![efpia — European Federation of Pharmaceutical Industries and Associations](logo)

Towards safer medicines supply

A vision for the coding and identification of pharmaceutical products in Europe

Business Case

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Abstract

The pharmaceutical supply chain in Europe has become increasingly complex, with billions of medicine packs moving around the EU each year. Its fragmentation as well as the overwhelming growth of wholesaler intermediaries and traders involved in the European flow of medicines have resulted in a decreased transparency of the supply chain, and an increase in the difficulties to track and trace medicines. In addition, recent cases relating to counterfeit medicines have shown that integrity of the supply chain in Europe is at risk.

Against this background, national requirements governing the identification and traceability of pharmaceuticals have become a growing trend in Europe.

However, there currently exists no industry recognised standard for the identification and coding of pharmaceutical products. Instead, there are an increasing number of different local coding systems being implemented or proposed across Europe, which only contributes to the increased fragmentation of the supply chain.

It has therefore become clear that an integrated approach to tackling the supply chain problems has become essential. This has led the research-based pharmaceutical industry, through EFPIA, to recommend the implementation of a standardized and unique coding solution for medicines at European level.

The key to delivering a successful product security solution will be to work together with all parties holding stakes in the identification of medicines (i.e. pharmacists, wholesalers, manufacturers, governments, EU Authorities, etc) to deliver an adequate legal, political and operational framework to support the integration of a technology system at the European level, which has the support of the national and EU authorities.

The proposed system relies on product being coded at the pack/dispensing unit level in a manner that is common with other products used within the same territory and unique among all products. This will be accompanied by the development of an end-to-end product verification process at pharmacy level that could help to significantly address these patient safety problems and improve the security and integrity of the supply chain.

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1. Problem Statement

1.1 The European distribution environment

The pharmaceutical supply chain in Europe has become increasingly complex, with billions of medicine packs moving around the EU each year. Its fragmentation as well as the overwhelming growth of wholesaler intermediaries and traders involved in the European flow of medicines have resulted in a decreased transparency of the supply chain, and an increase in the difficulties to track and trace medicines.

Furthermore, the growing problem of counterfeiting raises a significant threat within the current supply chain system. Whilst it is difficult to obtain accurate data on the scale of the phenomenon, the World Health Organisation (WHO) estimates that 8-10% of the global medicine supply chain could be counterfeit, rising to 25% in some countries[1]. Fake products are encountered at all stages of the supply network: manufacture, distribution and entry through wholesalers, pharmacists, black market and the Internet. They tend to originate mainly from non-EU countries. The lack of integrity in the supply chain is seen as a facilitating factor for entries of counterfeits and the lack of transparency does not enable to identify the clear extent of the problem.

Parallel trade also negatively affects the integrity of the supply chain and gives rise to unnecessary safety hazards. By definition, parallel trade leads to an increased number of intermediaries and to the repackaging of vast volumes of medicines. Parallel trade adds to the complexity of the supply chain as evidence shows that medicines can travel through as many as 20-30 pairs of hands before it finally reaches the patient[2].

1.2 Coding and identification of medicines in Europe – the status quo

Against this background, Member States' requirements governing the identification and traceability of pharmaceutical have become a growing trend in Europe. Initially, codification for pharmaceutical products was mainly used by manufacturers, wholesalers and pharmacists, for the management of trade flows and other logistical purposes. Today, the scope of codification systems has widened and is not restricted purely to logistics. Many national authorities have adopted a codification system for public health reasons (recognition of all presentations available on the market without any ambiguity) but also for administrative reasons, enabling a variety of control measures such as the authorities' desire to combat frauds and to prevent illegal reimbursement activity, as well as better dispensing accuracy and the possibility to facilitate an authentication system in the framework of a 'quality assurance system'. The idea of tracking and tracing pharmaceutical product has become an important element of the overall strategy by many national authorities to tackle the problems caused by counterfeit medicines and increased lack of transparency in the supply chain.

However, currently there exists no industry recognised standard for the identification and coding of pharmaceutical products. Instead, there are an increasing number of different local country coding systems being implemented or proposed across Europe by Governments (e.g. Belgium, Italy, Spain), each with its own objectives and motivation. In addition, various interested parties are promoting other technologies and solutions across the supply chain.

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[1] http://www.who.int/mediacentre/factsheets/fs275/en/
[2] IMS, June 2004

A study conducted by EFPIA has shown that in the majority of countries in Europe, codification has evolved on a national basis, either voluntarily to facilitate product distribution, or compulsorily in response to some legal requirements. As a result, codification systems for proprietary medicinal products vary from one country to another characterized by different code structures and bar code contents, since it corresponds in most cases to the (exclusively national) number for the identification of proprietary medicinal products.

Figure 1. National Coding Systems throughout Europe
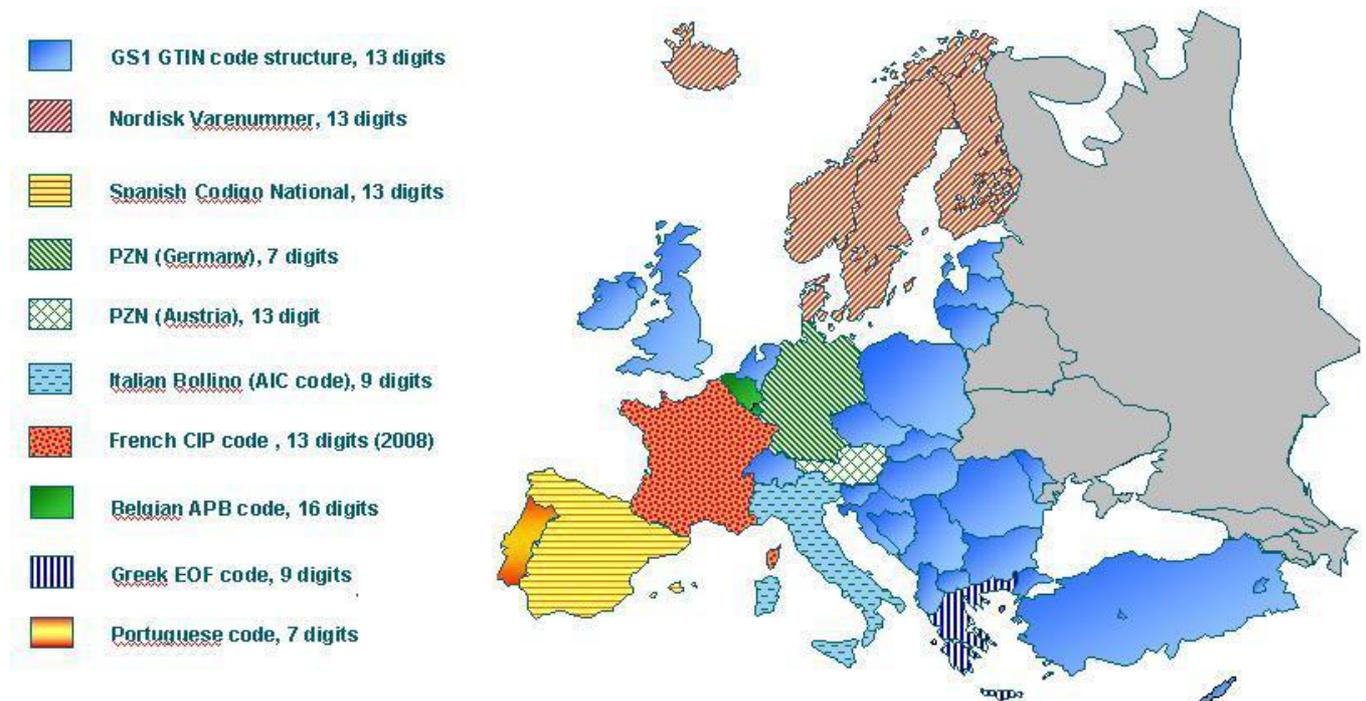
As illustrated in Figure 1:

- A majority of European countries use the internationally accepted EAN system managed by GS1 and have opted for the full EAN 13 code structure. This is the case of the UK and many of the central and eastern European countries. Other countries have adopted their own product identification number, which corresponds in most cases to an exclusively national number for the identification of proprietary medicinal products. While some countries have opted for their own code structure, others have incorporated their national product identification number into an EAN compatible code structure with product identification number allocated by a number bank or an external agency for the coding of pharmaceuticals (e.g. France and Scandinavian countries)

- The physical placement of the code is not identical in all cases: it is either displayed directly on the external packaging, on an adhesive label (e.g. France, Greece), or on an adhesive label consisting of special paper delivered by the authorities (e.g. Italy).

- In three countries, (i.e. Belgium, Greece and Italy), the authorities have mandated the use of a unique serial number within the code that will identify each pack uniquely in order to facilitate a traceability system. Thus, two packages of the same presentation will have two different codes and can be distinguished in order to control reimbursement fraud and to monitor consumption and expenditure.

As a result, the integrity of the medicines supply chain is continuing to fracture and opportunities to improve patient safety at a European level and enhance the control of the supply chain are being lost, while the multiplication of systems adds incremental production costs for manufacturing and increases further both the complexity and differentiation across the European market.

It has therefore become clear that an integrated approach to tacking the supply chain problems has become essential. This has led the Research-based Pharmaceutical Industry, through EFPIA, to recommend the implementation of a standardized and unique coding of medicines at European level that would help significantly to address patient safety problems and improve the security and integrity of the supply chain.

Following this recommendation in February 2006, the EFPIA board decided to take action to move ahead with the implementation of a coding proposal for pharmaceutical products, harmonized at the European level, so as to better meet the needs for patient safety, and supply chain security, tracking and logistics.

The key to delivering a successful product security solution will be to work together with all parties holding stakes in the identification of medicines (i.e. pharmacists, wholesalers, manufacturers, governments, EU Authorities, etc) to deliver an a adequate legal, political and operational framework to support the integration of a technology system at the European level, which has the support of the national and EU authorities.

In order to obtain key stakeholders support and progress the project in coordination with its supply chain partners, EFPIA set up in September 2008, a Steering Committee involving the European Association representing pharmacist (PGEU) and the European Association of full line wholesalers (GIRP). EGA, the European Generic Medicines Association, also participates in the Steering Committee as an observer.

2. Project Overview

2.1   Objectives

Patient safety is a primary focus for all aspects of the modern healthcare industry. There are numerous aspects with modern healthcare provision that can be improved by the application of appropriate technology.

The system proposed by EFPIA has the primary purpose of pharmaceutical product verification. Product verification provides the various system stakeholders with increased risk management capabilities that enhance patient safety by increasing the likelihood that the product dispensed to patients is both genuine and appropriate.

EFPIA has considered that there are two points where one needs to know that the product is safe. That is, when it goes into the supply chain and when it comes out of the supply chain. The system EFPIA proposes will verify the authenticity of each product at the point of dispensing (pharmacy level).

Figure 2. End-to-end product verification
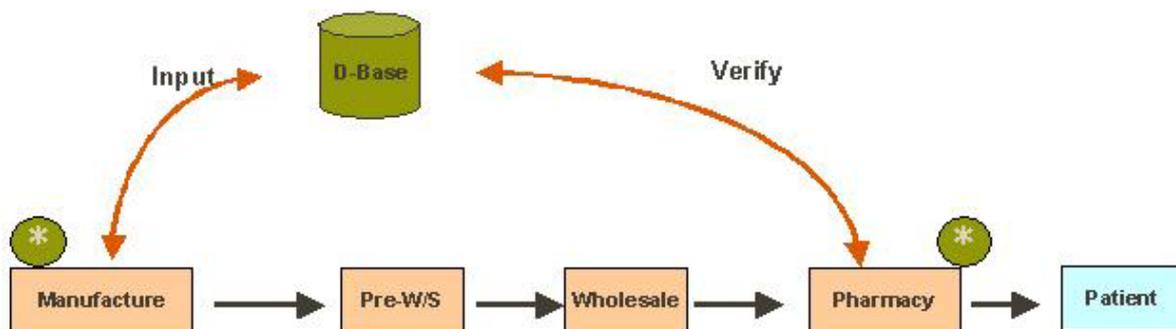
Being able to check the product 'status' at the point of dispense allows manufacturers to automate currently challenging processes such as product recall.

The system relies on product being coded at the pack/dispensing unit level in a manner that is common with other products used within the same territory and unique among all products.

Ideally the system would employ a common European product-coding standard in order to capture the cross border trade element of the current European supply chain environment. An important element of the project will be to attempt to harmonise coding systems across Europe. In order to do so, the instauration of unique coding standard for pharmaceutical products will be necessary.

2.2 The EFPIA Proposal

The project consists in two distinguishable parts:

2.2.1 <u>A unique coding standard</u>

In February 2006, the EFPIA Board recommended the adoption of a unique standard for the coding of pharmaceutical product across Europe based on the **2D (2 Dimensional) Data matrix ECC-200** to be introduced on <u>all secondary packaging of reimbursed products sold in Europe</u>.

EFPIA considers this to be the most effective and technologically sound system for the present time. However, the adoption of a '2D Data Matrix' system does not prevent the adoption of other technologies such as RFID (Radio Frequency Identification) at a latter stage, nor does it represent a double cost.

Figure 3.

2D Data Matrix ECC-200

Experience with RFID has shown that the technology is not workable at present. Reliability issues, lack of standards and unaddressed privacy and security issues have made RFID unsuitable to handle the identification of sensitive products such as medicines.

However, EFPIA recognizes that RFID has many significant benefits and would certainly be a natural progression of the system. In this respect EFPIA is participating in the RFID Stakeholder Group set up by DG Information Society (European Commission) to progress legal and operational issues relating to RFID.

2.2.1.1 Content of the bar code

The EFPIA recommendation for coding of pharmaceutical products is to encode in a 2D Data matrix barcode with four items of data. The preferred code structure would utilize the GS1 standards and in particular would make use of the AI (Application Identifiers) already in use throughout the supply chain today. The EFPIA preferred structure uses only four of the many AI's available to define the product code, the serial number, the expiry date and the batch code. These are arranged in a code as follows:

- The <u>product code</u>, referred to as a **GTIN**, uses the AI of 01 and is a fixed field length of 14 numeric digits.

- The <u>serial number</u> uses the AI of 21 and is a fixed field (in the EFPIA recommendation) of 20 numeric digits non-zero leading (i.e. the first digit cannot be a zero).

- The <u>expiry date</u> uses the AI of 17 and is a fixed field of 6 numeric digits in the predefined format of YYMMDD (Year=YY, Month=MM and Day=DD).

- The <u>batch code</u> uses the AI of 10 and is a variable length field, up to ten alphanumeric digits in length and is always placed at the end of the code structure.

2.2.1.2 The GTIN (Global Trade Item Number)

The GTIN (Global Trade Item Number) is the preferred option for a product code structure, which can unambiguously identifies each presentation available on the market. The GTIN is a 14 digit number code assembled according to GS1 standards and is a combination of the Company Number (Manufacturer Code) and the Article Number (Product Specific Identifier).

The main advantage of the GTIN is that it delivers trade item data in a consistent format and structure and more importantly for this project, allows the manufacturer to be determined. It employs the globally accepted and utilized EAN/UCC System whose language is understood by the global marketplace. It is managed by GS1, a non profit and neutral organisation who has taken a leading role in establishing a global multi-industry system of identification and communication for products, services and locations based on internationally accepted and business led standards.

The GS1 standard is already used by a wide range of sectors including pharmaceuticals at the consumer unit level and over the counter (OTC products) in a majority of European Countries. Many already widely used GS1 code structures such as the EAN 13 are compatible with the GTIN, which would facilitate its transition.

The GTIN is particularly well suited to meet the needs of a verification system at the point of dispensing, as it identifies the manufacturer directly, contains a manufacturer allocated product identification number linked to product information databases. It is therefore also well suited to enable a tracking and tracing system in the future. It can also be carried on any type of data carrier, including the EFPIA recommended data matrix ECC 200 or a Radio Frequency Identification tag, on the specific product or packaging.

2.2.1.3 Integrating local national systems

As already pointed out, most European countries hold their own coding and identification systems. Each of these systems meet the requirements imposed by the nature of these products and by each national mechanism, which are an integral part of arrangements for reimbursement by each country's health insurance funds. EFPIA recognizes the importance of harmonization as a general aim, but wishes to see standards properly incorporated into existing national regulatory frameworks.

It is therefore important to note that any proposal to harmonize the codification of medicinal products must, of necessity, take account of the special nature of the pharmaceutical industry and the existing codification schemes in European countries. It is foreseen that National codification schemes may have to be retained in the short term until a full comprehensive harmonization strategy should incorporate them as fully and elegantly as possible, to minimize change and disruption.

2.2.2 A product verification system at the point of dispensing

The system proposed by EFPIA is intended to be an <u>end-to-end</u> product verification process. Product verification is defined as the action of comparing the data held within the product code with a secure product record on a database and confirming that:

a) The product record exists and matches the data held on the product itself;

b) The product record has not been previously marked as 'dispensed';

c) The product record does not contain any warnings or advisory notices (such as recall, on-hold, etc).

Product verification does not guarantee the genuine nature of the product contained within the coded product pack. What it does is to provide a mechanism whereby product information such as expiry and batch codes can be determined, and duplicate instances of product code (implying an error condition) can be detected prior to widespread proliferation of a potential problem, such as counterfeiting or tampering.

Crucial to this proposal is the mechanism for the use of a **random number identifier** for each secondary packaging unit distributed and dispensed across Europe, which, in combination with a product code, uniquely identifies that individual pack and also its manufacturer.

This number identifier is sometimes referred to as a unique carton or pack number, or, as in this paper, and more commonly (though in some sense not strictly correct), as a serial number, and the process of generating and applying codes is called **mass serialisation**. This is the means whereby the identification and verification at individual pack level across the entire supply chain can be made, and therefore key to the solution for improving transparency and patient safety, and helping to fight serious problems like counterfeiting, reimbursement fraud and errors in dispensing as discussed above.

2.3   System Architecture

The proposed system is designed as an end-to-end product verification process. Product will be uniquely coded at the patient pack level by the manufacturing organisations and each item will be subsequently checked by each dispensing pharmacist.

Figure 4. EFPIA Proposal
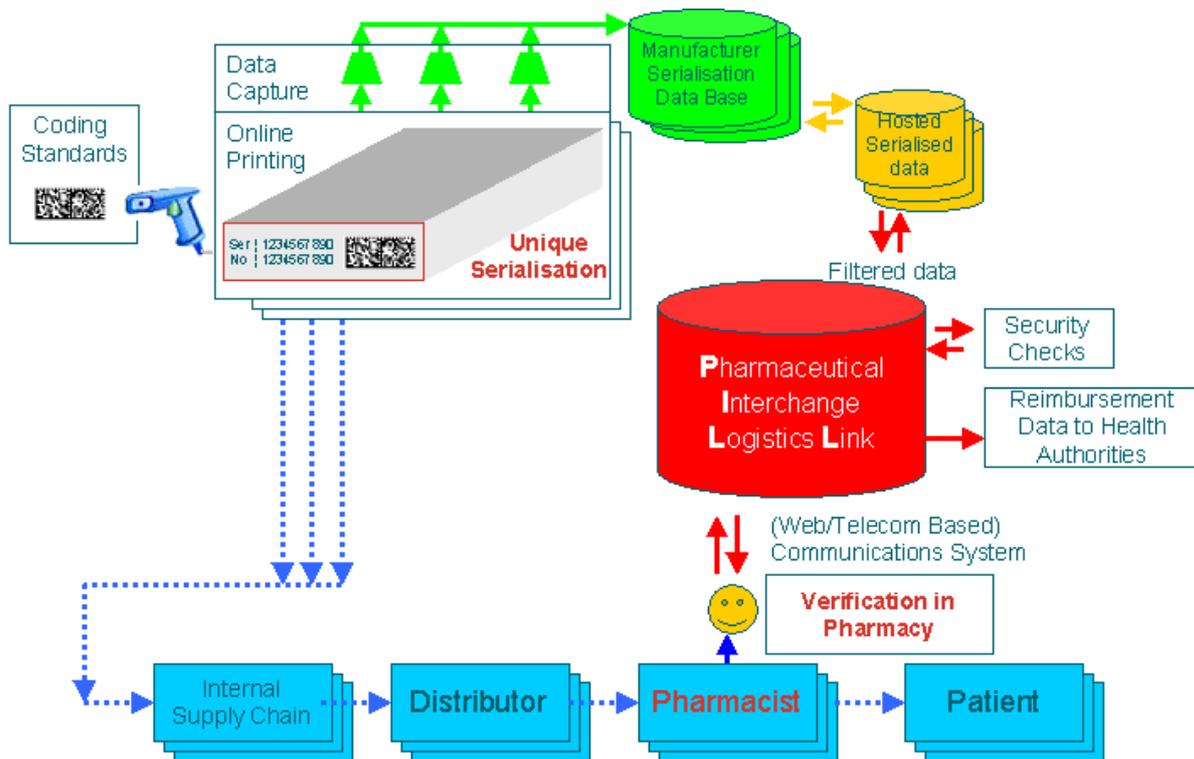
Just prior to the product being handed to the patient, each product that forms a prescription will be scanned and the system requested to check the product code validity. The system will, on receipt of the product code data, perform a number of key tasks:

1. First it will check the product code data against records held to confirm that the status of the product is acceptable. This will be done using Web-based or telecommunication links. The data in the code is transmitted via a data interchange network and crosschecked with the relevant manufacturer's product serialisation.

2. If acceptable, the system product record will be amended to show that the product has been dispensed and also the record will be amended to show which pharmacy client system dispensed the product.

3. Once the product record has been updated, a response will be formulated by the system and returned to the originating pharmacy system to inform the pharmacist that the product is acceptable and may be dispensed.

Additional features:

1. Reimbursement by national health authorities

An extended feature of the vision, which this system opens up, is the electronic relay of the information of the dispensing activity (plus e.g. other prescription information to the relevant National Health Service Department as required) and used for reimbursement purposes.

2. Data Provision

Each pharmaceutical manufacturer will collate all the data imprinted in the 2D data matrix for all of their packs (together with other identifying data) in a database system. This will enable the serialised data to be subsequently hosted for querying at the verification stage described below. For security reasons, the information in each hosted database set will remain the confidential property of the corresponding pharmaceutical company. However, verification requests of end users will be processed on demand.

3. Possible extension to track and trace capabilities

The proposed system design is not intended to support track and trace capabilities for the time being, however it is intended that the system be extended in a second phase so as to add information on movement of products by distributors using the same data interchange network, thus building up pedigree or full track and trace records.

2.4 Project scope

The system proposed by EFPIA is intended to be a harmonised one across the whole of the European Union. However, there is no reason why it cannot be implemented globally. Nevertheless, it is particularly suited to countries with a national reimbursement process.

The project scope covers the use of coding in relation to:

- Packaging by the manufacture,
- Verification,
- Dispensing by a pharmacist, and
- Reimbursement by national health authorities

The codes provided can be used to enhance patient safety in medicine administration, but the specific development of such systems, though facilitated, is not included in the scope.

Coding and identification is at individual secondary pack level (e.g. for tablets or capsules, a carton containing one or more blister strips). Included is the technical specification for the code in terms of both application and use.

Code database and information interchange systems between manufacturer, pharmacist and national health authority are also an integral part of the system. The proposal must be

extendable to include tracking and tracing throughout the distribution chain but in this phase, only the beginning and end stages are covered.

2.5   Central database and system Governance

The central piece of this IT infrastructure is a stratified central database system known as the 'Pharmaceutical Interchange Logistic Link' (PILL), the unit segregating the data transactions by manufacturer and linking back to the respective company product database

Agreement on structure and data ownership of the 'information/ data interchange systems' still needs to be agreed but will most likely require to be managed by an independent body. This will require the set up of a non-profit organization that will manage the day-to-day operations of the system.

It is foreseen that, in order to maximise the benefits to all parties and facilitate the smooth implementation of the system, the organization would be governed by a central, independent, non-profit organization governed by its stakeholders. This could involve all supply chain partners i.e. industry, wholesalers and pharmacists (e.g. CIP/ GERS model in France or IfA in Germany) but could also accommodate the integration of other parties such as the reimbursement authorities or data or market intelligence organizations.

Stakeholders can organize themselves country by country (i.e. CIP/GERS model in France) or on a pan-European level. An investment programme will therefore be necessary to implement the recommended system although it is foreseen that a self-financing mechanism could be set up through the establishment of a system allowing the neutral release of sales information based on regional data in return (not individual pharmacy information). The precise structure of the governance model will have to be defined according to the various stakeholders' requirements.

3. Business Impact

3.1 Key benefits

Aside from meeting its key objectives, offering a more secure, effective and efficient supply chain, with a better control on the medicine's location and greater protection against fraud and counterfeits, the proposed system has a number of additional benefits.

The verification process has the potential to facilitate and assist pharmacists in the avoidance of dispensing errors and the elimination of counterfeit medicine, while at the same time being incorporated in improved inventory management to facilitate product recall procedures.

An additional by-product of the system will be better and detailed supply chain data, which will become available to individual pharmaceutical companies. The value of this data can help in part to offset the high cost of introducing and operating the EFPIA system as discussed below.

3.2 Costs

This proposal will attract costs and resource needs for all those involved in order to achieve the various benefits in particular patient safety. It is difficult at this stage to quantify cases until further project specification will come in play. However, the following preliminary cost estimates can be provided but should be regarded as rough guidelines of the overall cost according to three main categories of expenditures.

1. Installation cost of data matrix "printing" & reading equipments + line data collection + products serialization database (costs for Industry)

    - ~ 50,000 –100,000 € / lines x 3,000 – 6,000 line
    - Altogether ~ 150 - 600 million €

2. Installation cost of 2D data matrix readers and software upgrade (costs for pharmacies)

    - ~ 1500 € per pharmacy (~ 300 € - 400 € / reader)

3. Cost of running/using data interchange network for verification of serial number at the dispensing point (& database update)

    - ~ 0.01- 0.02 € / pack (preliminary estimate)

It must be noted that comparatively speaking, it will be significantly less costly than systems involving expensive new technologies such as RFID, and, being based on proven technology, significantly more reliable. Also, this standardized system can be expected to be significantly lower in cost both in terms of implementation and operation, and higher in efficiency and effectiveness compared to implementing several different systems at European level. In any case the costs of inaction will far exceed the cost of implementation of the system in medium and long term.

EFPIA therefore firmly believes that its proposed system is the most cost effective option to deliver real significant net benefit to all the main stakeholders, and most importantly will enable significant improvements in patient safety to be realised.

3.3 Impact on Stakeholders

While the individual elements of the project are technically proven, the challenge, however, lies in bringing together the component parts to form a reliable and secure integral system that includes the requirements of all parties involved. A careful consideration of all the project's stakeholders is therefore a critical element to success. An outline of the main benefits and costs to the three main stakeholders – Member states, Pharmacists, and Wholesalers is given below.

3.3.1 Pharmacists

The interaction of the pharmacists with the proposed system is vital to the overall success. If the processes adopted by pharmacists differ significantly from that undertaken across Europe today, there is a significant risk that system adoption will be slow and could potentially fail. Therefore, one of the critical requirements will be that the interface between the system and the pharmacist has to be simple to use and offer benefit to the pharmacist as a means to encourage adoption.

Benefits

It is the intention of this system that the process of product authentication be undertaken by the pharmacy during the initial stock check-in process. It is an optional process but one which offers significant benefit to the pharmacist in terms of stock control and inspection. By undertaking the verification check at the point where new stock is introduced to the pharmacy, most error conditions can be detected before the pack is dispensed to a patient. The authentication process will allow the pharmacy staff to better assure the validity and compliance of stock held. The data ascertained from the authenticity process can be fed directly into leading pharmacy stock handling systems that rely on the product article code or product local drug code to operate. The process of authentication will further enhance the possibilities offered by pharmacy stock handling systems by automatically making the product expiry date and batch code available.

Costs

For pharmacists and hospitals, there will be two mains areas of costs. Firstly, the initial purchase of 2D matrix readers and installation/modification of related software. With mass use, one can expect the price of such scanners to fall to levels close to that of current linear code scanners. Secondly, there may be a contribution to the cost of running/ using the data interchange network.

3.3.2 Member States Health Authorities

An extended feature of the vision, which this system opens up, is the electronic relay of the information of the dispensing activity (plus e.g. other prescription information) to the relevant National Health Service Department as required and used for reimbursement purposes.

Reimbursement is the mechanism used by most EU Member States to provide financial provision for the dispensing pharmacy (be this retail or healthcare authority based). The reimbursement systems in use are generally heavily manual in nature and fraught with potential for error and misuse. Numerous Member States' healthcare authorities are investing in sophisticated IT systems to assist with the task of efficiently processing dispensing claims.

<u>Benefits</u>

A future benefit of the system is that data collected from the pack can be used to provide an enriched item identification system for use within reimbursement. The EFPIA system would also facilitate the tie in of dispensing information with national systems for healthcare data management.

Additionally, it is the national health systems that bear the brunt of the costs associated with dispensing errors. By helping to reduce these errors both in pharmacy dispensing and hospital administration, the EFPIA proposal will serve to reduce national health system costs and more importantly improve patient safety.

Similarly, patient safety will be improved by more efficient recall procedures, as any recall notice registered in the system will effectively block further dispensing of any recall product.

<u>Costs</u>

There will be administration costs for operating the EFPIA system. However, since precise, verified and accurate data on dispensing is transmitted by the system, it can realistically be expected that such costs will be offset by lower administration costs compared to current systems and elimination of reimbursement irregularities. For example, current paper systems can be eliminated in the long term.

3.3.3   Wholesalers

The proposed system is defined as an end-to-end product verification process and will therefore not have a direct impact on wholesalers operations. However, one element of the requirement of the proposed system will not support a full track and trace capabilities from the start. The system is scaleable, interoperable and can be extended to full track trace capabilities in the long term.

<u>Benefits</u>

In the short term, the system as currently being proposed will greatly facilitate product recall procedure, which wholesalers are heavily involved in.

In the long term, with evolution of the system to a track and trace capabilities, it will allow wholesalers to check that medicines are safe and will provide reassurance that their customers are getting the best and safest products.

3.4   Initial risk considerations

The EFPIA proposal as a whole is clearly a major innovation and is therefore an ambitious project that has the potential to bring significant benefits to a number of parties. The section below identifies a number of key concerns and challenges identified and a proposed approach to address them.

Initial investigation has not brought to light any technical reason why the EFPIA proposal could not be made to function as required. Its individual elements are technically proven either in the pharmaceutical industry (e.g. online printing and data collection) or in other industries (the analogy with the credit/cash card information interchange system has already been mentioned). The challenge is therefore in the putting together the component parts to form a reliable and secure integral system.

For the system to be capable of discharging its primary functions, it is essential that the architecture and design be such that reliability is assured. With this in mind, the system will

be designed and implemented using industry best practices. Potential vendors will have to show evidence of system design control and quality controls that are appropriate to software and system design. A detail 'user requirements specification' document will be released allowing us to subsequently solicit proposals from prospective service providers

At the heart of the security of the system lies the original manufacturers secure random unique serial number. Original pack dispensing retains this code for the verification in pharmacy process. Removing or interfering with manufacturers original packaging has now become common practice as parallel trader's repackage and over-label medicines. These practices may have to be reviewed with the introduction of a new, safer medicines verification system.

4. Project Development

4.1 Project Development plan

The EFPIA proposal is an ambitious long-term project. It is expected that the project will be fully implemented throughout the whole of Europe in the medium/longer term. The project deployment will have three main phases:

- A pilot experiment (focusing on a specific European region);
- A nationwide deployment of the pilot experiment in the given country where the pilot was implemented;
- A full European wide implementation rollout.
  The full implementation is expected to commence during 2009 and to be phased over a five-year period implementing the system on a European country-by-country basis.

4.1.1 The pilot experiment

In May 2007 EFPIA set itself the objective of implementing a pilot experiment in order to demonstrate the feasibility of a comprehensive system for the verification of individual pharmaceutical products at the point of dispensing.

The pilot, planned for Q4 2008, will focus on a single European location at a regional level. Current assumptions for the pilot are:

- A maximum pilot size of 200 pharmacy outlets;
- Allowance for up to 1 million line item packs to be individually coded;
- A single, hosted server system to provide most of the functionality required for the main pilot and its full implementation.

The system will demonstrate the capability to operate using specified performance criteria.

4.2 Recommandations

4.2.1 Technical solutions

A technical development programme should be implemented under EFPIA's leadership, which will pull together:

(i) Guidance and standards on coding and printing;

(ii) Development work (including evaluation of studies already carried out by others and pilots where judged necessary) to demonstrate the process and operation of an integral system, leading to a complete user requirement definition for the Manufacturer-Pharmacy-Government data interchange network and its interfaces, along with a proposal for its governance, and

(iii) Specifications for related hardware and software e.g. suitable scanners, their firmware, and software to integrate with pharmacy systems.

4.2.2 Dialogue with stakeholders

Alongside the technical programme, it is recommended that EFPIA customize its concept to national & European needs. A dialogue with each of the main stakeholders i.e. governmental (at Member States and European levels), pharmacy, and manufacturers, should be executed in parallel. Each of these are aimed at leading to mutual agreement on the coding system for Europe, along with the actions and regulations required for its implementation, and an agreed timetable. In addition, a dialogue is being initiated with wholesalers/distributors with regard to their engagement on subsequent full track and trace systems.

5. Conclusion

EFPIA and its members are committed to improve the safe supply of medicines to patients. Recent studies on dispensing and dosing errors, reimbursement issues, and cases of counterfeits in the legitimate supply chain have highlighted a lack of transparency in medicines supply and inability to authenticate a medicine's origin.

The introduction of a unique code for each medicine together with a system of verification at the point of dispensing, alongside with measures to protect a medicines' integrity, would allow all stakeholders to check and authenticate a medicine and trace its origin back to the original manufacturer.

The EFPIA proposal is an ambitious long-term project but represents an achievable, effective and efficient solution for delivering much needed improvements in patient safety at a European level while delivering a concrete response to various governments' proposals for specific national coding solutions.

The project is expensive and will require significant investments but it must be noted that the cost of non action may be significantly greater if faced with an increasing number of national coding solutions that increases further both the complexity and differentiation across the European supply chain, but also adding significant incremental production costs to manufacturing & logistical operations without delivering real patient safety benefits.

The project is technically feasible as demonstrated by other similar projects such as in the banking industry (the analogy can be made with the credit/cash card information interchange system). It is also scalable to allow the extension to a full track & trace in the long-term.

The challenge in achieving safer medicines supplies therefore lies in putting together the component parts to form a reliable and secure integral system. As a result, all stakeholders will need to work together constructively to deliver real patient safety benefits.

Annex 1. Highlight of Key Stakeholder Benefits

Objectives	Industry	Governments/ Purchasers	Pharmacists	Wholesalers	Patients
Improve product security	▪ Reduce risk of counterfeits entry into the legitimate supply chain ▪ Facilitate effective product recalls	▪ Address the growing risks of counterfeits entering the legitimate supply chain ▪ Improve effectiveness of product recall procedures (pharmacovigilance)	▪ Reduce pharmacists' liability risk for delivering counterfeits or corrupted products ▪ Prevent dispensing errors ▪ Facilitate product recall procedures	▪ Reduce wholesalers liability risk for delivering counterfeits or corrupted products ▪ Facilitate product recall procedures	Reassure patients on the quality of medicines they are dispensed
Improve patient safety	▪ Prevent dispensing and dosing errors ▪ Ensure the quality of the medicine being dispensed	▪ Prevent dispensing and dosing errors (and avoid associated costs)	▪ Improve patient services provided by pharmacists	▪ Provide wholesalers with the possibility to verify expiry date, batch n° and national identification n° (if applicable)	
Harmonise standards for product coding systems	▪ Avoid incremental production costs for manufacturing and logistics due to 27 different coding systems ▪ Ensure the ability to trace back a medicine's origin throughout Europe (inefficiency of national systems to protect the EU market against counterfeits due to the free movement of goods) ▪ Reduce the complexity and differentiation across the European market	▪ Ensure interoperability of national coding systems (necessary condition to effectively tackle counterfeits in the EU) ▪ Address market access hurdles linked to specific coding systems (clear legal basis for developing pan-European guidelines on identification and authenticity of medicines)	▪ Standardises pharmacy equipment across Europe	▪ Ensure interoperability of national coding systems (efficient logistical supply chain)	
Increase traceability in the supply chain	▪ Allow control and monitoring of the medicine's origin ▪ Provide access to improved data sources on sales (possibly real time)	▪ Prevent reimbursement fraud ▪ Support administrative handling of reimbursement procedures	▪ Support administrative handling of reimbursement procedures ▪ Speeds up payment mechanism	▪ Enable the development of a full track & trace system in the long term	

Annex 2. Overview of Coding Systems in Europe

	Country	National Identification Number*	Code Structure*	N. of Digits of Natl' code	Bar code*	Body in charge of codification	Legal Coding Requirements*	Is the code used for reimbursement purposes?
1	Austria	Pharmazentralnummer (PZN)	Country ID (2) + Sector (4) + PZN (6) + check (1)	13	EAN 13	Austria Association of Pharmacists EAN (barcode authority)	no	yes
2	Belgium	Code National (APB code)	APB (7) + sequential number (8) + check digit (1)	16	Code 128 subset c	Association Pharmaceutique Belge (APB)	yes	yes
3	Bulgaria	n/a	GTIN	14	EAN 13 or EAN 8		no	no
4	Croatia	National code number	ATC (generic) code (7) + product (SKU) ID (3)	10	no bar code	Croatian Ministry of Health Croatian Institute for Health Insur.	no	yes
5	Cyprus	n/a	EAN Structure/GTIN	13	EAN 13 or EAN 8	GS1 Cyprus (?)	no	no
6	Czech Rep	n/a	EAN Structure/GTIN	13	EAN 13	State Institute for Drug Control	yes	no
7	Denmark	Nordisk Varenummer	704626 + NMD (6) + Check Digit (1).	13	EAN 13	Nordic article number office (Norsk Medisinaldepot (NMD) DLI - Dansk Lægemiddel Information	yes	no
8	Estonia	n/a	EAN Structure/GTIN	13	EAN 13 or EAN 8		no	no
9	Finland	Nordisk Varenummer	704626 + NMD (6) + Check Digit (1).	13	EAN 13	Nordic article number office (Norsk Medisinaldepot (NMD) Lääketietokeskus Oy	yes	no
10	France (till end 2010)	AMM code (also called CIP code 7 digits)	CIP code (7)	7	Code 39	Club Inter Pharmaceutique (CIP) AFSSAPS (French Health Products Safety Agency)	yes	yes
	France (2011)	AMM code (also called CIP 13)	Prefix 3400 + "AMM" (Market authorisation) + check digit (1) / AMM will be considered on 13 digits from 2009	13	2D Data Matrix	Club Inter Pharmaceutique (CIP) AFSSAPS (the French Health Products Safety Agency)	yes	yes

11	Germany	Pharmazentralnummer (PZN)	PZN (6) + check digit (1)	7	Code 39	Informationsstelle fur Arzneispezialitäten GmbH (**IfA**)	yes	yes
12	Greece	Unique Product Code (assigned by EOF)	EAN number for medicinal products (3) + EOF product code (9) + Check digit (1)	13	UCC/EAN-128	EOF (National Organization for Medicines) ELKESIP, EAN/UCC barcode authority	yes	yes
13	Hungary	n/a	EAN Structure/GTIN	13	EAN 13	Hungarian Ministry of Health	no	yes
14	Ireland	IPU code	EAN Structure: Country ID: 539 (3) + Manufacturer (4) + product ID (5) + check (1)	13	EAN 13 or EAN 8	ANAI Article number association of Ireland Irish pharmaceutical Union (IPU)	yes	no
15	Italy	AIC code	AIC code (9 characters)	9	Code 39/ code interleave 2/5	Italian Ministry of Health	yes	yes
16	Latvia	n/a	EAN Structure/GTIN	13	EAN 13	GS1 Latvia	no	no
17	Lithuania	n/a						no
18	Malta	n/a	EAN Structure/GTIN	13/8	EAN 13 - EAN 8	EAN Malta CSSD (the Central Sterilization Department of the Maltese public hospital)	no	no
19	Netherlands	KNMP product code	KNMP (7) + check digit (1)		Code 39	Royal Dutch Association of Pharmacists (KNMP)	no	yes
	Netherlands	EHIBCC code	Labeller + trade product number + identification unit of measure + check digit	14	Code 39	Royal Dutch Association of Pharmacists (KNMP)	no	no
	Netherlands	EAN code	Country + manufacturer + number + check digit	13	EAN 13	GS1 Netherlands	no	no
20	Norway	Nordisk Varenummer	704626 + NMD (6) + Check Digit (1).	13	EAN 13	Nordic article number office (Norsk Medisinaldepot (NMD)	yes	no
21	Poland	Registration number (MoH)	590: Country Prefix (3) + Authorities Prefix (4) + Reg Number (4) + Pack ID (1) + check (1)	13	EAN 13	Polish Ministry of Health	yes	no

22	Portugal	Registration Number of Medicine Presentation	start character + sequential number (6) + check digit (1) + end character	9	Code 39	INFARMED	yes	yes
23	Roumania	n/a	594: Country Prefix (3) + 47MM Manufacturer ID (4)+ Product ID (5) + Check digit (1)	13	EAN 13, EAN 8 and ITF-14	EAN Romania	no	no
24	Slovakia	n/a	EAN Structure/GTIN	13	EAN 13		no	no
25	Slovenia	n/a	383:Country Prefix (3) + 700X Authorities Prefix (4) + Reg N. (5) + check (1)	13	EAN 13		yes	no
26	Spain	"Código nacional" CN	84 7000 + CN(6) + Check digit (1)	13	EAN 13	SANIDAD - Spanish Ministry of Health	yes	yes
27	Sweden	Nordisk Varenummer	704626 + NMD (6) + Check Digit (1)	13	EAN 13	Nordic article number office (Norsk Medisinaldepot (NMD)	yes	no
28	Switzerland	Swissmedic number	EAN Structure: Country ID (2) + Sector (2) + Product ID (5) + packing code (3) + check (1)	13	EAN 13	Swiss Foundation REFDATA Swissmedic (Swiss registration autority)	no (except narcotics)	no
29	UK	n/a	Country ID (2) + Manufacturer (5) + product ID (5) + check (1)	13	EAN 13	ANA Article number association (EAN Member org)	no	no
30	Serbia & Montenegro	n/a	EAN Structure/GTIN	13	EAN 13, EAN 8	GS1 Serbia & Montenegro	yes	no