre has developed a scenario-based consultancy tool which helps its clients to ‘shape’ their future in this way. Scenarios are not designed to serve as a crystal ball, as a juxtaposition of ‘best case/worst case’ alternatives or as variations around a midpoint. Instead, they are used as a tool to explore and rehearse the range of future possibilities with which a company may have to contend. Each hypothetical ‘vision’ of the future is interrogated for its implications; strategies can then be put into place to manage change and its associated risks should any aspects of these scenarios be borne out in reality.

A case which is often used to highlight the importance of scenario planning is that of IBM within the personal computer market. In 1980, IBM forecast that the world market for PCs would reach 225,000 units by 1990. It made a serious underestimation: the market was 60 million by 1990. A broader future-oriented planning process would have enabled IBM to consider a world very different from the one posited in their forecasts and to formulate an alternative strategy accordingly.

The utility of scenarios developed for a particular purpose lies in the framework around which they have been constructed. Scenarios of this kind tend to combine two axes to form a ‘2 X 2’ matrix. The axes are designed to capture the essence of those trends which are expected to have the highest impact in shaping the future, and also the highest levels of uncertainty in the direction they will take or the effect they will exert. It is also vital that the axes are practical in their focus - that they can help the organisation gain strategic insight into its significant issues.

Narratives are then developed around the four different possible futures, which should be stretched to their logical extremes (even to the extent of being ‘far-fetched’), whilst still remaining essentially plausible and coherent. In practice, it is likely that the future will include aspects of all the scenarios, with different elements being played out by different people or groups or at different times.

Figure 11. Scenarios
Scenarios for the future of RFID

Scenario frameworks and narratives are usually developed by Henley Centre as part of a lengthy, structured process which involves the input of the company and its stakeholders for whom we are working. In this case, we have assembled the RFID scenarios within a more abbreviated process to provide a mechanism for thinking about RFID’s future.

The axes have been selected as follows:

- Which industry players take the initiative in driving RFID forward? At one end of the axis, RFID is driven by the ‘private sector’, i.e., pharmaceutical manufacturers, retailers, or their trade bodies. At the other end, it is driven by the ‘public sector’ - by government, NHS or regulatory bodies such as the MHRA.

- What is the rationale for promoting RFID? In line with the two broad areas of benefits outlined earlier in this report, we have differentiated between ‘patient focus’, (i.e., safety issues or customer-centred strategies), and ‘supply-side focus’ (commercial imperatives around greater efficiency or security of the supply-chain).

This framework makes an assumption that RFID will play an important role in the pharmaceutical industry in future, and explores different ways in which this situation may come about, together with its implications. An alternative axes framework could be structured around commercial, political or economic trends which have a less direct relationship with RFID - the resulting scenarios would then discriminate between how likely was RFID to be implemented under each set of conditions.

These scenarios can form the basis of strategic workshops which pose a number of critical questions to be debated and resolved by a group of people within a company. Workshops of this kind often work best when facilitated by an external, independent party which is able to ensure that difficult issues are properly addressed, that some consensus is reached by the end of the session, and that clear action-points are drawn up to take the agreed strategy forward.

Below, we set out the four scenarios for 2014, developed to explore the future for RFID:

**Scenario 1: Retailers Rule**

There has been an increasing encroachment of US retailers into the UK market, with Wal-Mart rebranding its ASDA stores and other big players such as Target buying big supermarket groups. This greater US influence has accelerated the adoption of RFID in the UK, and remaining UK-owned retailers are riding on their tail, demanding the same supply chain economies from their suppliers in order to compete.
At the same time, the proliferation of new in-super pharmacies has squeezed out smaller pharmacy stores and chains which had been struggling to make the necessary investment in RFID.

Pharmaceutical manufacturers are now mandated to use RFID by their retail customers, causing some resentment about the changing balance of power in favour of retailers. RFID’s returns on investment have been more questionable for pharmaceutical manufacturers, so have put pressure on their cost structure. R&D investment has therefore been further squeezed, and the move towards partnering or outsourcing amongst pharmaceutical companies has accelerated.

At first, the mandate was at pallet level, but wholesalers are now demanding case-level tagging so that they can break apart pallets before distribution for greater efficiencies.

As there is a ‘back-office’ motivation for adoption, the consumer viewpoint is hardly relevant here. In fact, this viewpoint hardly exists: as consumers have little exposure to RFID technology, they have low awareness of it or interest in it.

Scenario 2: Crackdown on Crime

The success of the FDA in straightening out the US pharmaceutical supply chain, combined with the more open borders of an enlarged EU, contributed to a marked increase in counterfeiting, parallel trading and prescription fraud within the UK. These problems became impossible to ignore or play down, and the MHRA was forced to take a stronger stance in protecting supply chain security and the industry’s legal profitability.

FDA-type legislation has been set down in the UK, and the EU is trying to coordinate a wider net of control across Europe which would introduce item-level tagging for those drugs at highest risk of counterfeit.

However, the more stringent control of these products has begun to drive miscreants underground. The ‘grey market’ in which parallel trading previously operated has now descended into a highly-sophisticated black market, producing wider price discrepancies between legitimate and illegitimate pharmaceuticals.

Although the crackdown is really about supply-side security, the regulators have put the onus on patient safety when explaining their actions in the public sphere. This has had the unintended effect of bringing pharmaceutical crime and risk to the public’s attention, where previously awareness of these issues was low. Patients are now expressing reduced confidence in the pharmaceutical industry, which is having an effect on levels of compliance. The greater visibility of these security issues has been exacerbated by an awareness that drug pedigrees can only ensure authenticity up to the point of dispensing, but not beyond the point of sale. The end consumer is therefore not safeguarded by the new security measures which have been taken.
Scenario 3: The Safety-first State

Following a few high profile patient fatalities due to counterfeit prescription drugs and also medication errors, patient safety is now high on the public and government agenda. The greater use of RFID has been driven by government policy and NHS reform, supported by the MHRA.

Pharmaceutical manufacturers were initially incentivised to adopt RFID quickly via tax breaks and ‘preferred supplier’ status. This impetus had the effect of driving up RFID volumes and thereby driving down the price of tags, so manufacturers have been better able to balance the costs and benefits of RFID.

However, some concerns are now emerging that the pharmaceutical industry is becoming over-regulated, which is stifling innovation and even compromising patient service in some cases. The pharmaceutical companies fear that their commercial activities will be even more heavily controlled in future, to the extent that they may attract the same kind of scrutiny as tobacco companies.

The benefits of RFID are largely appreciated by patients, although there are inevitably some conspiracy theories about ‘big brother’ keeping tabs on them. Tagged products have been opening up many patient-focused innovations, e.g. smart medicine cabinets and automatic drug administration, which are beginning to transform the face of public healthcare.

Scenario 4: The Caring Corporation

Innovative pharmaceutical manufacturers have seized the RFID initiative, recognising the CSR (corporate social responsibility) and branding opportunities associated with RFID for the patient’s benefit. This kind of brand protection and differentiation has become particularly important for manufacturers as their patents expire and there is a more open market for generic drugs. By publicising the authenticity of a brand and the security measures it employs, strong brand reputations can be built to allay patients’ concerns around safety issues - and of course to sell more of the product.

The greater visibility of pharmaceutical brands with the end-consumer has increased manufacturers’ power over retailers, wholesalers and pharmaceutical providers. Direct distribution of drugs from reputable sources is rising, and the authorities have allowed this to happen as they approve of the industry’s willingness to take on the investment in greater patient safety.

Patients are divided in their appreciation of the greater role played by pharmaceutical companies: some are sceptical about the manufacturers’ apparently altruistic motives, believing this primarily to be a marketing initiative; others understand that the benefits are mutual, and are willing to engage in a relationship with pharmaceutical companies or pharmacies, exchanging personal/personalised information and further reducing the authority of doctors as intermediaries.
Response from BT

BT commissioned the Henley Centre to perform this independent research in June 2004, as mixed messages from industry were being received. The prime aim was to understand the current-state and potential barriers to delivering value with RFID utilisation within the healthcare supply chain.

BT’s key conclusions from this research are:

- The diversity of vision, beliefs, direction and understanding of parties within the healthcare industry has been supported by the findings

- The USA is leading the adoption of product tracking - driven by initiatives such as the proposed FDA legislation to ensure the authenticity of drugs at the point of dispensing

- It appears that Europe will follow with the mass serialisation of pharmaceutical products - for many organisations this is likely to be with the use of barcodes, with a migration to RFID over a period of years

- BT is uniquely positioned to support this approach and ensure that patient safety can be delivered in the most cost effective way. This can be achieved through the use of BT’s auto-ID platform, which is based upon open standards and can accept data from many sources and in multiple formats (e.g. RFID tags, scanned barcodes, data from third party systems, etc.).

- BT has created a pharmaceutical and healthcare innovation centre - to partner with the healthcare industry and quantify how tracking technology can benefit patient safety and increase supply chain efficiency. This will provide assistance to the wider understanding of RFID technology and the benefits of adoption. This innovation centre is scheduled to operate until mid 2005 and is open to all interested parties.

BT is running a programme of events, in collaboration with individual companies and industry associations, to ensure a shared understanding of the benefits, opportunities and issues - thereby helping set direction for the benefit of all.
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