Building **R**adio frequency **ID**entification for the **G**lobal **E**nvironment

Pharma Traceability Pilot

Problem analysis

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About the BRIDGE Project:

BRIDGE (**B**uilding **R**adio frequency **ID**entification for the **G**lobal **E**nvironment) is a 13 million Euro RFID project running over 3 years and partly funded (€7,5 million) by the European Union. The objective of the BRIDGE project is to research, develop and implement tools to enable the deployment of EPCglobal applications in Europe. Thirty interdisciplinary partners from 12 countries (Europe and Asia) are working together on : Hardware development, Serial Look-up Service, Serial-Level Supply Chain Control, Security; Anti-counterfeiting, Drug Pedigree, Supply Chain Management, Manufacturing Process, Reusable Asset Management, Products in Service, Item Level Tagging for non-food items as well as Dissemination tools, Education material and Policy recommendations.

For more information on the BRIDGE project: www.bridge-project.eu

This document:

This Pharma Traceability Pilot, referred to as WP6 in the BRIDGE Project, aims to demonstrate the implementation and benefits of full supply chain traceability, from point of manufacture to the hospital pharmacy “Goods In”, through the creation of an automatic identification and data capture system, coupled with product and party authentication throughout the chain, for medicines in the European pharma market.

Disclaimer:

This document results from work being done in the framework of the BRIDGE project. It does not represent an official deliverable formally approved by the European Commission.

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Note

The views expressed in this document are the views of the joint authors and the *Community* is not liable for any use that may be made of the information contained herein.

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1. Introduction

This document is the first of a series of deliverables of this BRIDGE Work Package number 6, referred to hereinafter as the Pharma Traceability Pilot project.

The document aims to set the scene for the project – its origination and background, the project's scope, outline and timing as well as the issues of the pharmaceutical market, many of them complex and over-lapping, that the project aims to address - all set in the backcloth of the ultimate vision for a safer, more certain, European healthcare environment, delivering improved patient safety, and served by more efficient and effective supply chains.

The core content of this document has been developed from many different sources involving numerous European pharmaceutical sector initiatives in which the work team has participated over the past few years. These range from face-to-face meetings with supply chain participants (all functions, from manufacturer to patient), trade bodies and associations, healthcare providers, professional bodies, regulatory and administrative bodies, including the European Commission and EMEA (European Medicine Evaluation Agency) as well as government agencies. Additionally, valuable information has been gathered through attendance at numerous conference arenas and, most importantly, by working with collective groups such as GS1 Europe's HealthcareTask Force Programme, the Pharmaceutical Supply Chain Working Group in the UK and the Unisys European Guardian Programme. As such, we are confident that the views expressed in this document and therefore the premise for this project, have a firm foundation.

The expectations and objectives for this project are high. Through the delivery of a successful pilot, as judged by key market stakeholders, we believe that the implementation model developed here will help to form the benchmark for traceability systems for the European pharmaceutical market supporting a range of applications including, for example, electronic pedigree, product authentication and financial reconciliation systems in the medium term.

We owe considerable thanks to the European Union's Sixth Framework Programme for Research and Technical Development and its funding of the BRIDGE project which enabled this project, as a work package within BRIDGE, to get underway. Project participants look forward to working with GS1 and all Consortia Partners to share our experiences and learnings in order that maximum benefit to the RFID and pharmaceutical sectors in their entirety can be delivered.

2. Executive Summary

Improving patient safety is at the top of the healthcare agenda for the European Commission, the Council of Europe and the governments of all Member States – for citizens of all kinds: the politicians, the healthcare professionals, the practitioners, the service providers, the suppliers and most notably for the patients themselves.

There are multiple factors affecting patient safety. Medical error is one of the most significant hazards in the European healthcare sector – medication errors, which account for more than 20% of the total, is the fastest growing segment. Patients are at real risk of incorrect medicine administration causing harm, severe harm or even death. These issues are exacerbated by the increasing risk of counterfeit medicines or use of poor quality medicines from unknown sources. Improved supply chain

efficiency and effectiveness is also a key driver for all parties involved in the healthcare supply chains of Europe – lower stock levels, reduced capital tied up, lower administrative costs, improved cash flow and higher quality of product and customer service, could all help to reduce the cost of providing healthcare services across the entire community.

The adoption of standard technologies, such as unique identifiers, data carriers (bar codes and RFID tags) and electronic messaging, already in common use in other sectors for decades, such as retail grocery, can bring significant benefits to the healthcare sector. When coupled with computer databases and information networks, these automatic identification and data capture (AIDC) technologies provide the platform for secure and accurate traceability systems. Identification of the lifecycle of a drug, from point of manufacture to the patient's bedside, with all steps and parties involved defined, increases the certainty of the medicine administration process, significantly increasing patient safety and reducing supply chain risk.

This Pharma Traceability Pilot, referred to as WP6 in the BRIDGE Project, aims to demonstrate the implementation and benefits of full supply chain traceability, from point of manufacture to the hospital pharmacy "Goods In", through the creation of an automatic identification and data capture system, coupled with product and party authentication throughout the chain, for medicines in the European pharma market.

This pilot does not attempt to fulfil the ultimate vision for improved patient safety as envisaged by GS1, but lays the fundamental building blocks for future developments. These will facilitate the introduction of scanning/reading at the point of administration enabling links to intra-hospital patient-care systems, for example, the Electronic Patient Record, as well as back-office systems for inventory and financial management. These will then bring even greater patient safety improvements together with supply chain efficiency gains.

3. The vision for improved patient safety in European Healthcare

Overview

Envision a European healthcare sector:-

- where every item in the healthcare supply chain is uniquely identified so that its lifetime history, from manufacturer to patient, can be recorded with total accuracy.

- where medical products are identified with certainty and their dates, batch and serial numbers of manufacture recorded through every step of the supply chain.

- where the patient can be treated in the sure knowledge that the right treatment has been applied at the right time, with the right frequency, with the right medicine or drug, to the right dosage and with the right route of administration.

- where customers, suppliers and manufacturers can meet the ever-increasing demands of patients and regulatory bodies for greater patient safety and improved patient care.

This world is enabled by the tracking and tracing of healthcare products, of all kinds and at all points of the supply chain, inside and outside the hospital, wherever they are - for greater certainty of medicine administration, better product re-call, inventory management, servicing and asset management and improved patient safety.

This is the vision for the European healthcare sector.

What is traceability in healthcare?

"….. The capability to follow the path of a specified unit of a healthcare product through the supply chain as it moves between organisations – from manufacturers to distributors to hospitals to patients. Products are tracked routinely for obsolescence, inventory management, potential recall and logistical purposes…"

"... The capability to identify the origin of a particular unit and/or batch of product and its location within the supply chain (including the hospital) by reference to records held upstream in the supply chain. Products are traced for purposes such as product recall, investigating complaints, and product servicing and repair …."

(Source: GS1 Fresh Produce Traceability Guidelines: 2001)

Whilst the requirement for traceability is currently indicative of supply chain pressure, increasing legislative moves at national, European and global levels indicate that traceability will become a regulatory necessity within the healthcare sector throughout Europe.

Enabling track and trace

What is required is a method of bringing certainty to the whole process of patient care and its associated supply chain, and that means supporting human action with automation through the use of proven, reliable technology.

Traceability requires each organisation within the supply chain to implement compatible and accurate data management systems based on open standards. This means that organisations need reference to common definitions and data structures throughout the whole supply chain, with no interruptions. The GS1 System provides the basis for such systems. Effective traceability systems require the long-term commitment of all organisations involved since traceability breaks down wherever there is a failure to meet the necessary standards. Any re-labelling operation puts traceability in danger, as it introduces a new source of potential errors. We believe that source marking of healthcare products is the key to accurate traceability.

The basic requirement for any traceability system is to uniquely identify the item that is to be traced. This is normally done by an appropriate and neutral data element (the item identifier), which is carried in a bar code or RFID tag. this allows for automatic identification thus minimising errors and processing time. Item identification is then communicated to other members of the supply chain and entered into a database from which information can be retrieved using this unique item identifier as the key.

Traceability systems may track items at individual product level (the single vial, the single blister pack) or at the trade item level (the carton or pallet) depending on the supply chain's specific requirements. Further, for medical devices and medicines, it will be increasingly necessary to track specific production batches, and increasingly single items, right through to the individual patient in order to ensure quality administration processes for improved patient safety.

Applications enabled by traceability systems

Traceability systems are enablers of a variety of related applications. For example, the electronic pedigree of a particular medicine includes all traceability information captured during the tracking and tracing process identifying the product's *chain of custody* as the product changes ownership along the chain. By validating the authenticity of the product against manufacturer-supplied data – the unique identifier for that product – the electronic pedigree effectively becomes an "electronic certificate" of the product's provenance.

Electronic pedigree systems are examples of just one area of applications enabled by full supply chain traceability. Other applications enabled by traceability systems include product recall systems, inventory management systems for goods receiving parties, financial reconciliation as well as patient administration and patient care systems.

In Summary

The ultimate vision for improved patient safety in European healthcare is the mass adoption of traceability systems, based on automatic identification and data capture techniques linked with databases and network systems supported by open, global information standards, that link the identification of the medicine at its original point of manufacture with the administration process at the patient's bedside, identifying all steps, and the parties involved, along the way - both inside and outside the hospital.

The Pharma Traceability Pilot – laying the foundations of the vision

The plan for this Pharma Traceability Pilot is to use European formatted products - predominantly patient packs (and perhaps blisters) rather than jars or pots as used in US - to trace product from the point of manufacture through to the 'Goods In' at the hospital pharmacy.

A number of products, serially identified at all levels of packaging, will be tracked from the production line, through the normal transport and distribution stage, to the wholesaler picking, ordering and direct distribution stages and on to the entrance to the hospital pharmacy. The second phase, out of scope of this project, will be to track product from the hospital pharmacy 'Goods In', through the storage and internal prescribing, picking and checking phases, on to ward storage, through to distribution and administration to the individual patient. The eventual vision is to be able to electronically tie the product to the patient and the prescription and be able to track each and every patient pack back to the point of production through the chain of custody. As the product moves along the supply chain, information will be added recording events and actions, physical movements and locations at every stage.

4. Background to the Pharma Traceability Pilot

Patient safety and supply chain efficiency – drivers of change

The improvement of patient safety and increased supply chain efficiency are the two key drivers of change in European healthcare. Leveraging the use of technology, specifically globally recognised data standards and technologies to enable greater certainty of identification – of medicines, devices, patients, assets and locations – and the automatic data capture and processing through reading devices coupled with computer based systems, is a key objective of all pharma stakeholders, including GS1, the global standards organisation.

The European Healthcare Initiative

The *European Healthcare Initiative* (EHI) was created in 2003 by GS1 Europe to create awareness and promote greater usage of the GS1 System of Standards in the healthcare supply chains of Europe, focusing largely on pharmaceuticals and medical devices and their supply by manufacturers through to the end user (the patient), in hospitals and the community at large. As an awareness creation, standards development and piloting programme, EHI – with a tag line of "*reducing risk through certainty*" - has been highly successful in demonstrating the fundamental role of automatic identification and data capture (inc bar coding, RFID and eMessaging) based on global standards (the GS1 System). Robust global standards are a key enabler for the implementation of traceability systems which are vital for greater patient safety and improved supply chain efficiency. Without such standards, organisations are reluctant to implement these solutions for fear of investing in obsolete technologies that have to be replaced when standards are eventually agreed.

In 2004 and 2005, EHI's primary project in the pharmaceutical market, the European Pharmaceutical Supply Chain Working Group *Task Force*, embarked upon a series of pilots and trials designed to prove a set of published Voluntary Application Guidelines for identification, marking and electronic messaging standards, based upon the GS1 System. At that time, the key stakeholders were actively discussing the need for traceability systems which could enable tracking of products, particularly medicines, at the 'item' level, that is at the patient pack level (as prescribed by a pharmacist or purchased 'over the counter') or even a blister pack of tablets or other form, that could both ensure accurate medicine identification and linkage to the Electronic Patient Record, as well as to financial and stock management systems.

Mass serialisation enabling traceability

Such traceability systems require unique identification of not only the product but also the specific instance of that product by the adoption of a 'serial number'. The combination of product number, the GS1 Global Traded Item Number, or GTIN for short, and a randomly or serially generated unique item number compiled what is now accepted as "the serialised GTIN" or "SGTIN" enabling "mass serialisation". By allocating the SGTIN at source as part of the manufacturing process, and embedding it within a data carrier such as a linear or 2-D Data Matrix bar code or RFID tag, the adoption of reading, information capture and database systems enables complete item visibility and traceability throughout the chain.

The use of the SGTIN is one example of an approach for mass serialisation. The EPCglobal Healthcare & Life Sciences group has done considerable work in this area to draft other approaches, for example, the GSIN, for specific US markets. Note the technique to be adopted for mass serialisation will be discussed in the next WP6 deliverable, Requirements Analysis.

An objective of the *Task Force* group was to demonstrate the feasibility of a mass serialisation system in a live production environment and the benefits for improved patient safety and supply chain efficiency.

Growth of counterfeit medicines

Coincident with these *Task Force* developments, the threat of counterfeit medicines in the supply chains of Europe was perceived by the pharma industry to be increasing at alarming rates – as they still are today. Forecasts by WHO (World Health Organisation), the Council of Europe, the FDA and many other notable bodies (see also references in Appendix) evidence these industry concerns, the key issues being the danger of counterfeit medicines to the health of patients as well as the risk of lost consumer trust in the safety of both branded and generic medicines. The industry trade body EFPIA (European Federation of Pharmaceutical Industries and

Associations) added its considerable weight to the topic with the publication of a Position Paper "*Combating counterfeit medicines and protecting patients through a partnership approach*." What was required, it stated, was a range of anti-counterfeit measures – including consumer awareness generation, legislation, business practice and technology systems and others – to tackle the imminent global threat. The Pharma Safety Chain vision of a "safety chain-of-custody" was one of these technology-based counterfeit deterrent measures suggested by some organisations within the industry.

The Pharma Safety Chain

The vision for the Pharma Safety Chain is founded on a full traceability system dependent upon the "mass serialisation" of product items in the chain, the capture and storage of traceability data at each node within a commonly-accessible information network, and authentication of the genuine origin of the product by each party - all this information being captured within an "electronic pedigree" for that product (item), evidencing its authenticity. There is widespread agreement that the use of open, global standards for product identification, the data carriers (bar codes and RFID tags), as well as the electronic messages used to communicate information between trading partners, are prerequisites of such systems.

Electronic Pedigree

A pedigree is a secure file that stores data about each move a product makes through the supply chain. Pedigrees can help to reduce counterfeiting in drugs and other products.

The term 'Electronic Pedigree' has a very precise meaning and purpose in the US intended exclusively to combat the threat of counterfeit drugs.

Whilst electronic pedigree systems, largely focusing on the use of RFID tags as the data carrier, are increasingly being rolled out in the USA to meet emerging State regulations, as encouraged by the FDA, they have not as yet reached Europe. Whether the European market will in the future be required to comply to the strictures of US-defined electronic pedigree we do not know. However, we believe the principles it propounds will become a requirement whether mandated by regulation or encouraged as 'industry best practice'.

The closest example of an interpretation of electronic pedigree we know of – and a landmark for Europe - is the recent EPCNetwork pilot which linked to the existing track and trace solution already implemented by the NCHCD in Ireland for haemophilia treatment products (temperature sensitive factor concentrates) used both by patients for home treatment as well as in treatment centres across the country. The driver here was improved certainty of product integrity based upon a full traceability log of product movements from manufacturer to patient. As an industry view is that it is only a matter of time before this requirement for *improved supply chain certainty* becomes a pan-European one, the Pharma Traceability Pilot was formed by EHI's *Task Force* with a team consisting of user companies, solution providers, trade bodies and other interested parties, with a brief to report on the issues of implementation and deployment and the contribution and benefits to greater patient safety and supply chain efficiency.

The funding made available by the European Commission's support of the BRIDGE project, has enabled this Pharma Traceability Pilot, as a component of BRIDGE, to now get underway.

5. Project Scope

The scope of this project is limited to the implementation of a full supply chain traceability system for medicines flowing from the manufacturer to the hospital pharmacy "Goods In", based on mass serialisation of products using global standards and information systems. Products will be tracked and recorded within a traceability system, supporting the principles of the electronic pedigree showing not only the chain of custody for the medicine (by ensuring product management at each transactional nodal point) but demonstrating the authenticity of its manufacture thus bringing reduced risk of patient harm.

The electronic pedigree will provide this improvement to patient safety because each product, be it drug or device related, will have a readily accessible 'statement of provenance' that will specifically show where the item has been, who has held it and where it came from. For example, genuine items will be fully traceable back to a known/accepted manufacturing source whereas in a counterfeit scenario, using the authentication mechanisms of the pedigree, it would not possible to trace the source to a licensed manufacturer or distributor. Also if items are inserted into the supply chain using duplicate item serial numbers for products that have already been dispensed or products which are already 'in the supply chain', an immediate warning will be raised at the first point where these 'suspect products' are electronically read (which they have to be in order to obtain a pedigree). Thus, any suspect items can be immediately flagged as problematic and removed from the supply chain before causing harm or unnecessary extra expense. Moreover, because items (shipments) will be electronically read at goods receipt by the various trading partners, each partner will receive an immediate indication of the 'acceptability' of the goods being received.

Whilst the pilot is aimed at the development of a full supply chain traceability system supporting electronic pedigree information for medicines, importantly it also lays the building blocks for future developments (out of scope for this pilot) including validation at point of care and integration of traceability information with patient administration and back-office systems, needed to provide the certainty of product information required to substantially reduce medication errors. Thus, the groundwork set by this system will provide for even greater patient safety benefits and supply chain efficiency improvements in the future.

As already indicated, the counterfeit issue and its combatant measures is a wide-ranging and complex subject. Measures promoted to help combat counterfeit range from tamper-proof packaging techniques, legal action, enforcement measures, public awareness generation as well as track and trace systems, require all supply chain stakeholders – customers, suppliers, regulatory agencies, healthcare service providers and trade bodies – to collaborate to resolve the issue.

The scope of this project is limited to just one of these combatant strategies, that of exploiting emerging and extant technologies within a traditional pharmaceutical supply chain environment using systems of unique identification techniques based on interoperability between RFID tags and linear and 2-D bar codes (that is, in a mixed 'hybrid' environment), data capture technologies and a network-based system allowing stakeholders to store, access and analyse the captured information in an open supply chain environment. The different characteristics of RFID versus optical barcodes will be considered in the next WP6 deliverable, the Requirements Analysis – for example, RFID tags can be read at a distance without having line of sight to the tag and this poses a potential problem in terms of patient privacy and also supply chain security, because:

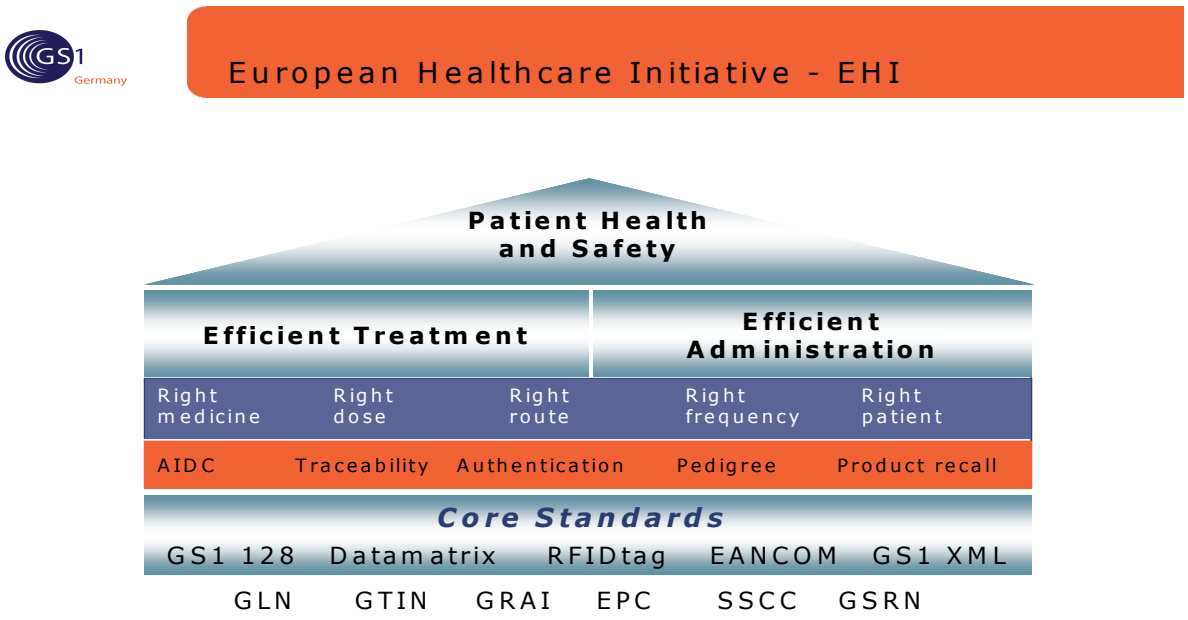
i) The medication (and especially drug type) a patient may be carrying on their person might be read by a third party and the information used in a prejudicial or discriminatory way, without the patient's knowledge or consent.

ii) Pharmaceuticals in transit have a high monetary value in a relatively compact volume and are an attractive target for would-be thieves or hijackers. Thought needs to be given to making the identity of the goods as 'anonymous' or opaque as possible, to reduce the likelihood that a thief possessing an RFID reader may be able to selectively target pharmaceutical packages in transit.

The effectiveness of the technologies will be analysed in this pilot as well as the business case (costs and benefits) developed for each participant

The Pharma Traceability Pilot will be 'for real' – in other words, involving the flow of actual medicines in a production environment as supplied by pharmaceutical manufacturers, via their contract packers and logistics partners, through to the wholesaler and on to the 'Goods In' department in a hospital pharmacy. The parties involved represent an international supply chain being based in Ireland, The Netherlands and the UK. In view of the fact that it addresses the identified objectives of key industry players, the Council of Europe and Healthcare providers, it is anticipated that this pilot will establish the *de facto* way business will be done in the future in the European pharmaceutical supply chain. As such this project has the potential to become phase one of a full market-wide roll-out, to the benefit of greater patient safety, improved supply chain efficiency and counterfeit medicine combatance.

In conclusion, and by way of summary, we see that the "Patient Health and Safety" model developed by GS1 Europe's *European Healthcare Initiative* aptly describes the relationships of the core technologies to be implemented in this project and the healthcare applications they support, all leading to improved patient care and patient safety.



6. Project Objectives

The key objectives for this Pharma Traceability Pilot are to demonstrate the implementation and feasibility of a full supply chain traceability system supporting the 'Pharma Safety Chain', that is the vision developed by some members of the European pharmaceutical industry to bring greater certainty and surety to the supply and use of medicines through the development of an electronic pedigree.

The 'Safety Chain' vision embraces some key principles where each stakeholder:

- Is responsible for the safety and integrity of the medicine at the time they own it;
- Is responsible for ensuring the pedigree of authenticity of the medicine;
- Uses common global standards and processes;
- Operates within a transparent system to ensure safety and enhance public confidence.

Fundamentally, all stakeholders must be involved - the supply chain is only as strong as its weakest link.

The mass serialisation of medicines required of traceability systems entails the unique identification and automatic capture of data, such as product identifier, expiry date, batch number as well as the unique serial number, via scanning and electronic reading techniques. When integrated with computer-based systems, such as inventory management and goods receipting systems as well as patient care administration systems, efficiency and patient safety improvements e.g. the reduction of medication errors, can be dramatic. Thus, an objective for this pilot is to provide the platform for future implementations (out of scope of this project) where such further benefits can be made.

The scope of the pilot will include the implementation of a variety of AIDC technologies - for example, the use of RFID tags combined with traditional 2-D and linear bar codes in a mixed 'hybrid' environment, and the use of open systems networking. Equally, the pilot will examine the business issues raised by changes to traditional business practices and the impact of the visibility of product traceability information in the context of the 'open' supply chain environment.

7. Problem Definition

7.1 Introduction

The pharmaceutical sector is a complex one and, like other sectors, has various issues that organisations of all sizes have to face in day-to-day business. Included below are some of those that are related to the scope of this project.

7.2 The key issues

Medical error

The known level of occurrence of adverse events across the world varies between 9% and 11.7%. Some of these lead to patient deaths, others are thankfully not so serious. However, they do result in extended hospital stays of between 5 and 8 days above the average bed occupancy level. It must be stressed that the known level is the very least extent of the problem as the figures are typically based on reporting by

clinical staff - it is believed there is a degree of under-reporting due administration issues and a natural fear of possible consequences.

Medication error

Making mistakes in the administration of medicines – getting one of the 'five rights' (right patient, right medicine, right route, right dosage and right time) wrong - is all too common.

In Europe, as in all countries, medication error, that is mistakes made in the prescribing, dispensing and administration of medicines to patients, causes thousands of patients' deaths each year unnecessarily.

For example, in the UK:

- Whilst difficult to quantify precisely (as accurate records are not maintained), it is estimated that hundreds of patients in the UK die each year due to preventable medication error. For example, the National Patient Safety Agency (NPSA) suggests 50% of the estimated 72,000 deaths in the NHS are caused by medication errors overall. 34% of all medication errors that cause problems for patients are associated with drug administration. Many of the medication errors occur as a result of a lack of machine-readable codes, which significantly increases the risk of human visual identification errors (many packs are of similar name, size and appearance).

- Patient safety is a key issue for the UK Government. Authoritative reports such as '*When Errors Happen'* (Bates et al) and recent UK reports such as '*A Spoonful of Sugar'* (Audit Commission) and '*Organisation with a Memory'* (Department of Health) have underlined the extent of medication errors. Causing harm to people in hospitals, where patients should be very safe, is just not acceptable.

- As *A Spoonful of Sugar* also identified, the knock on costs of a high patient risk environment leads to significant costs in additional hospital stays plus clinical negligence claims. Adverse events cost approximately £2 billion a year in additional hospital stays alone.

- The NHS pays out every year around £400 million settlement of clinical negligence claims

- Very recently the NPSA urged that hospitals in England do more to reduce the 40,000 medication errors per year of which 2,000, they say, cause patients harm or severe harm or death, as in 36 cases. (See BBC article *'NHS Drug error crackdown urged*" in Appendix)

And in the US,

"*To err is human*" published by the US Institute of Medicine in 1999 reported that 98,000 people die annually in the US from medical errors, of which 7000 are due to medication errors.

- 2% of admissions to 2 US hospitals experienced a preventable adverse drug event

- 'The cost of adverse events in hospitalised patients' (1997) showed that medication errors increased length of stay by 4.6 days, costing $4600 per admission; based on a 700 bed hospital, this extra cost was $2.8m per year

Sub-standard medicines and outdated medication processes

When quality problems are identified with medicines and related products (e.g. contaminated blood-related products), effective mechanisms are required to recall all related products entirely and speedily. Today's manual systems do not allow medicines at the patient pack level to be traced throughout the supply chain – the whereabouts of products, and the patients treated by potentially faulty medicines, is simply not known. As a result, 100% effective and timely recalls are not possible and therefore the risk of medication error and thereby patient risk is considerably increased.

Supply Chain inefficiency

The typical healthcare supply chain in Europe significantly lacks the exploitation of technology that forms the basis of more modern supply chains such as in the retail/FMCG, military, aerospace and automotive sectors. Here the use of AIDC technologies, network based systems and integrated application environments, amongst others, have all enabled profound transformation of re-engineered supply chains bringing improved logistics, reduced administrative costs, better utilisation of people, reduced capital tied up, lower inventory levels, reduced lead times and improved product quality.

There are many similarities of product and information flows of pharma supply chains compared to those of retail and other sectors. Accordingly, many of the benefits these sectors have witnessed are yet to be gained by pharma - there is much low hanging fruit to be picked.

For example:

- Scanning at the 'back door' by the wholesaler to automate the receipting process;
- Enabling automated data capture to support First In First Out (FIFO) stock management
- Efficient management of the product returns process
- Automated receipting at the hospital goods-in and integrating this process with the pharmacy administration / financials system – for improved invoice/order/receipt reconciliation processes
- Greater use of eMessaging techniques, based on EDI and XML, for faster, more-up-to-date order placement, advance notifications of deliveries and transport scheduling
- Bedside scanning at the point of administration, would reduce patient risk as well as reduce staff time spent on manual recording.
- Given the constant pandemic threats, the existence of accurate and visible supply chain information could rapidly identify the precise location and quantities of critical medicines required to tackle an outbreak.

Counterfeit medicines

Most authorities agree that the risk of counterfeit medicines in the healthcare supply chains of Europe is growing. The World Health Organisation (WHO) estimates that 5-

10% of world pharmaceuticals are counterfeit and as much as 25% in Third World markets.

There is also a growing threat to the health of consumers and patients. There is widespread worry among health authorities that new strains of bird flu may emerge rapidly as a result of counterfeit (ineffective) medicines. In the United Kingdom, officials seized 5,000 packets of counterfeit Tamiflu in early 2006, estimated to be worth £500,000. At about the same time, the Dutch Healthcare Inspectorate warned consumers not to buy Tamiflu through the Internet, after counterfeit capsules were found in the Netherlands containing lactose and vitamin C, and no active substance. The WHO is getting actively involved to prevent counterfeiting from increasing the already dangerous risk of pandemic. As recently as a few weeks ago a counterfeit batch of a critical branded drug was discovered in the UK market.

In addition to these challenges, there are also concerns that counterfeit drugs with a reduced active ingredient (rather than no active ingredient) could lead to existing viruses developing a resistance or new strains to develop unchecked.

While patient safety is priority one and will be the focus of mandates and regulations, there are clearly staggering economic risks to pharmas, with counterfeiting potentially costing the industry up to $30 billion annually. The impact includes sales lost to the “grey market” and to parallel trading; increased cost of goods sold and reduced returns on huge investments in development. The problem is returning to markets once thought to be safe. For instance, the UK went 10+ years without a significant counterfeiting event, but then experienced four in the space of one year.

Further, the problem is likely to worsen before it improves. Sales of counterfeit drugs are projected to reach $75 billion in 2010, up 92% from 2005. "The business of selling fake prescription drugs to unsuspecting consumers is burgeoning, and is a global industry," said Peter Pitts, Director of the Center for Medicines in the Public Interest (CMPI). "Nearly $39 billion, or 11 percent of global pharmaceutical commerce, will be counterfeit this year. By 2010, the number will nearly double." In addition the profits from these activities could be used to fund other illegal operations.

In an industry that relies upon the integrity of its brand, to ‘do nothing’ is not an option. The potential liability exposure is huge - given that pharmaceutical manufacturers and suppliers can be held responsible for all actions of all of its partners, the impact of this could be catastrophic.

Under current supply chain processes, visibility and control are often lost as drugs move from node to node. Though many manufacturers require pre-wholesalers to record the numbers of the batches they receive, there is little or no tracking from wholesaler to pharmacy or pharmacy to patient. Product diversion (and the resulting undersupply of drugs in some markets), safety concerns from poor re-packaging, management of product authorisation (PA) coding, uncertainty about cold chain integrity, lack of forecasting insight and overall lack of supply chain transparency are other related business issues.

But solving the problem is not easy. The counterfeit organisations are highly sophisticated in their approach. The counterfeit product’s ‘look and feel’ is often almost identical (if not better) than the original so straight forward visual checks are not enough. The industry accepts and promotes parallel trading, which makes the original source of the drug almost impossible to identify and when considering the huge volumes of drugs that are handled every day, it is not practical to check all drugs given the current processes and identification of medicines today. Customs Authorities across the world are powerless to prevent the cross border movements of

counterfeit medicines and only the availability of the track and trace type of solutions will change this situation.

With no formal legislation, standards or guidance then there is no readily available method and/or service to tackle this issue. Without this capability within the pharmaceutical supply chain the counterfeit market is set to grow significantly. Another threat is the burgeoning growth of internet pharmacy sites which invariably retail counterfeit products.

Counterfeit regulations

To date, there is no global or pan European legislation/standard in place to address the challenge of counterfeit drugs. The pharmaceutical industry might look to EU legislation on food tracking and tracing (EU directive 178/2002), which came into effect in 2005. That legislation required "farm to fork" traceability, though not complete pedigrees for each product.

Further afield, legislation in the US bears watching because it may also offer instructive lessons and because European pharmas producing drugs for these markets must comply. For now, the action has been at the state level. Three US states have passed prescription drug pedigree laws. They are Florida and California, which have the largest prescription volumes, and Nevada. Another 15 states are working on legislation. Most US regulations focus on drug pedigrees that would provide players in the supply chain with detailed chain of custody records for drugs, from manufacturing to the point of dispensing. Florida was the first state to enact specific drug pedigree legislation. Initially, it specified pedigrees – though not necessarily electronic pedigrees – for the 34 top-selling drugs. For now, the Florida regulation applies only to pharmaceutical wholesalers and distributors, though it's expected that manufacturers, pharmacies, hospitals, doctors, and others will soon be required to collect, store, and certify accurate pedigrees on the drugs they sell and dispense. California is expected to require electronic pedigree tracking for all drugs sold in the state effective January 1, 2009. At the federal level, several legislators in the US House of Representatives have introduced a bill to mandate use of RFID technology for at-risk pharmaceuticals by the end of 2007. And the US Food & Drug Administration (FDA) has very recently announced enforcement of the pedigree requirements from its Prescription Drug Marketing Act (PDMA) – as recommended by the FDA Drug Safety Task Force Report 2006.

There is a sense of inevitability in the US, as in Europe, that more legislation is on the way. While pharma stakeholders recognise the importance of industry guidelines and are confident about meeting them, significant questions remain. For instance, clarity is required about the data standards that will be used in the first instance for Data Matrix at each packaging level.

In Europe, regulators are stepping in to address the shortfalls. Many believe batch traceability, currently required in Spain, will soon become a legal requirement across Europe. In Spain, medication labels include data on the "denomination of the active ingredient, the authorisation owner, administration method, contained quantity, lot number, expiration date, precautions for conservation, dispensing conditions." Additionally, each package includes both the lot and unit number to "allow for individual identification by mechanical, electronic and computer means." Further, "Wholesalers and pharmaceutical laboratories are obliged to guarantee the maintenance of the cold chain." Public administration agencies are focused on "supporting the creation of its own medicament and health product information centres, through promotion and coordination on the utilisation of resources and information technologies that allow professional health institutions and other entities to access information on such products." Italy, Belgium and Portugal have tried to

develop national solutions which are neither practical nor cost effective in a trans-national supply chain like the pharma sector.

In November 2005 EFPIA (European Federation of Pharmaceutical Industries and Associations) recommended that its members (manufacturers) adopt the use of machine-readable, 2-D Data Matrix codes containing manufacturer name, product name, batch number and expiry date, and enabling the use of random serial numbers to provide product traceability. This is viewed as a significant stepping-stone to achieving supply chain security in a commercially viable way. Assuming the appropriate network and database linkages can be made, the implementation of these recommendations will allow authentication at point of dispensing and thereby address the number one industry requirement of ensuring consumer/patient safety. While RFID is seen as a potential mid-term to long-term technology solution, EFPIA recommended Data Matrix as the pragmatic short-term solution because the technology is not yet ready and current implementation costs are high.

7.3 Pharma Market Challenges

As we have already identified, the pharma sector is a complex one facing many challenges. Described below are just some of them:

Information Standards:

Common standards and approaches (across Europe as a minimum) are essential to minimise the investment costs, reduce complexity and ensure success of any technology solution. The lack of uniform standards is one obstacle to technology adoption, though there are signs that outliers, including Italy, Belgium and Portugal, are increasingly willing to adopt uniform standards such as those promoted by EFPIA, the Council of Europe and many other key sector stakeholders. The GS1 system of standards is increasingly perceived as the appropriate information standards for the healthcare sector.

Return on Investment (ROI):

Because there are few legal requirements (exceptions are Spain and those emerging in France concerning the right of the patient to the patient record on completion of a treatment episode), any significant new investments in track-and-trace and authentication systems will require a clear business case, with quantifiable ROI. The question around ROI is critical (particularly in a time of tightening margins and shrinking pipelines) and each supply chain actor has different business objectives. For instance, it is likely that wholesalers would invest in track-and-trace systems for the potential efficiency gains in key replenishment and distribution processes. Without the spur of regulation, ROI models are necessary to justify investments. While patient safety is the top priority, improving operational efficiency, accurately recording key information, reducing costs and enhancing overall supply chain performance are also hugely important in justifying additional investments in product coding and packaging. In determining the business case, the key question is: what new capabilities (like automated replenishment and streamlined returns processes) can be enabled to deliver business value alongside standardised authentication systems?

Compared with those in retail, automotive and other sectors, the pharma supply chain is not generally considered to be a ”best in class” model for efficiency and integration. Therefore, ample opportunities exist to improve business performance by making investments in track-and-trace and authentication processes and technologies. For

instance, batch tracing can help make returns processing more efficient, in addition to safeguarding products. For manufacturers, the loss of visibility of their products once they are sold to wholesalers, as well as 'on-shelf availability' problems are key factors.

***Collaboration**:*

For any authentication or track-and-trace system to work effectively, all supply chain actors must work together. This is particularly the case for traceability solutions enabling electronic pedigree systems. This also means that all European industry and governing bodies must work together. However, it's important to note that the process all starts with manufacturers; they have to show leadership and recognise the challenges that exist in the end-to-end supply chain.

***Business Process Change**:*

Process change is still another variable – and, obviously, the most operationally oriented one. Specifically, how will track-and-trace impact existing processes? How do these changes integrate or potentially conflict with existing compliance requirements? How will the introduction of the electronic pedigree and the information transparency that it implies impact traditional business practice? And how can new authentication capabilities drive improved efficiency? For instance, early adopters are already focused on item serialisation and determining the cost of quality. Of course, the issue isn't just what will be impacted and what needs to change within the enterprise, but also how will new processes be implemented across the supply chain and how can these changes be leveraged to provide improved ROI.

From a distributor perspective, paper pedigrees may look attractive, especially as a way to limit near-term costs. However, paper pedigrees and handwritten signatures provide a much less secure audit trail than those achieved with electronic pedigree and digital signatures, because the digital signatures are linked to both the content that is signed as well as the signatory - so are therefore much more difficult to forge - and furthermore, digital signatures can serve as a 'tamper-evident' seal around the signed data, so that any subsequent alteration to that data is immediately evident in a way that can be checked automatically by computers. This area will be examined further in the Requirements Analysis deliverable of WP6.

Diversity in the flow of inbound products is a major issue on distributors' agenda; they have a fair amount of "how to" thinking, planning and testing to complete before any advanced track-and-trace capabilities can reach acceptable levels of effectiveness. Another example of an open issue related to process change is authentication. Is this a strategic capability that could be implemented and adopted more rapidly than other track-and-trace capabilities?

There is growing support for GDPs, or good distribution practices. The European Association of Pharmaceutical Full-line Wholesalers, known by its French acronym GIRP, has called for a quality system similar to good manufacturing practices, or GMPs. According to GIRP, such a system should be "operated by distributors (wholesalers) of medicinal products" and "should ensure that medicinal products that they distribute are authorised in accordance with Community legislation, that storage conditions are observed at all times, including during transportation, that contamination from other products is avoided, that an adequate turnover of the stored medicinal products takes place and that products are stored in appropriately safe and secure areas. In addition to this, the quality system should ensure that the right products are delivered to the right addressee within a satisfactory time period. A tracing system should enable any faulty product to be found and there should be an effective recall procedure." The guidelines offer particular recommendations for

premises and equipment, documentation and what to do in the event that counterfeits are discovered.

Packaging Level/Data Carriers/Data Content:

The project aims to utilise a variety of real-world packaging scenarios. What is of vital importance to the project is to ensure that all the testing and piloting conducted is undertaken in such a manner that it highlights any issues and problems that will need to be overcome before a wider scale adoption program can be undertaken. Clearly we would also hope to be able to solve many of the issues as we proceed.

In general this equates to either a pack of blistered tablets, a bottle of liquid or a pack containing a vial. However, the work package team fully understands the complexities in this area surrounding the use of various multi-dose formats and will aim to include scope for expansion of the system to handle such dose forms within a subsequent project phase. It is not the intention of this work package to explore the issues surrounding individual tablet coding although it is our aim to review the concepts and implementation of individual blister pocket coding.

There is a full expectation that the package levels used during this project will range from the individual blister at the lowest level through to the pallet onto which they are eventually placed. The design will also encompass the use of mixed item pallets and the use of returnable totes. The system design will be such that the number and variations of packaging level will be designed to be wide enough to cope with anticipated requirements.

In general the data carried by each item will, as a minimum, be the GTIN and serial number. This equates to the use of the data element of an EPCglobal compliant SGTIN-96 tag. However, in order for the system to make full use of the GS1 standards and identifier keys, and indeed make logical sense in terms of product designation, the system will utilise a broad spectrum of appropriate identifiers such as GRAI (for returnable transit units (e.g.'tote' style containers), SSCC's and GLN's. The hierarchical use and relationship between these identifiers will change dependent upon the process requirements at the various stages of the supply chain process.

For numerous reasons, during the requirements gathering we have been requested to provide extended data within the carrier indicating the batch number and expiry information (which may not always be possible, for example, when coding a tote or pallet of mixed items). Although the batch number and expiry information for the product will be available from the network system, (i.e. the EPCglobal Information Services (EPCIS)), it is recognised that in the early transition period, it is not always realistic to expect back-office system integration to be at a high enough level to realistically obtain such information from the network. Therefore, where possible, we will develop and trial the use of both an EPCglobal Information and EPCglobal Discovery Services network linked system where such additional information can be gathered in real time, and an off-line system where the extended information can be used to provide internal process improvements even though the scanning/reading operation will not provide extra transactional information for the pedigree. It is thus a current intention of this work package to provide extended product information within the various data carriers where appropriate and possible.

When discussing the topic of data carriers, it is important to stress that this work group project is not biased towards any one form of data carrier device. The industry perspective is currently very mixed, and for good reason. On the one hand, the EPCglobal compliant RFID tag with its built-in silicon wafer level unique tag ID (TID), in association with the information network provided by the EPCglobal Information Service (EPCIS) and Discovery Services, is a powerful concept in terms of anti-

counterfeit and absolute package identity. However tag technology taken as a whole (tags, application requirements, physical reader/antenna installation and availability of required standards, etc.) remains an area where in the short term at least, more product reliability, volume and user acceptance of certain dynamics and constraints is required before it could be realistically viewed as the ideal solution for all pharmaceutical and healthcare products. It is however generally recognised that the tag will become a dominant code carrier in the healthcare market. In balancing this view, the printed code is also not without some similar drawbacks. In certain cases the addition of a printed code may require the re-licensing of a pack design incurring a cost to the license holder. Some existing production facilities may need additional or replacement printing equipment in order that the Data Matrix code can be successfully printed and applied. A principle aim of this project will therefore be to highlight any issues discovered while designing and implementing the trial system so that further focus may be provided to the groups responsible for providing improvement.

As stated, the project will utilise both the RFID tag and the Data Matrix code as the prime forms of data carrier and the application and use of each will be carefully chosen such that we maximise the value to patient safety while ensuring that any cost impact is both minimal and appropriate to the application needs. Given that both data carrier technologies have their own set of strengths and weaknesses, this project will aim to explore many of these and hope to put them into a framework that allows more informed choices to be made for subsequent wider scale adoption.

As yet, the mix of product for the pilot remains to be fully determined and therefore the determination of the mix between RFID and Data Matrix technology has yet to be identified. What we do however understand is that in order to make maximum use of the product available and the cooperation of our partners, many products will be carrying dual codes – that is both a Data Matrix and RFID tag.

Data management:

The area of data management is both critical and complex. There are many constraints and requirements placed on the issues surrounding data management including:

- Security and privacy
- Ownership
- Access
- Availability

The above is not intended to be an exhaustive list but instead provided to give a flavour of the issues we will have to contend with. By way of an example, the areas of access and availability can often present serious issues when discussing and solving the area of security and privacy. Also, the issue of data ownership is critical with so many different parties involved in the process of manufacturing product, through shipping and distributing the product through dispensing and administration of the product. Not only have we issues of commercial confidentiality to understand and resolve but also issue of European Law in terms of access to data regarding product that key stakeholders may not own.

In many respects, the issues surrounding data management are likely to be the most complex to resolve and we are looking forward to cooperation with other work packages within the BRIDGE programme in order to be able to pool our ideas and experiences. Specific work packages that involve this area are WP2 (Serial Level

Lookup Service), WP4 (Security Framework) and WP5 (Anti-counterfeit Business Application).

Technology Performance

We know the ROI improves as technology costs drop – a key driver of the tipping point. But, technology performance on a large scale remains a critical concern for both regulators and the market generally. Confidence in technology is vitally important to driving further adoption, and continuing advancements and innovations are on the way. The security and visibility capabilities are central questions, but consumer and data privacy is becoming more important as deployment of RFID and AIDC techniques generally become more widespread. Regulatory bodies, industry, trade groups and other outreach organisations must make a clear, compelling case to the public that emphasises the security and safety gains of AIDC, and specifically for RFID if this technology is to be generally accepted. Considering the highly sensitive nature of medicines and healthcare, the privacy issue cannot be ignored.

This variable can greatly influence more rapid adoption as technology providers and integrators, along with market players, put real pilots and capabilities in place that aim to test and solve, among other issues, questions around performance across different packaging and product forms, security, encryption, frequency, etc. It is only through practical, real-world experience that the technology performance and reliability in large-scale deployments can be "proven." As with any emerging technology, solution providers should compete based on performance, price and availability, while planning for flexibility, because the standards and requirements will continue to evolve (e.g. EPC number format, regional needs).

Lastly, cost and performance must be properly balanced and aligned. Real, bottom-line benefits can be gained from enhanced supply chain visibility and security. They include faster stock turns, reduced inventory costs, optimised partner relationships and reduced risk.

8. The Pharma Traceability Pilot

8.1 Objective

How we intend to address the above challenges

Project Description

- To implement a traceability system to increase patient safety in the branded and generic pharma supply chain for all types of pharma products.
- To clearly demonstrate a business case and the feasibility, cost efficiency, and interoperability of the technology suite, regardless of:
  - Pharma product packaging level and product type
  - Serialised data tag (RFID or 2-D barcode)
- To adopt the operating principles of:
  - Use of open, interoperable and global industry standards based on the GS1 System of standards
  - Speed to result – 15 month timeframe for pilot completion

  - Development of a clear business case for each participant
  - Openness and experience sharing with all interested parties
  - Practical and manageable scope.

- To provide a means of automatically/efficiently authenticating data provided by supply chain partners and to verify the integrity of this data at each stage and for 100% of the items - and that the source of the data can be traced with total certainty to a legitimate, licensed operator in the pharmaceutical supply chain
- To implement a data confirmation solution at the product packing points to ensure that unique data has been applied to each pack.
- To implement a method of publishing the unique data for each pack to a secure external system at the point of shipment
- To provide a means of scanning / electronically reading the product at each transactional nodal point within the supply chain (contract packer, pre-wholesaler, distributor, hospital pharmacy).
- To provide a means of tracking product and maintaining relevant data relating to the item in a remote, secure location, such that life history and authenticity of goods can be assured.

Potential Benefits

- Patient safety enhanced as 'business as usual'
- Enhanced brand image and protection, secure consumers' and regulators' confidence in safety of the supply chain
- Efficiency through hands of management in relation to: Receive – Store – Pick – Ship, processes
- Delivery of a practical demonstration of the Pharma Safety Chain industry vision as an effective anti-counterfeit measure
- Identification of the business case for each supply chain participant
- Demonstration of the feasibility of an epedigree technology suite for branded and generic pharma products at all packaging levels
- Establishes the building blocks for the integration of traceability data to patient administration and back-office systems for further patient safety and supply chain efficiency gains
- Provision and demonstration of a technology platform to support the secure and scalable sharing of data among the supply chain participants in a pilot scale, but one that can migrate to full 'market wide' implementation
- Development of a benchmark for the pharma sector for the adoption of AIDC techniques, including RFID, enabling full traceability and electronic pedigrees for medicines with the potential to effectively integrate to patient-care and administrative systems leading to even greater benefits for improved patient safety and supply chain efficiency.

8.2 Timing

The current market interest in the pharma sector in the use of AIDC techniques, traceability systems, electronic pedigree information and the need for urgent action to exploit these for improved patient safety and reduced risk has never been higher. Questions are outstanding on the use and potential benefits of RFID. The pharma sector requires technology-based solutions that address the real market need in the short term – a window of opportunity to establish a benchmark for the European sector therefore exists; but not for long.

Accordingly, the timescales for this Pharma Traceability Pilot have been established to reflect the urgent requirement. The intention is, therefore, to prosecute the project with pace in the collapsed timescales of approximately 15 months duration (commencing July 2006).

We see five phases to the project as follows:-

- Phase 1: Analysis phase, months 1-5
- Phase 2: Design phase, months 3-7
- Phase 3: Build phase, months 6-9
- Phase 4: Test and Report phase, months 10-15
- Phase 5: Marketing & Information Dissemination phase, from month 14

9. Summary

Challenged by the significant numbers of errors made in the administration of medicines, many of them causing patient harm and even death, exacerbated by the increasing risk of counterfeiting activity and with it the inevitability of regulation, the European pharmaceutical sector must create a robust model that can demonstrate advanced supply chain security for improved patient safety and greater efficiency. Several factors must be balanced, including the necessity of ROI, collaboration with business partners and governing bodies and the need to establish standardisation and compliance rules.

The largest concerns are the risk of doing nothing, and allowing squabbling about standards or the funding of pilot programs to lead to ongoing delays. Technology maturity – a concern closely linked to overall costs – is another top concern. There is much work to do in the near term - by demonstrating leadership and collaboration today, the sector can then expect to reap future benefits beyond the improved supply chain security and patient safety.

The Pharma Traceability Pilot, BRIDGE WP6, will set the way forward for the pharma sector to exploit technologies available today to ensure correct product identification / administration and counter the threats in the form of counterfeit products in the short-term; but, moreover, will lay the foundations for systems bringing even greater benefits for improved patient safety and supply chain efficiency in the medium to longer term.

10. Appendices

10.1 References

Some Papers relevant to the subject of patient safety, counterfeit and counterfeit combatance are listed below in (no priority order):-

"*Combating counterfeit medicines and protecting patients through a partnership approach*" published by EFPIA (European Federation of Pharmaceutical Industries and Federations), dated May 2005

"*Counterfeit Medicines*", published by World Health Organisation in Fact Sheet No. 275, dated February 2006

"*EU Guardian Working Group Report*", published by Unisys, dated April 2006

"*Counterfeit Medicines in less developed countries – problems and solutions*", published by International Policy Network, dated 2006

"*Pre-Report to the feasibility study on a Council of Europe Legal instrument*", published by Hugo K. Bonar, European Committee on Crime Problems, dated June 2006

"*Industry welcomes new EU-US joint strategy to fight soaring trade in counterfeit and pirate goods*", Press Release published by a number of key stakeholders in the pharma industry (including ACG, AIM, APM, BSA, EFPIA, GMA, BASCAP, IFPI, IFSP, IMPA, MPA, UNICE and others), dated June 2006

"*FDA Drug Safety Task Force Report – 2006 Update*", published by the FDA Counterfeit Drug Task Force, dated June 2006

"*Combating counterfeit drugs – a report of the Food and Drug Administration annual update*", published by the FDA Counterfeit Drugs Task Force, dated May 2005

"*Countering counterfeit drugs – a report of the Food and Drug Administration*", published by the FDA Counterfeit Drugs Task Force, dated February 2004

"*Underpinning Patient Safety*", published by the Pharmaceutical Supply Chain Working Group (PSCWG), dated December 2004.

"When medication errors happen", published by Bates et al JAMA 1998. 280 No. 15 (21 October)

"Spoonful of Sugar", published by Audit Commission (UK), dated December 2001

"Organisation with a Memory", published by the Department of Health, dated 2000

"*To err is human*", published by the US Institute of Medicine, dated 1999

10.2 Recently published BBC article - medication errors in the UK

NHS drug error 'crackdown' urged

Hospitals have been told to do more to cut out medication errors after figures showed 40,000 mistakes a year are made.

Most errors caused no harm, but 2,000 led to moderate or severe harm, or death, as in 36 cases.

The Healthcare Commission urged the NHS to improve how it prescribed and dispensed drugs as it published ratings for all 173 hospital trusts in England.

The watchdog classed 85 trusts as fair or weak. NHS chiefs said hospitals needed to be honest about the problems.

The medication errors figures, given to the Healthcare Commission by the National Patient Safety Agency NPSA, cover incidents in England and Wales the 12 months to July.

> **The only way the service will achieve real improvements for patients is by being frank about the problems and challenges that it faces**
> Maria Nyberg, of the NHS Confederation

They showed about 80% caused no harm, 15% low harm and 5% moderate or severe harm.

Only 18 trusts in the watchdog's review of medicines management were rated as excellent, while 70 were good, 73 fair and 12 weak.

The Healthcare Commission said more needed to be done to discuss side effects with patients, to give out written information as required by law, and to minimise risks from injected drugs.

Trusts were measured in 21 areas, including whether patients had had a comprehensive medicines review and if they had a complete medicine record for their stay in hospital.

The review did find areas of good performance, including 40% of trusts prudently using antibiotics to help cut MRSA rates.

But the watchdog said there was a need for improvement, including making sure patients understand the purpose and potential side effects of medicines.

The report said pharmacists also needed to spend more time on the wards to minimise errors, with 11 of the 12 trusts that scored weak overall performing poorly in this area.

Other areas needing attention included hospital patients not being given control of their medicines, even though they managed perfectly well at home - 69% of trusts said this was not possible on a fifth of their wards.

Parkinson's disease

Parkinson's disease patients were cited as a group who often preferred managing their medication as timing of dosing is vital.

Commission chief executive Anna Walker said while many trusts were getting the basics right, there was still "some way to go when it comes to involving patients in decisions about medicine".

"Trusts need to do more talking to patients about their medicines and their potential side effects.

"They need to make sure patients feel empowered to discuss any concerns."

Steve Ford, chief executive of the Parkinson's Disease Society, added: "Difficulties could be avoided if ward staff had a better understanding of the condition and of why the timing of Parkinson's drugs is crucial."

Maria Nyberg, policy manager at the NHS Confederation, which represents NHS trusts, said there were some examples of good practice, but the publication was a positive as "identifying weaknesses or problems" helped to tackle them.

"The only way the service will achieve real improvements for patients is by being frank about the problems and challenges that it faces."

And a Department of Health spokeswoman added: "Hospitals are working very hard to ensure that patients are getting the most from their medicines. "There is, however, room for improvement in some areas."

The NPSA said the number of medication errors and deaths should be seen in the context of the 1m people seen by the NHS every day.

Story from BBC NEWS:
http://news.bbc.co.uk/go/pr/fr/-/1/hi/health/4780487.stm
Published: 2006/08/10 23:05:00 GMT